Diabetes, Depression and Distress: The 3D Study

An Explorative Study to Inform Practice in the Identification and Management of Depression and/or Diabetes-Specific Distress in Individuals with Type 2 Diabetes

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PhD Thesis

University of Leicester

2016

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Abstract

The 3D-study sought to explore depression and/or diabetes-specific distress (DSD) in people with Type 2 diabetes (T2DM), or 'the 3-Ds', to gain novel data and inform the design of a potential care pathway for this poorly identified and inadequately managed population.

Firstly, a review of existing literature was performed to determine current understanding. Two systematic reviews with meta-analyses were performed: firstly, to determine the prevalence of DSD in people with T2DM; and secondly, to identify existing interventions that are successful in reducing DSD and physiological measures. A qualitative interview study was then conducted, with both patient and healthcare professional (HCP) participants, supplemented by field notes from development work, to elicit and explore the understanding, perceptions and experiences of the '3Ds'. The findings were then mapped against existing programmes of care, identifying areas lacking within current provision and informing the design of a proposed model of care.

The 3D-model identified a lack of HCP understanding of 'the 3-Ds' and their interplay, and poor representation of holistic and patient-centred care, highlighting a fundamental need for training and education prior to any patient-level intervention. The model also identified a need for a change in how psychological concerns are identified, with a need for screening within meaningful discussion and adequate exploration of an individual's wider-life circumstances. The model recognised a need for patient-choice, offering a stepped model of education and psychological support, utilising established programmes and building upon these with a specific '3Ds' education programme. The model recommended a collaborative care design, with a sole care-coordinator to allow continuity of care, accessibility, and encourage shared-decision making and empowerment.

The 3D-study formed the development phases of the Medical Research Council's Framework for the development and evaluation of complex interventions, providing novel data to the field and laying the foundations for future work.

Acknowledgements

I would like to thank my supervisors (Prof. Kamlesh Khunti, Prof. Melanie Davies, Dr. Noelle Robertson and Dr. Helen Eborall) for their invaluable guidance, advice and providing me with the opportunity to undertake this PhD, and in particular their understanding and support through the last five years.

I would also like to thank everyone in the wider research team, with special thanks to Yvonne Doherty, Frank Snoek, Alison Dunkley, Margaret Stone, Naina Patel, Navneet Aujla, Danielle Bodicoat and Laura Gray. I would also like to thank my fellow PhD students, especially Michelle Hadjiconstantinou and Shaun Barber who not only offered academic support, but also offered continued encouragement and much needed laughter along the way.

I am grateful to all the general practices that were involved in the study, as well as the healthcare professionals, patients and other professionals who participated in my research. Additional thanks goes to the National Institute for Health Research's Collaboration for Leadership in Applied Health Research and Care for awarding a grant that allowed the study to be conducted.

Lastly, but most importantly, I would like to thank all my family and friends for their love, patience and understanding. Particularly my parents, who have supported me and allowed me the freedom to focus solely on my work when needed. To my friends, whom have all pushed and encouraged me along the way, particularly Jane Parker and Vicki Aldridge, who gave me invaluable reminders of their own experiences and kept me going when I doubted myself. And lastly, my greatest thanks goes to Sarah Duffy, to whom I would like to dedicate this thesis, without your unwavering support and daily encouragement to 'just keep swimming' I don't think this could have happened. Thank you.

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- ACT: Acceptance and Commitment Therapy
- ADA: American Diabetes Association
- ASSIA: Applied Social Sciences Index and Abstracts
- BDI-II: Beck Depression Inventory version 2
- BME: Black minority ethnic
- BMI: Body mass index
- CBT: Cognitive Behavioral Therapy
- CED-D: Center for Epidemiological Studies Depression Scale
- CCM: Collaborative Care Model
- CFT: Compassion Focussed Therapy
- CHD: Coronary heart disease
- CI: Confidence interval
- CINAHL: Cumulative Index to Nursing and Allied Health Literature
- CSM: Common Sense Model
- CVD: Cardiovascular disease
- DDS: Diabetes Distress Scale
- DES: Diabetes Empowerment Scale
- DESMOND: Diabetes Education and Self-management for Ongoing and Newly Diagnosed
- DSC: Diabetes Symptom Checklist
- DSC-r: Revised Diabetes Symptom Checklist
- DSD: Diabetes-specific distress
- DSM-V: The Diagnostic and Statistical Manual of Mental Disorders 5th Edition
- EASD: European Association for the Study of Diabetes
- EMBASE: Excerpta Medica Database
- Emotional-DSD: Diabetes-specific emotional distress
- EPHPP: Effective Public Health Practice Project
- ES: Effect size
- GP: General Practitioner
- HADS: Hospital Anxiety and Depression Scale

- HbA1c: Glycated hemoglobin
- HCP: Healthcare professional
- HPA: Hypothalamic-pituitary-adrenal
- IBM: Illness Beliefs Model
- ICD-10: The International Statistical Classification of Diseases and Related Health Problems 10th Edition
- IDF: International Diabetes Federation
- IPE: Interprofessional education
- LDC: Leiceser Diabetes Centre
- LTC: Long term condition
- MBCT: Mindfulness-based cognitive therapy
- MBSR: Mindfulness-based stress reduction
- MDD: Major Depressive Disorder
- MEDLINE: Medical Literature Analysis and Retrieval System
- MeSh: Medical subject headings
- MI: Motivational interviewing
- MLT: Modifying Label Theory
- MRC: Medical Research Council
- NHS: National Health Service
- NICE: National Institute for Clinical Excellence
- PAID: Problem Areas in Diabetes
- PCT: Primary care trust
- PHQ-9: Patient Health Questionnaire
- PICOS: Population, Intervention, Comparators, Outcomes, Study Design
- QOF: Quality and Outcomes Framework
- QOL: Quality of life
- RCT: Randomised controlled trial
- REC: Research Ethics Committee
- REDEEM: Reducing Distress and Enhancing Effective Management
- SLT: Social Learning Theory
- SME: Self-management education

- SNS: Sensory nervous system
- Symptom-DSD: Diabetes-specific symptom distress
- T1DM: Type 1 diabetes
- T2DM: Type 2 diabetes
- TMC: Transtheoretical Model of Change
- UK: United Kingdom
- Vs: Versus
- WHO: World Health Organisation

- DB – Danielle Bodicoat
- FS – Frank Snoek
- KK – Kamlesh Khunti
- LG – Laura Gray
- MD – Melanie Davies
- NA_1 – Nuzhat Ashra
- NA_2 – Navneet Aujla
- SB – Shaun Barber

Declaration

I would like to take the opportunity to highlight that due to personal circumstances and ill health, an eighteen-month suspension had to be taken from my PhD studies, across four separate time periods, between 2013 and 2016.

I offer this statement of declaration to clarify the timeline of my thesis, as the periods of suspension impacted upon the chronology, namely that the dates for the systematic reviews and meta-analyses are reported as *after* the qualitative study, but they precede the study within the thesis structure. This is because initially the systematic reviews and meta-analyses were conducted at the beginning of 2012, but due to repeated time off from my studies I chose to re-run the searches and analyses upon return so as to bring them up to date. As such, the final searches for the reviews and meta-analyses were performed in 2015, while the qualitative study was completed in 2012, but the structure of the thesis retains the original chronology as the original searches as analyses were performed as such.

The word count for this thesis is 72,897. This includes footnotes and appendices but excludes the table of contents, tabulated data, diagrams and the bibliography as per the College of Medicine, Biological Sciences and Psychology regulations.

Chapter 1 Introduction to thesis: Literature review

1.1 Chapter overview

In this chapter, I set the scene for the thesis by providing the background and rationale for the 3D-study through an in depth review of the existing literature on diabetes itself, depression and diabetes-specific distress (DSD), and the interplay between them. I then go on to outline the current issues in the assessment and treatment of these comorbid conditions, before lastly outlining the specific aims and overview of my research.

1.2 Background and rationale

1.2.1 Diabetes

The two most commonly recognised forms of diabetes mellitus are Type 1 (T1DM) and Type 2 (T2DM), although numerous other subtypes are recognised.

T1DM is more typically identified in children but can be diagnosed at any age, with the exact mechanisms for its causality remaining unknown. It is an autoimmune disease characterised by the body's incapacity to produce insulin due to permanent damage to beta cells in the pancreas. As such all patients with T1DM will require lifelong insulin administration in order to manage their condition (1).

T2DM is a serious chronic disease defined by elevated levels of blood glucose as a consequence of impaired insulin production by the pancreas and/or insulin resistance in the body's cells (2). It is the most common form of diabetes accounting for around 90% of all cases (3). Historically T2DM was typically seen in older adults, being colloquially labelled 'mature-onset diabetes', however since the turn of this century there have been cases of children, adolescents and young adults being diagnosed with T2DM in the United Kingdom (UK) (4). Rates of obesity have almost doubled since 1980 and more than 42 million children under the age of 5 were classed as overweight in 2013, consequently rates of T2DM diagnoses have been

increasing in both children and adults alike, with a global prevalence estimated at an alarming 9% in 2014 (5).

The causes of T2DM are complex and multifactorial depending on the way an individual's genetic predisposition interacts with behavioral and environmental risk factors. Heritable risk factors include: a person's ethnicity, particularly in black minority ethnic (BME) populations where the risk of T2DM is significantly increased (6); a variety of specific genes identified as increasing the risk of developing T2DM (7); and research demonstrating an increased risk when a family history is evident, particularly that of a first-degree relative (8). Environmental influences include lifestyle characteristics such as a poor diet, reduced physical activity and/or a sedentary lifestyle (9,10), which can lead to obesity, a principle risk factor in a person's susceptibility to T2DM. Additional factors to consider include an individual's age, where susceptibility increases from 45 onwards and even more so from 65 years of age, high cholesterol and/or blood pressure, and some less defined factors such as pollutants in the environment, and stress (11-14).

The majority of patients with T2DM do not achieve optimal glycaemic control, which can lead to a number of poor health consequences (15). In the short-term, it can lead to increased symptom experience and debility, but in the long-term more serious complications can occur, including macrovascular complications such as coronary heart disease and stroke, microvascular complications such as neuropathy and retinopathy, limb amputation, renal failure, and even premature death (16,17).

The increasing prevalence of diabetes in the UK is a major cause for concern, with recent reports by Diabetes UK stating that current figures estimate that someone in the UK is diagnosed with T2DM every 3 minutes (18,19). There are approximately 3.4 million people in England living with the condition, with an expected increase to 5.6 million forecast by 2035/2036 (1), reflecting global trends rising from an estimated 108 million to 422 million since 1980 (5). Further to such concerning figures about those diagnosed and living with T2DM in the UK, it is estimated that 500,000 people currently have T2DM unknowingly, with a further 5 million people demonstrating blood glucose levels (6.0-6.4%) that put them at high risk of developing it (20,21).

The increasing prevalence of diabetes in the UK has a reciprocal negative effect on costs for the National Health Service (NHS) with dramatic figures showing that diabetes currently accounts for 10% of the entire health resource expenditure, with 80% of diabetes spending being used for potentially preventable complications (1,22). A recent report looking into the costs of drugs and treatments for diabetes alone noted that there has been a 56.3% increase since 2005/2006, which is alarming when recognising that the cost of treatments is only a small fraction of the total cost of diabetes (23). Diabetes cost £23.7 billion in the UK in 2010/2011, which can be broken down into direct and indirect costs. Direct costs are costs that are associated with treatment, intervention and complications. Indirect costs account for factors such as costs related to increased death, illness, work loss and need for informal care. In total £9.8 billion was spent in direct costs (£1 billion for T1DM and £8.8 billion for T2DM) and £13.9 billion spent in indirect costs (£0.9 billion for T1DM and £13 billion for T2DM). These figures are expected to rise to £16.9 billion for direct costs (£1.8 billion for T1DM and £15.1 billion for T2DM) and £22.9 billion for indirect costs (£2.4 billion for T1DM and £20.5 billion for T2DM) by 2035/2036, which would account for 17% of the total UK health resource expenditure (1).

1.2.2 Depression and Type 2 diabetes

The International Statistical Classification of Diseases and Related Health Problems 10th Edition (ICD-10) (24) and the Diagnostic and Statistical Manual of Mental Disorders 5th Edition (DSM-V) (25) define depression as a mood disorder characterised by the presentation of a variety of symptoms, and the extent at which these symptoms impair an individual's functional capability. Symptoms include a dysphoric mood (a state of unease of dissatisfaction which can often accompany anxiety or agitation), apathy (lacking in interest or enthusiasm), anhedonia (an inability to experience pleasure in previously enjoyable activities), disturbances in appetite, energy levels and a disruption of sleep pattern.

The prevalence of depression is high amongst people with T2DM with approximately 30% of patients demonstrating either sub-threshold or major depression; this high prevalence rate is seen across the globe (26-34).

Literature demonstrates that patients with T2DM are twice as likely to experience depression with it being more recurrent and chronic when compared to a non-diabetic population (26,28,32,35). Prevalence rates do, however, fluctuate depending on the method of assessment used, such as standardised diagnostic interviews versus self-report questionnaires, with rates ranging from 11% to 30% (26). In a recent review of the literature, is was discussed that prevalence of depression in people with T2DM varies considerably, with limitations to only those with a formal diagnosis of T2DM, leaving a large margin of potentially missed individuals from the figures. Variation continues further when accounting for increased rates in those with poorer health outcomes, multimorbidity and/or more demanding care-plans (36).

Depression can be particularly detrimental in a T2DM population since it has the potential to stand as a profound barrier to self-management. It is associated with a negative impact on self-care behaviours such as reduced medication adherence, decreased diabetes knowledge (or disinterest in seeking appropriate knowledge), and poor compliance with preventative health practices such as a healthy nutritional intake and regular physical activity (37-40). This in turn can increase the risk of chronic complications and poorer diabetes-related outcomes, feeding into a ‘vicious circle’ and leading to further psychological impact as a result of complications, such as worsened glycaemic control, cardiovascular disease (CVD) risk factors, magnified symptom burden, reduced health-related quality of life (QOL), disability and functional impairment, and increased mortality (41-52).

Due to the high prevalence rates and associated risks of co-existing T2DM and depression, a large body of epidemiological research has been conducted to determine the association between depression and T2DM. The relationship is complex, likely bi-directional, with T2DM posing a 20% increased risk of incident depression (53) and depression associated with a 60% increased risk of T2DM (29,53), and both conditions sharing a number of biological pathways (54). In spite of an abundance of research, there remains a lack of clarity to the exact mechanisms linking them (55-58), the varying stances are discussed below.

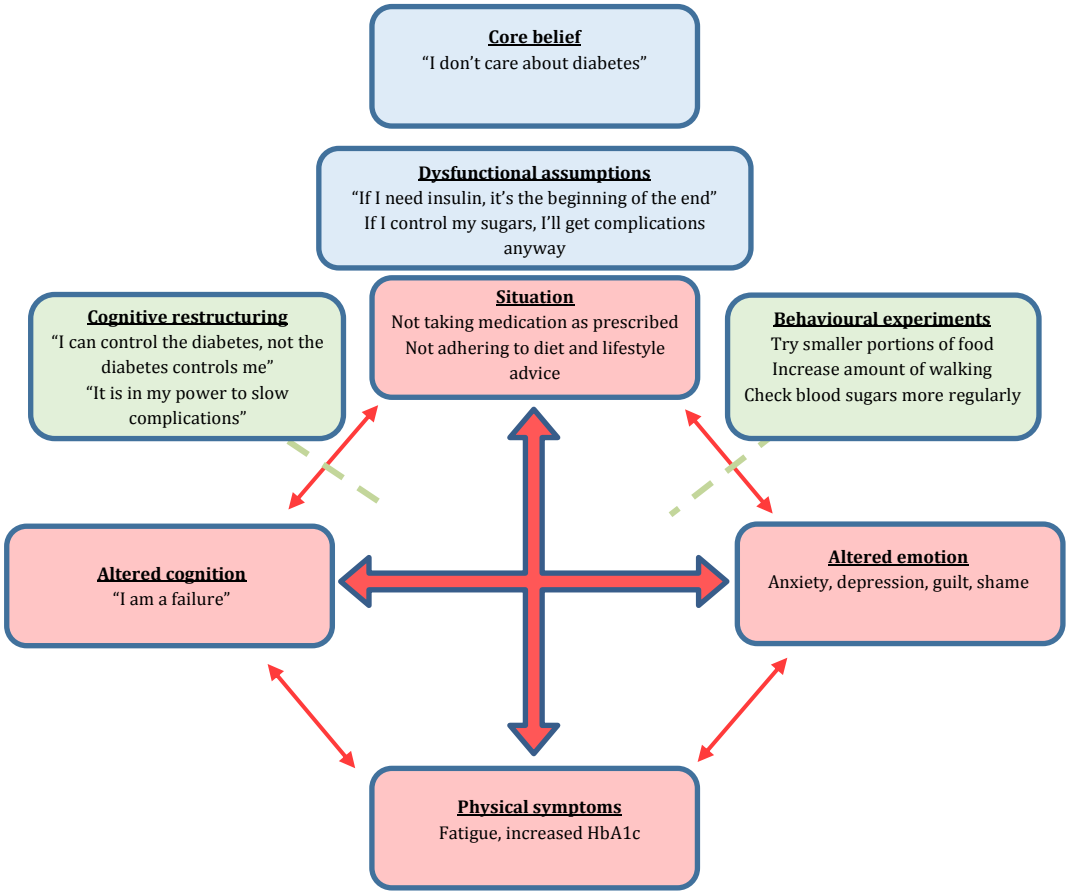
The impact of being diagnosed with T2DM and/or the burden of living with such a chronic disease could lead to increased depressive symptomatology. The manner in which a healthcare professional (HCP) conveys the diagnosis of T2DM and the subsequent support they offer could be paramount in moderating the emotional status of the patient (59,60). Psychological deterioration could be due to negative cognition related to diabetes, such as perceived disability or fear of complications (61). Should HCPs deliver a diagnosis and subsequent care in a patient-centred manner, the demanding nature of self-management in T2DM, such as adhering to a strict diet, exercise and medication regime and having to monitor blood glucose levels, could also lead to worsened psychological affect. Further to this, the chronicity of T2DM can cumulatively impact affect further, requiring patients to develop coping skills to deal with the possibility of future medical complications, decreased mobility and/or quality of life (62). This notion is further complicated by the likelihood of existing poor coping mechanisms, such as disordered eating, a factor which can often precipitate and/or coexist with T2DM (63).

The presence of T2DM associated complications has been shown in various studies to have a potentially important role in the aetiology of depression, complications such as micro- and macrovascular complications and sexual dysfunction, can all have a devastating effect on quality of life (32,45,61,64,65). This conventional model that the clinical burden of T2DM causes depression is supported by research demonstrating there to be no significant difference in rates of depression with people with undiagnosed T2DM, impaired glucose metabolism and those with normal blood sugar levels (33). Furthermore, a study reporting the impact of the Diabetes Education and Self-Management for Ongoing and Newly Diagnosed (DESMOND) programme showed that while prevalence of depression is high in people with T2DM, this is not the case in newly diagnosed, although still slightly higher than non-diabetic population (66). This is suggestive of the ongoing experience of T2DM could play a significant part in the onset of depressive symptomatology, which is further supported by a systematic review and meta-analysis determining the prevalence rates of depression in people with impaired glucose metabolism and undiagnosed diabetes, which

indicated lower rates in risk of depression compared to people with a diagnosis of T2DM (33).

Cognitive behavioural theory has been applied to the relationship between T2DM and depression, suggesting that the burden of living with T2DM influences a reduction in mood and negative thoughts about their condition, which adversely impacts upon self-care behaviours. Moulton *et al* (67) describe their model (Figure 1-1), built upon the cross-sectional formulation model, or 'hot-cross bun' model', with four stages (thoughts, mood, behaviour and biology) that interact bi-directionally to create the fifth overall stage of the environment or situation that an individual is in as a result of the interaction between the previous four stages (68).

Figure 1–1: Cognitive behavioural formulation for the links between depression and Type 2 diabetes, adapted from Moulton *et al* 2015(67)



The application of this model to the experience of T2DM suggests that a core-belief about diabetes instigates the development of dysfunctional assumptions, which then lead to issues in a patient's self-management of their

diabetes. Issues in self-management lead to negative emotions, physical symptoms and negative thoughts, which all interact with one another, generating and maintaining a cognitive behavioural cycle.

Research into the biological mechanisms involved in both conditions has demonstrated that biochemical factors involved in diabetes could account for an increased risk for depression. Factors such as elevated blood glucose and subsequent arousal of the nervous system, dysregulation of the hypothalamic-pituitary-adrenal (HPA) axis and low-grade inflammation have all been implicated in the potential for depression onset in people with T2DM (33,69-73). It should be acknowledged, however, that the increased prevalence of depression in a T2DM population is not unique, it is also observed in numerous other long-term conditions (LTCs), such as chronic pain syndrome, asthma and heart disease (74). This seems to suggest that the chronicity and burden of the experience of T2DM may be more influential in the development of depression, with biological mechanisms playing a more secondary role in the aetiology.

The converse theory that depression increases the risk of onset of T2DM is not a recent premise (75,76), with reviews demonstrating a 37% increase in risk for T2DM in adults experiencing depression (77). This notion derives from a variety of psychological, physiological and social factors, which are outlined below.

The nature of depression itself characterises patients to experience a reduced interest and/or pleasure in activities, which could lead to them being less likely to feel motivated to engage with self-care behaviours such as attending routine appointments, administering appropriate medication, self-monitoring their blood glucose levels, ensuring a healthy nutritional intake and regularly engaging in physical activity (38,52). Self-care behaviours such as eating healthily are often a challenge for people with depression with research showing that they are less likely to include fruit and vegetables in their diet, a key risk-reducing factor in both depression and T2DM alike(78-80). Similarly physical inactivity and sedentary behaviours are more commonplace in people with depression (81), once again increasing the risk for T2DM and it complications (10). Both factors promote overweight and obesity, supported

by a positive association between depression and higher body mass index (BMI) (82-84).

Another commonly observed symptom of depression is an altered sleep pattern, either by sleeping too much or too little, thus disrupting a person's circadian rhythm (85-87). A review of epidemiological studies of chronic sleep restriction shows that disruption to sleep, as seen symptomatically in patients with depression, plays a significant role in altering a person's metabolism and increased insulin resistance and thus the risk of developing T2DM (88).

Biological mechanisms associated with depression have also been shown to increase the risk of developing T2DM through their effect on glucose metabolism (41). Depression is associated with hyperactivity of the HPA-axis and sensory nervous system (SNS), which can result in raised levels of cortisol, a stress hormone known to elevate the production of glucose and reduce insulin sensitivity (89-93). Persistent increases in cortisol levels are associated with the development of metabolic syndrome, a syndrome that is characterised by central adiposity and insulin resistance, which in turn increases the probability for developing T2DM (77,94). Prolonged psychosocial stress, such as job strain, has been shown to increase risk for both T2DM (95) and depression (96). Depression is again associated with elevated cortisol levels through the activation of neuroendocrine and inflammatory responses, which increase the release of not only cortisol, but also catecholamines, hormones released in response to physical or emotional stress, and pro-inflammatory cytokines, which can cause insulin resistance and subsequent risk for T2DM (71,97).

An association has been made between depression and insulin resistance with insulin-sensitivity shown to reduce following successful treatment of depression (98-100), however this is dependent on the treatment approach taken since antidepressant medication has shown the potential to increase risk of T2DM and impaired glucose-regulation (101). Although causality was not proven in the latter review, this could be due to the fact that antidepressants can cause increases in weight (102), which, when combined with the biomedical changes previously discussed, has the potential to have a 'cascading effect' which can lead to the onset of T2DM (62,77). However, physiological responses to antidepressants such as weight gain are highly

subjective and vary widely across the literature, with both increases and decreases in blood glucose being seen (101).

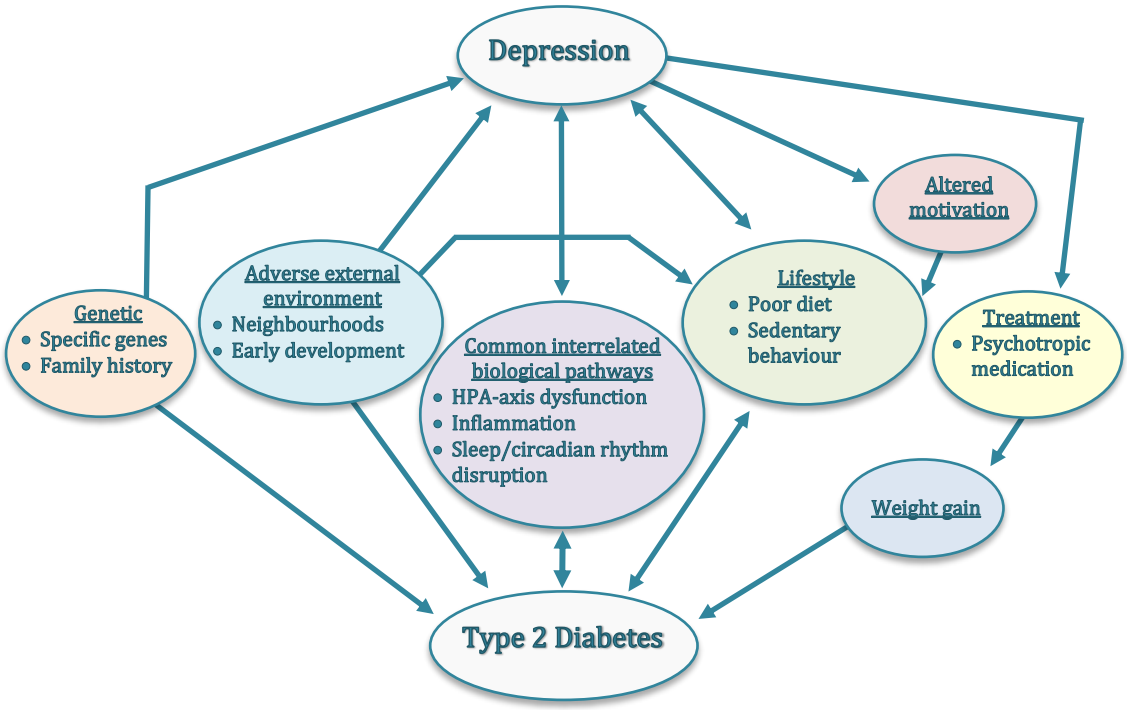
Lastly environmental factors can play a role in influencing both depression and T2DM through their shared biological mechanisms such as early developmental disruption, childhood adversity (such as abuse, deprivation, and/or neglect), socioeconomic deprivation, and poor physical and/or social environments (60,67). Early developmental factors include intrauterine environment and birth-weight which has been shown to stand as an indicator for a predisposition to T2DM (103). Childhood adversity can activate the HPA-axis and elevate cortisol levels and increase a child's risk of stress-related metabolic disruption (60). From early development through to adulthood and on to old age, adverse social environments such as living in noisy, dangerous or overcrowded neighborhoods can influence an individual's biological mechanisms which can in turn increase their risk of depression and/or T2DM such as through the disruption of the HPA-axis and increased cortisol, disturbed sleep patterns and increased inflammation (60,104,105).

The relationship between depression and diabetes is complex and multi-faceted, with authors likening the debate to that of the 'chicken and the egg' (106,107), however the relationship is unlikely to be understood in a linear fashion and is most likely bi-directional within a bio-psycho-social model (Figure 1-2). The evidence discussed in existing research suggests that depression and T2DM have the potential to develop parallel to one another through their shared biological mechanisms, most notably through inflammatory responses, the HPA axis, circadian rhythms, and insulin resistance, which are all interconnected and reactive to each other (67).

Despite ever-mounting evidence demonstrating a problematic interplay between T2DM and depression, it is still a highly under-recognised and under-acknowledged construct that creates a significant barrier to holistic T2DM care pathways (60,108,109). Research suggests that depression may be unrecognised in between 30%-75% of primary care cases (110,111) with later research suggesting that depression remains unrecognised in half of patients with T2DM (30,112,113). These concerning figures present in spite of national and international guidelines for people with T2DM to be assessed for their

psychological status and be referred to appropriate psychological services (114,115).

Figure 1–2: Bi-directional mechanisms linking Type 2 diabetes and depression, adapted from Holt *et al* 2004 & 2014(60,116)



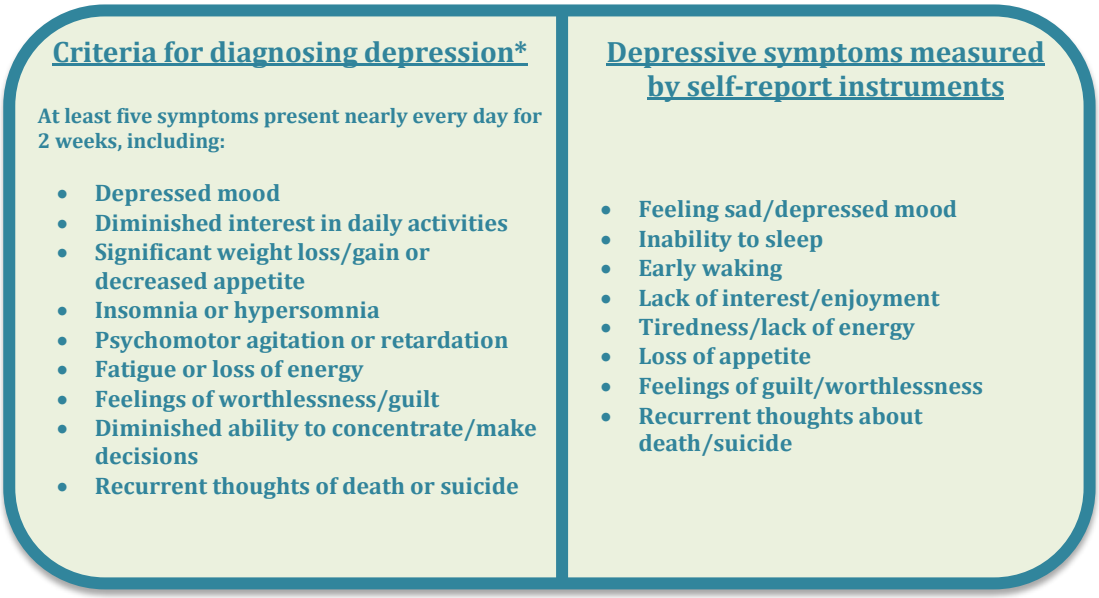
Low recognition of depression could be, in part, due to stigma surrounding mental illness. In spite of efforts in recent years to reduce this through increased awareness and interventions, stigma remains a significant barrier to the recognition and acceptance of diagnoses of depression and subsequent treatment (117,118). Recognition is further hindered by the manner in which a patient may present to a practitioner with many symptoms of depression overlapping with somatic symptoms of T2DM, such as poor appetite, weight loss, insomnia, low energy and fatigue (119).

In order to diagnose a person with clinical depression a clinical interview would be conducted to determine whether they meet diagnostic criteria defined in the DSM-V (25) or the ICD-10 (24). Although this is the more thorough and preferred diagnostic method for determining where cases of depression may be evident, in both clinical practice and research settings this is often too demanding in terms of time and resources. As such self-reported screening measures are often employed using psychometrically based cut-

off points to determine if depressive symptoms are present, which, although functionally more appropriate, lack the specificity of clinical interview (120).

Regular screening for depression is recommended by the National Institute for Clinical Excellence (NICE) (114), the International Diabetes Federation (IDF) (115), and the American Diabetes Association (ADA) (121). Validated brief screening instruments include the Patient Health Questionnaire (PHQ-9) (122), the Beck Depression Inventory (BDI-II) (123), the Center for Epidemiological Studies Depression Scale (CES-D) (124) and the Hospital Anxiety and Depression Scale (HADS) (125). Although other scales exist, these were identified as the most regularly by a recent review summarising screening tools used in diabetes studies, with the authors identifying the BDI-II, CES-D and HADS as showing the most clinical specificity and sensitivity, but that the PHQ-9 demonstrating the best validation of people with diabetes (118), which is the most routinely used within primary care in the UK. The diagnostic criteria for clinical depression and the depressive symptoms observed in the screening tools are closely linked with the majority of instruments approximating clinical depression to the best of their ability (please see Figure 1-3).

Figure 1–3: Comparison of the diagnostic criteria for depression versus depression symptoms assessed using validated self-reported measures, adapted from Lloyd 2008 (126). * Criteria taken from the Diagnostic and Statistical Manual of Mental Disorders version 5(25)



The Quality and Outcomes Framework (QOF) was a voluntary incentive programme for general practice (GP) surgeries in the UK, which, at the time of this study, encouraged regular depression screening in people with diabetes by rewarding primary care physicians for 'enhanced services for depression' (127). The QOF screening protocol consisted of asking patients two initial screening questions about their affect, and should this highlight the potential for depression then move onto assessment using a validated screening questionnaire. While these self-administered tools do not take long to administer and are relatively straight forward to use, deliberation exists as to whether they are suitable for people with diabetes due to the overlap between symptoms, such as tiredness, decreased energy levels and disturbances of sleep patterns (118).

Although screening for depression is recommended, it is debatable as to whether screening is appropriate and effective, namely when initiated without established and readily available follow-up interventions. In a review of screening for depression in general population samples, it was shown that screening in such a context was both ineffective and unjustified (128). This was corroborated within diabetes research where it was demonstrated that screening without suitable integration with follow-up treatment did not significantly improve depression, irrespective of an increased use of mental-health services (129,130).

In addition to concerns with screening for depression in people with T2DM, treatment delivery is hindered by the availability of services, knowledge and adherence to guidelines. In a UK survey of 464 UK diabetes centres, it was reported that only 24% of centres met the NICE guidelines for recognising depression. Of these centres, 68% stated that more multi-disciplinary training was required, and 87% stated that more psychological staff were needed to be able to meet the guidance standards (131). In an online survey conducted by Diabetes UK looking into care for patients with diabetes, only 24.4% of patients reported being offered emotional or psychological support from a specialist healthcare professional or service, highlighting a stark need for improvement to meet the unmet needs of many patients with T2DM (132).

1.2.3 Diabetes-specific distress and Type 2 diabetes

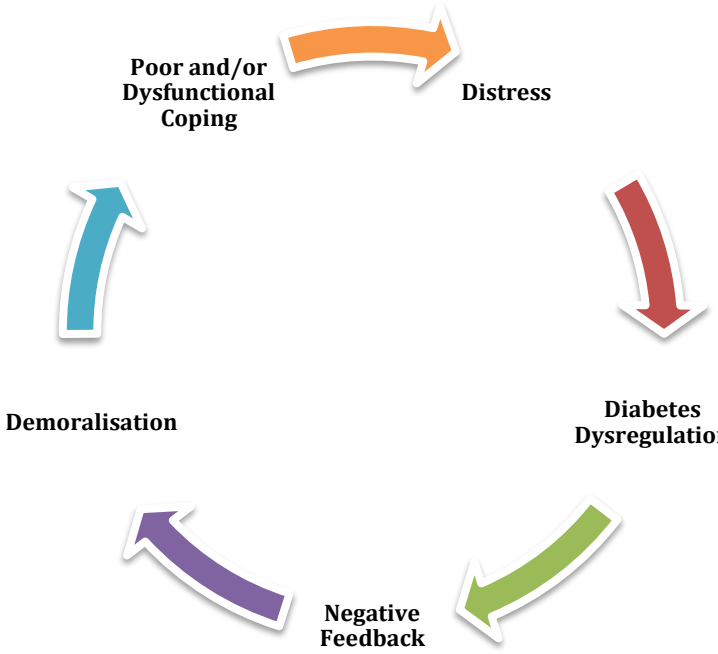
Recently linked to T2DM is diabetes-specific distress (DSD); a distinct psychological paradigm that encapsulates a much wider affective experience compared to depression (67). It constitutes distinctive emotional concerns within the 'spectrum of patient experience' for those living with the progressive severity and chronicity of diabetes, resultant treatment and the impact on patient experience and the future (36,133,134).

DSD can be broken down into two constructs; diabetes-related symptom distress (symptom-DSD) and diabetes-specific emotional distress (emotional-DSD). Symptom-DSD refers to the burden of physical symptoms related to T2DM, such as pain or lethargy. Emotional-DSD refers to psychological distress specific to living with diabetes, such as feeling overwhelmed by the demands of self-management; carrying fear of future complications or hypoglycaemia; or harboring potential feelings of guilt or shame, such as in relation to obesity or unhealthy lifestyle choices such as sedentary behaviour or poor nutritional intake (135-137).

DSD has a cyclical nature as it can lead to poor self-management of T2DM, in turn providing negative feedback and thus demoralisation to the person suffering, leading to poor coping and again feeding back into further DSD and so forth (Figure 1-4) (138).

In terms of T2DM literature and understanding, DSD is a relatively new construct. To date there has been no single review of the literature to determine the prevalence of DSD in people with T2DM, such as that done by Ali *et al* for the prevalence of depression in T2DM (28). Leading research in the field of DSD has shown that point prevalence rates of elevated DSD in people with T2DM range from 18-35% (139), with severe rates of DSD presenting in 10-30% of people with T2DM, although this varies according to case mix and location (134). Observational research noted that of 506 people with T2DM assessed three times at nine month intervals, nearly a third reported DSD at least once, and 22% demonstrating high DSD across all three time-points (140). Due to its recurrent nature, DSD, much like depression, can pose as a persistent and unrelenting condition to those that experience it.

Figure 1–4: The vicious cycle of diabetes specific distress, adapted from Snoek 2002(138)



There are a number of scales available to assess DSD, which are divided into those assessing symptom-DSD and emotional-DSD. The predominant scales for determining symptom-DSD are the Diabetes Symptom Checklist (DSC) or its revised version (DSC-r) (141), while the predominant scales to assess emotional-DSD are the Problem Areas in Diabetes (PAID) scale and the Diabetes Distress Scale (DDS) (140,142). Unlike depression, however, there are no clear and validated diagnostic criteria to define DSD, such as that in the DSM-IV or the ICD-10, meaning that a lack of clarity and uniformity exists in the literature and understanding of DSD varies, with no single distinct definition of the condition. Furthermore, the majority of standardised measures for assessing DSD do not account for the source of distress, in spite of DSD being a reactive condition to contextual circumstance, such as coping with fluctuating HbA1c levels, beginning insulin therapy and/or having to balance dosage, fearing hypoglycaemia, discovering a diabetes-related complication or burden of self-management (134). Such lack of comprehensiveness in existing scales hinders understanding of the wider context of patient experience and thus the ability to offer true efficacious patient-centered therapy (36).

Similarly to depression, DSD has been shown to have low recognition rates that can hinder successful management, with only 20-30% of patients who scored high on emotional distress scores being reported by diabetes nurse specialists (112). In a later study designed to enhance the identification and treatment of emotional concerns in people with diabetes, a computer-assisted assessment programme was used to monitor patient's wellbeing and DSD, with the collected data then used to form a discussion between patients and their healthcare professional (HCP) about their case-management. Of the 1,567 patients screened, 28% of cases exhibited depressive symptoms and/or high diabetes-related distress. Of particular interest was that 86.9% of these cases were only newly identified within the study, with 41% of patients with depression being referred for further psychological support, emphasising the need to improve and increase recognition and management of emotional problems in patients with T2DM (143,144). A key issue in successfully identifying DSD is a necessity to ascertain specific reliable and validated criteria that can define it, as is established in depression diagnosis, allowing for appropriate assessment and/or treatment, as well as increasing consistency in research and providing uniformity in identifying patients at risk (139).

Unlike depression, which is a syndrome classified and diagnosed solely by symptoms alone without accounting for cause in its identification (145), there is no need to debate causal attribution in DSD since, by its very nature, is diabetes-specific and resulting directly from having T2DM. DSD has, however, been shown to have linkages to many behavioural and biological mechanisms, similar to that debated in the T2DM-depression relationship, that feed into theories of cause and effect and how these factors interplay.

Cross-sectional research has demonstrated links between DSD and a number of psychosocial variables such as beliefs and cognitions regarding T2DM, insulin use and quality of life (134). Associations have also been demonstrated between DSD and burden of self-care, more frequent blood glucose testing, higher HbA1c, increased complications, greater frequency of self-reported symptoms, female gender, younger age and inadequate diabetes self-management, such as poor adherence to diet, physical activity and medication recommendations (63,135,142,146-148). In a study

conducted in the Netherlands, DSD was shown to be significantly reduced in primary care patients (4%) compared to secondary care patients (19%), suggesting a potential mediation through the severity and progression of T2DM and subsequent treatment burden (149).

DSD is common among patients with T2DM who also demonstrate depressive symptoms, which is not surprising since they are highly correlated constructs with a substantial overlap between symptoms (144,150-154), however, in spite of a strong association existing between the two, there remains a great deal of variance that is still unaccounted for in the relationship (134). While the two conditions have similar presentations, research has drawn a distinction between them suggesting that DSD is more widespread (18.0% vs 10.7% point prevalence) than depression (146). In addition, the literature is indicative of DSD being more impactful and closely associated to diabetes self-management and diabetes-related behavioural and biomedical outcomes than depression, of particular notability is the effect of DSD on HbA1c where depression yielded contradictory results (69,140,155-158). In multivariate cross-sectional analyses of associations between psychosocial attributes, self-management and glycaemic control, DSD was shown to have the most powerful negative effect on HbA1c (136). However, due to methodological incapacity, cross-sectional studies are unable to determine a direction within these effects and as such the mechanism underpinning these relationships is not understood.

1.2.4 Diabetes, depression and diabetes-specific distress: Interplay between the '3-Ds'

As discussed prior, both depression and DSD are shown to manifest with poor adherence and glycaemic outcomes in T2DM, however the underlying mechanisms are likely complex, can differ, and are poorly understood.

Depression could be a reason for, or a result of, hyperglycaemia; it may or may not share underlying mechanisms; and both the causality and mechanism demonstrate variability by time, episodes and the individual. As such longitudinal studies are necessary to assess the causality of these relationships, however from the minimal evidence available, it appears that

alterations in one over time do not appear to be associated with the other (157).

Studies that have explored the effects of treatment for depression on affective and glycaemic outcomes have also shown mixed results (155,159-161). In terms of pharmacological treatment, studies assessing the effects of this on glycaemic control remain unclear, with some pointing to adverse effects, and some reporting modest positive effects on HbA1c (162-165). Psychological therapies, such as Cognitive Behavioural Therapy (CBT) and counselling, have equally shown mixed results, with moderate to good effects on glycaemic control shown in some, but improvements in depressive symptoms not being associated with HbA1 in others (166-169). It has been suggested that this variability could be accounted for by the complexity of a patient's self-management routine, with supporting research showing that depression significantly correlates with HbA1c in patients with the most intensive treatment. Intensive treatment was defined as three or more insulin injections per day, which compared to no relationship in patients who's regime consisted of diet/exercise control, oral medications or one to two injections per day (170).

While results are inconsistent in demonstrating a clear relationship between depression and HbA1c, research exploring the relationship between DSD and glycaemic control is more promising. Using the PAID scale it has been shown that DSD is positively associated with HbA1c and it stands as a strong indicator to poor adherence to treatment not involving general emotional distress (142). A number of studies have shown that, whereas glycaemic control was not associated with depressive symptoms, it demonstrated a significant association with emotional-DSD (140,156,157, 171-174).

It has been suggested that the uncertain relationship between depression and glycaemic control demonstrated in the research could be explained in part by the correlation between depression and DSD, and that DSD may in fact be driving any association between depression and glycaemic control in the first place (172). This hypothesis is supported by three studies showing that DSD mediates the relationship between depression and glycaemic control in T2DM, through both cross-sectional and time-varying longitudinal

relationships (157,175,176). One study demonstrated a three times higher risk for elevated HbA1c when depression was combined with high DSD (175) suggesting that rather than depression alone, it is the interplay between depression and DSD that hinders a patients capacity to manage their diabetes (177). Consideration of this has led leading authors to consider it possible that the relationship between depression and glycaemic control is largely indirect, such as through an individual's self-management behaviour, but that DSD has a direct influence on HbA1c, potentially through stress-hormones, as discussed earlier (134).

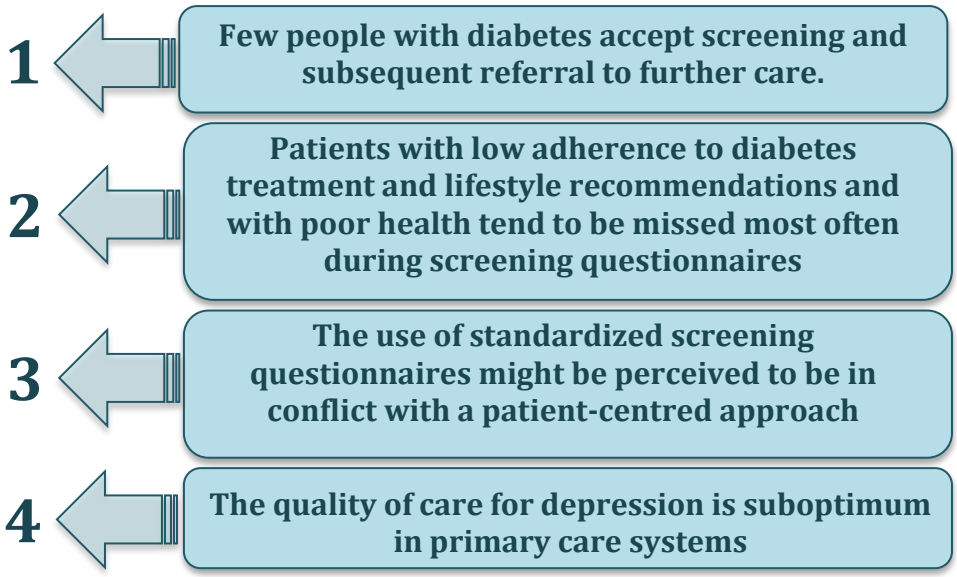
Leading research in the field of DSD has proposed that people with T2DM displaying depressive symptomatology may not necessarily be clinically depressed, but could in fact be suffering from heightened DSD, which is particularly clouded when self-reported measures are used (133,156). Fisher and colleagues found that 70% of patients demonstrating elevated depressive affect in self-reported measures, when given a structured clinical interview, did not actually meet the diagnostic criteria for depression (156). An additional finding from this study showed, more importantly, that DSD, but not depression, was associated with problematic diabetes self-management, suggesting that DSD and depression, while closely related, are distinct constructs with independent relationships to diabetes, highlighting a need to differentiate between the two in clinical practice (133). This has been further supported by data from the DESMOND study group showing that depression improved following a diabetes self-management intervention, suggesting that the presentation of depression in these patients may have in fact been DSD, or a combination of the two, since participants responded to treatment targeted specifically at T2DM rather than depression (66).

1.2.5 Assessment of the '3-Ds'

As discussed above, with both depression and DSD being highly prevalent but poorly recognised in patients with T2DM, despite clinical recommendations to routinely monitor psychological health an integral part of diabetes care, there is warrant for careful regular assessment of both. However, a number of concerns lie in the efficacy of screening for psychological health in people with T2DM. In a recent series paper looking

into the treatment and healthcare delivery for depression in diabetes, Petrak *et al* (59) reviewed the scientific evidence for the benefits of screening and highlighted 4 major concerns (Figure 1-5).

Figure 1–5: Reasons for low effectiveness of screening for depression in people with Type 2 diabetes, adapted from Petrak *et al* 2015(59)



The authors surmised that unless screening is embedded within a comprehensive diagnostic and treatment approach, it does not serve either as an effective or ethical tool, arguing that only when appropriate healthcare facilities exist, is there a strong rationale to offer screening. This has been supported by research into collaborative care interventions for diabetes and depression, which demonstrated positive effects on depression when screening was followed by diagnostic confirmation and appropriate treatment pathways (178,179).

Further concerns with psychological screening in people with T2DM lie in the substantial misunderstanding between depression and DSD, which is partially instigated by difficulties in assessment and rooted in an unclear distinction between the two in both research and clinical practice (36). The terminology for depression and DSD are often intermingled, lacking in appreciation for the different historical and theoretical perspectives from which they derive (36). Depression derives from a tradition of research in clinical diagnosis and psychopathology. It can defined and measured across

three different areas; either as a syndrome that meets diagnostic criteria assessed using structured interviews; as depressive symptoms that would be measured through inventories such as those discussed earlier; or interspersed with DSD and not clearly separated.

The construct of DSD was formed from two very different theoretical models to depression; research on stress and coping, and research on emotional regulation in response to specific or acute stressors: with both areas determining distress as reactive to specific contexts, unlike depression which is identified through symptoms alone (36).

In spite of this, the predominant theoretical model that underlies the current understanding of DSD is the psychiatric diagnosis of depression, signifying that the majority of treatments for DSD are drawn from the treatment literature for depression (156). Over-application of this model is exacerbated by the fact that the existing diagnostic system for depression does not acknowledge the situation in which symptoms occur, overlooking the aetiology or disease process (145). As such, it is unable to differentiate between what could be a reasonable reaction to a significant life event, such as being diagnosed with T2DM, and what could be deeper rooted in psychopathology (180). Furthermore, the physical symptoms of T2DM can ‘muddy the water’ of DSD assessment further by inaccurately being interpreted as the presentation of depression (133).

Such ambiguity in definition and assessment only serves to fail in acknowledging the context and derivation of a person’s symptom presentation, and could lead to a misclassification of depressive affect, and subsequent inappropriate treatment. This is supported by the results of a review that demonstrated that 44-77% of positive scores of depression were likely to be false-positives (118). A validation study the following year demonstrated that the PHQ-9 can substantially over-diagnose depression with the authors concluding that this could be driven by the symptoms of T2DM (181). A study published in the same year as the review also demonstrated that of 2053 participants who were screened using the PHQ-9, over half whom scored positively did not demonstrate the necessary symptoms for a diagnosis of Major Depressive Disorder (MDD) (182). This suggests that screening tools, when used in isolation, do not adequately

account for situational circumstances in which a patient's presentation of symptoms occur and could inaccurately pathologise people with T2DM and lead to inadequacies in appropriate treatment. As such, recommendations have been given so that, should any positive results occur during screening, these be confirmed or denied using a formal clinical assessment with consideration for potential differential diagnoses (59).

With a clear need to assess for both depression and DSD in people with T2DM, but also to ensure a dissemination between the two, it is possible that using both depression and distress scales during assessment, alongside a purposeful discussion, could allow for an awareness of underlying causes of symptoms, which would serve to better inform treatment decisions (118). In a recent study aimed at identifying potential strategies for depression screening in patients with T2DM it was noted that screening not only for depression but also for DSD would allow for a better understanding of a patient's treatment needs (119). By identifying patients with depression, depressive symptoms and/or DSD, and determining the causes of their symptoms, it allows for the recognition of those who may require specific psychological intervention, or those tailored to glycaemic control and the management of T2DM complications.

1.2.6 Treatment of 'the 3-Ds'

There are well-established treatment options for depression ranging from pharmacotherapy through to psychosocial and psychiatric therapies, which can be used in isolation from, or in combination with, one another. For sub-threshold to mild depression, low intensity psychological treatments, physical exercise, computerised CBT and guided self-help and advice are available and recommended. For moderate to severe depression, problem solving, medication (such as selective serotonin reuptake inhibitors (SSRI) or trycyclic antidepressants), CBT, and/or interpersonal psychotherapy may be suitable (183). While these treatments are well established in the general population, they should not be overvalued in T2DM, as poor treatment response and adherence remains a major impediment to improving care, with a lack of clarity as to the 'best' treatments for these comorbid conditions (59). A substantial proportion of patients do not respond to treatment, as

demonstrated in the Pathways study, where 28-46% of patients either did not respond or had relapsed at twelve month follow-up (159).

More recently recommended are the use of complex interventions such as stepped-care and collaborative care model (CCM) approaches. Stepped-care interventions provide treatment of varying intensities through a sequential treatment plan, with established cut-off points to indicate transition up or down each stage (184). CCM approaches are usually algorithm based and utilise any of the aforementioned range of treatments depending on the individual case, preference and response (59). The approach defines and sets targets, offering self-management and support services using a case manager who implements the care plan (114). Delivery of a CCM approach typically involves multidisciplinary collaboration between HCPs, regular monitoring of outcomes, active follow-up with patients, monitoring of care providers, delivery of evidence-based treatment choices, self-management training and on-going support for patients (184).

With an increasing body of work casting light on the importance of DSD on glycaemic control, there is a call for investigation into interventions directed at reducing distress in addition to, or separately from, depression (172), with regular appraisal of wider-life contexts and disease-specific stressors in a patients experience (146). There are few established treatment methods designed specifically for the treatment of DSD. In a recent systematic review and meta-analysis of randomised controlled trials (RCTs) in which DSD was assessed, researchers found that intervention content and method of delivery improved DSD and HbA1c in interventions using a psycho-educational or generalist interventionist approach, involving more than 6 sessions, and more than 3 months in duration, with motivational interviewing (MI) showing as a specific treatment modality that improves both DSD and HbA1c (185).

Only one known study to date has tested an intervention designed to specifically target DSD. In the Reducing Distress and Enhancing Effective Management (REDEEM) study (186), 392 adults with T2DM were randomised and assessed across three interventions, all aimed to reduce DSD. The first intervention was a computer-assisted self-management program; the second being the same programme with additional DSD specific problem solving; and the last being a computer-administered minimal support

intervention. The authors used the DDS scale to assess overall DSD, but also analysed results from the DDS subscales assessing emotional burden and regimen distress, in addition to participant's nutritional intake, physical activity and medication adherence. The study found DSD was significantly reduced by all three intervention arms, but that the second intervention that including self-management and DSD specific problem solving demonstrated the greatest merit. Regimen distress was shown to produce the most distress in participants and was the most responsive to the interventions, with results indicating that participants with higher baseline regimen distress benefited most from the intervention including DSD specific problem solving and that the self-management programmes alone were insufficient. The authors noted that the effects were not altered by subject demographics or T2DM variables, and did not diminish over time even with minimal patient contact, suggesting the utility of the interventions for most people with T2DM. An interesting observation was that the rate of reduction in regimen distress varied between age groups, with older participants responding earlier in the intervention, but younger patients responding later. This lead the authors to consider that younger people may be managing more concerns and problems outside of their T2DM, highlighting the need to account for individual circumstances when planning care for anyone with T2DM and DSD.

A concern involved in the treatment of depression and/or DSD in T2DM is that management programmes for the treatment of DSD, due to a constricted focus on interventions originally designed for the treatment of depression, are incapable of properly addressing the factors that might underlie the condition. For example, interventions that attempt to reduce the severity of depression alone, such as pharmacological management or psychotherapy, may fail to acknowledge the life context of a person living with T2DM and as such would not address co-occurring issues. The influential reciprocity between DSD and diabetes-self management increases the risk for poor treatment outcomes in patients with T2DM, thus interventions aimed at deciphering the causes of a patient's presentation and targeting the conditions respectively could be better equipped to influence change as opposed to those that focus on either in isolation (187). Acknowledging and addressing the importance of diabetes-related issues in the context of depression has been suggested to help

improve diabetes outcomes (175). Contextual recognition of the lives of people with T2DM is paramount to understanding the relationship between T2DM, depression, and DSD, and subsequently providing effective treatment.

A community based study of T2DM patients found that wider life circumstances not only impacted directly on T2DM management, but the results suggested that they may interact with factors such as HbA1c to affect DSD (146). Attending to the emotional concerns associated with living with T2DM should therefore facilitate improvements not only to psychological well-being but to biomedical outcomes (175) and could potentially optimise the likelihood of treatment success.

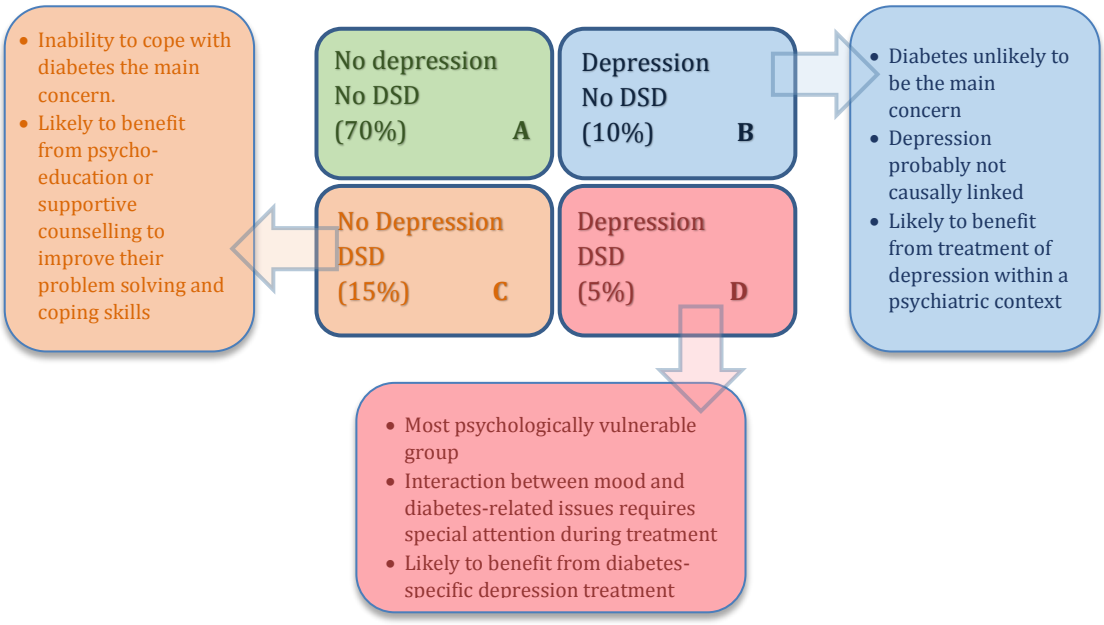
A further problem caused by the over-use of the depression model in relation to DSD is that depression treatment can include challenging management programmes that could actually contribute or attenuate the experience of DSD, resulting in poor treatment response. There is a scarcity of compelling evidence that amelioration of depression alone can improve diabetes self-care and HbA1c levels (133,188), which is further compounded by the fact that self-management interventions alone can reduce depression scores without specific psychological treatment (66). This suggests that other factors need to be considered, such as depression being misconstrued as DSD, or both conditions co-existing alongside T2DM. Further to this, longitudinal research into affective disorders in people with T2DM demonstrated that one-third of participants who reached the criteria for MDD did not display DSD (140), further highlighting that there is a need to discriminate between the two and understand the cause of psychological symptoms in people with T2DM. Research has led to the recommendation of appraising both life context and diabetes-related stressors in routine care of T2DM and embedding screening within a collaborative care approach that tailors treatment; using a patient-centred and stepped-care approach, considering both depression and/or any DSD which could necessitate particular focus during the treatment and management processes (119,137,146).

In spite of the issues outlined above, one should not discount the significance of recognising depression among people with T2DM and, where appropriate, offering the traditional model of treatment. However, greater

significance must be placed on incorporating strategies to ensure that potential DSD is identified and care tailored in accordance with this, as treatment targeting one condition may not necessarily target another. An intervention that acknowledges, and differentiates between, depression and DSD, and facilitates the management of any emotional concerns alongside the provision of support for diabetes self-management would allow for a greater likelihood for improvements in patients with T2DM (133).

In a recent series looking depression and DSD in people with diabetes, Snoek *et al* (134) defined 4 potential clusters of co-existing or absent depression and DSD in diabetes (Figure 1-6).

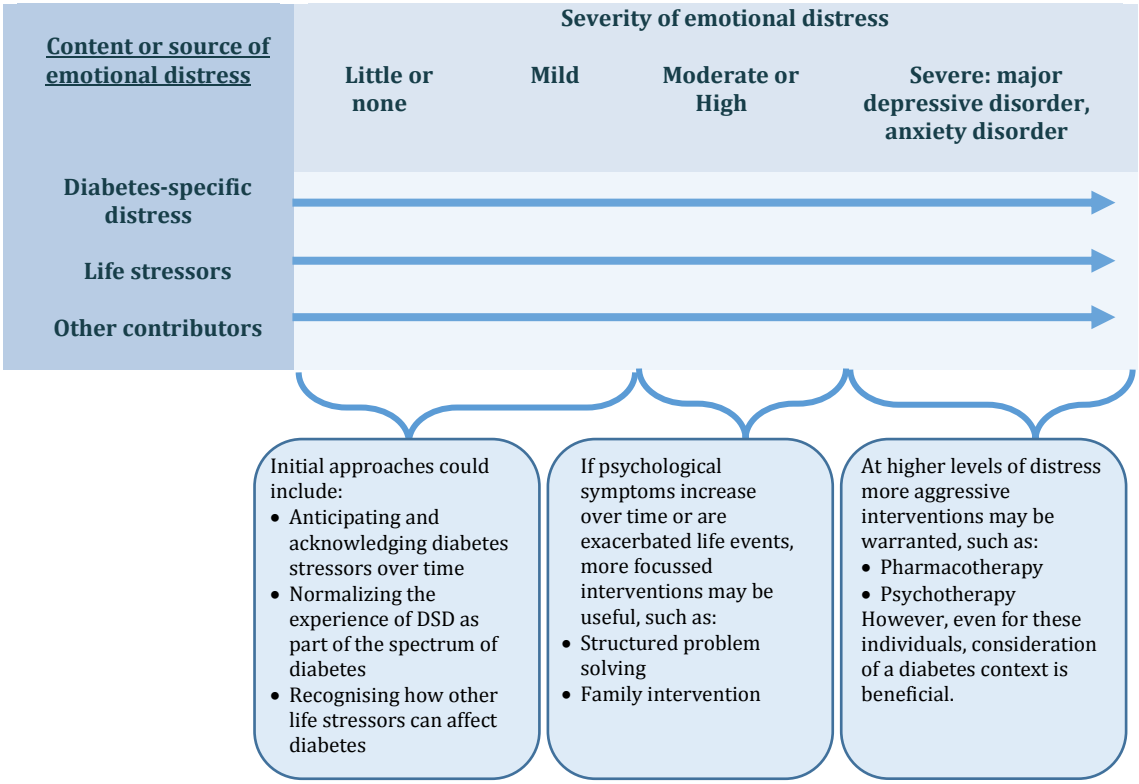
Figure 1–6: Co-occurrence of depression and diabetes-specific distress, adapted from Snoek *at al* 2015(134)



The authors estimated mean percentages based on epidemiological research, finding that around 70% displayed no depression or DSD (group A), which they acknowledged to fit with the stress-vulnerability model of depression, which suggests that when people are faced with life-stressors, only a subgroup of approximately 30% will report serious distress or depression. Within the subgroup they noted that 10% demonstrated depression but no DSD (group B), 15% demonstrated no depression but DSD (group C) and 5% demonstrated both (group D).

Even once DSD and depression are identified and distinguished in patients, it is worth noting that the causal attribution of either condition needs exploring in order to tailor treatment appropriately. In a recent paper, Fisher *et al* (36) highlighted that emotional concerns in people with T2DM can be caused by one or more of three inter-related stressors. Either as a direct result of T2DM and its management, such as fear of complications or diabetes burn-out; as a result of life-stressors unrelated to T2DM, such as family, employment or finances; or as a result of other causes, such as personal characteristics, life history or genetics (Figure 1-7).

Figure 1–7: Model acknowledging the importance of recognising context and severity in the assessment and treatment of psychological concerns in diabetes, adapted from Fisher *et al* 2014 (36)



They argue that both context and severity need to addressed during assessment and urge that when assessing psychological health in patients with T2DM, focus be given to both diabetes-related and non-diabetes-related concerns, since wider-life concerns, either historical or present, can exacerbate any diabetes-specific difficulties. Furthermore, adopting such a model allows not only for aetiology and severity, but also for an appreciation of the inter-relatedness of stressors, which serves to support and enhance

appropriate treatment acquisition and management of patients with T2DM, depression and/or DSD (55).

DSD and depression are both clearly associated with problems in diabetes self-care and clinical outcomes, and as such should both be acknowledged as crucial indicators to the design of interventions for tackling both DSD and depression. For example, incorporating diabetes-specific concerns in psychological therapy could be more likely to show increased positive treatment outcomes rather than addressing either in isolation, as it would resolve psychological issues that are associated with the life context of T2DM, which may have otherwise been overlooked. For example traditional depression treatments could be enhanced through specific focus on diabetes-related emotional problems such as concerns regarding future complications or fear of hypoglycaemic events (151). It is important to decipher each individuals presentation in the clinical management of psychological concerns in T2DM so as to understand how best to manage each case according to their levels of depression and/or DSD, with an ideal treatment model demonstrating integrated treatment through person-centred multi-disciplinary collaboration of diabetes and mental health professionals (134).

1.2.7 Conclusion

Every patient with T2DM should be able to access support for psychological or emotional concerns as this can be crucial to sustaining good self-management and reducing the risk of future complications.

The significant under-recognition and subsequent under-treatment of depression and DSD in patients with T2DM calls for screening measures to improve identification of cases (137), but only when appropriate treatment facilities can follow on from this (59).

Figures for patients with T2DM and coexisting depression and/or DSD are expected to rise considerably over the coming decades, highlighting the necessity to further our understanding of the association between T2DM, depression and DSD, with a view to better understand treatment for both management and prevention worsening diabetes related outcomes. To date there is limited data on the efficacy of psychological treatments in T2DM (189).

Research is needed to establish treatments that effectively identify and manage all three conditions together or those that co-exist, rather than isolating and treating them separately. Integrating research and clinical practice whilst allowing for reciprocal influence remains a challenge in the field of health research; nonetheless research that offers an insight into reasons why patients may struggle with their self-management or adherence to a particular treatment can only serve to improve services and their delivery and could improve outcomes (190).

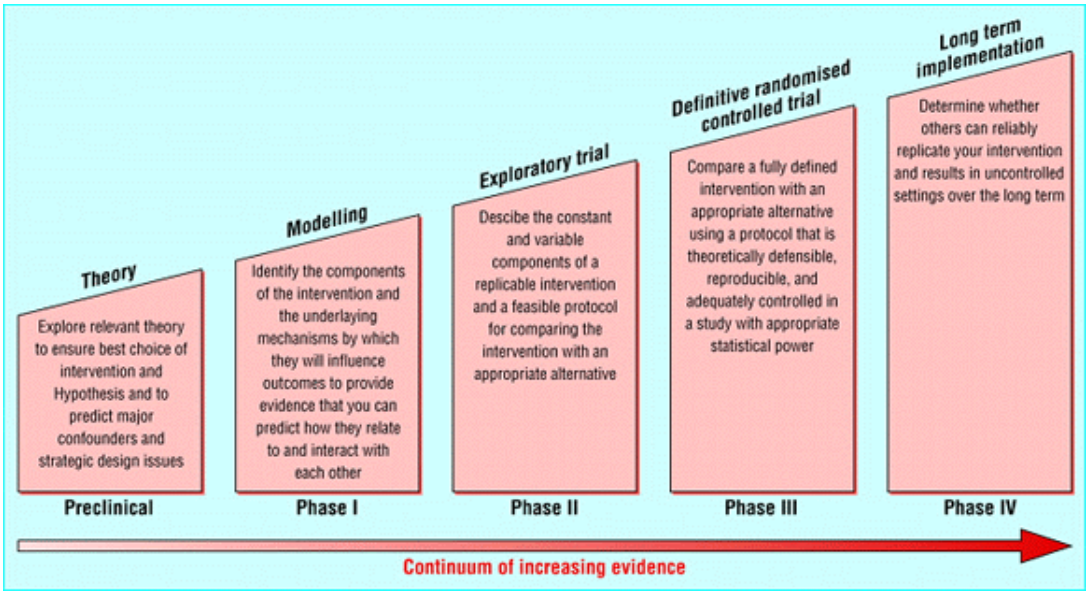
1.3 Methods and rationale for the 3D-Study

1.3.1 The development of complex interventions

This thesis was undertaken as an exploratory study with the aim of better understanding the relationship between T2DM, depression and/or DSD, and to discern how best to identify and treat these comorbid conditions. Interventions targeted at the improvement of health, particularly in cases of multi-morbidity, can be understandably complex in nature. The Medical Research Council (MRC) defines a complex intervention as "built up from a number of components, which may act both independently and interdependently" (191). The MRC developed framework to stand as published guidance to assist the recognition and application of correct procedure when developing and evaluating studies of interventions of a complex nature (Figure 1-8).

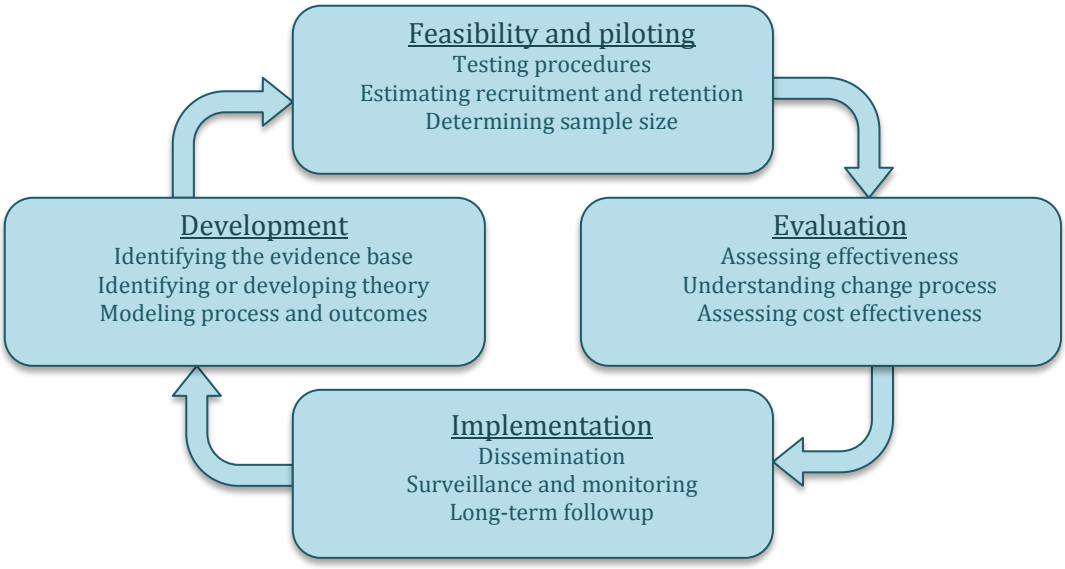
The MRC framework has been widely cited as respected guidance for methodology in the development of complex intervention, however, through progression in research and improved understanding, the model invited criticism and the recognition of limitations, namely in its implication of a linear process in research, when this is in fact often cyclical and bi-directional in nature (192,193). Further criticism included an over-emphasis of clinical trials, a lack of evidence base, and adopting a model that is 'unhelpfully' analogous to phases of drug development.

Figure 1–8: The original Medical Research Council Framework for the development and evaluation of complex interventions(191)



The framework was subsequently updated to account for these critiques (Figure 1-9.)

Figure 1–9: The new Medical Research Council Framework for the development and evaluation of complex interventions (193)



The updated MRC guidance recognises flexibility in its process, with each stage ascertaining equal importance and the inclusion of development and implementation phases, which had been previously understated. Although the diagram suggests a process between the different phases, the report concedes that the process may not adhere to a cyclical process as is implied,

but suggests the use of an iterative approach which could travel back to an earlier phase if needed, with reporting considered a crucial denominator at every stage.

1.3.2 Aims, objectives and methods of the 3D-Study

In order to better understand the relationships between diabetes, depression and/or DSD, and inform the development of a complex intervention to identify and manage these in people with T2DM, work was completed in an exploratory fashion in accordance with the MRC framework, fulfilling the development phase. At the time of undertaking this programme of work, the original intention had been to develop, test, and evaluate an intervention. However, through the exploratory nature of the study and the acquisition of data, it became apparent that the development an intervention that could adequately identify and manage people with T2DM, depression and/or DSD would fall outside of the scope of this PhD. The structure of the PhD developed and adapted as new data emerged, with each stage informing the next, leading to the outline of a potential treatment model for people with T2DM, depression and/or DSD.

The 3D-study consisted of two systematic reviews and meta-analyses, the first to determine the prevalence of emotional-DSD in people with T2DM (Chapter 2), and the second to see if and what existing interventions have proven effective in reducing emotional-DSD in people with T2DM (Chapter 3). The data from these was combined with existing research on the prevalence of, and treatments for, depression in people with T2DM, to provide a foundation to potential treatment pathways. This then led into a qualitative interview study to elicit, explore and understand the views of HCPs and patients, in the context of living with T2DM, or providing health care for people with this condition, with or without depression (Chapters 4 to 6). Alongside the interview study, development work was conducted, which led to the mapping of the 3D-study data against existing programmes in practice, to inform the design of a potential treatment model (Chapter 7). Lastly, the work was evaluated, discussing the key findings, the strengths and limitations, and the implications of the work in relation to academic and clinical practice, with recommendations for work going forward (Chapter 8).

1.4 Chapter summary

This chapter has outlined the background and rationale (section 1.2) for the 3D-study, detailing the guidance on the development of complex interventions (section 1.3), and defining the aims of the work in relation to these, before lastly describing how these were achieved through the varying stages of this exploratory project (section 1.4). The following chapter (Chapter 2) will describe the first stage of exploration, which consisted of a systematic review and meta-analyses to determine the prevalence of emotional-DSD in people with T2DM.

Chapter 2 The prevalence of diabetes-specific emotional distress in people with Type 2 diabetes: A systematic review and meta-analysis

2.1 Chapter overview

In this chapter, I report the findings from a systematic review and meta-analysis undertaken to determine the prevalence of diabetes-specific emotional distress (emotional-DSD) in people with Type 2 diabetes (T2DM).

Within this chapter, the background and rationale for carrying out the systematic review and meta-analyses is given, stating the aims and objectives (section 2.2). Following this, the methods used to carry out the systematic review and meta-analyses are discussed (section 2.3), with further details given alongside the reporting of the results (section 2.4). Lastly, the key findings are discussed, reflecting upon the strengths and limitations of the review and its implications in relation to existing research and clinical practice (section 2.5), before concluding the chapter (section 2.6).

2.2 Introduction

2.2.1 Background and rationale

In order to fulfill the aims of this thesis, to better understand and inform the development of suitable treatment pathways for the co-existence of depression and/or diabetes-specific distress (DSD) in people with T2DM, understanding of the rates of depression and DSD in this population was needed. As discussed in chapter one, to date there had been no single review conducted to determine the prevalence of DSD in people with T2DM, such as that done by Ali *et al* (28) for the prevalence of comorbid depression in people with T2DM. While estimates have been made about the prevalence of DSD in people with T2DM ranging from 18-35% (139), there is a gap in the literature for a distinct analysis that was sought to be filled with the current systematic review and meta-analysis.

2.2.2 Aims and objectives

The aim this systematic review and meta-analysis was to determine the overall prevalence of emotional-DSD in people with T2DM, with secondary analyses to understand prevalence rates against a number of other bio-psycho-social variables including gender, age, glycated haemoglobin (HbA1c), duration of T2DM, depression, ethnicity, culture, and study region. The aims of determining and collecting this data were to use this in conjunction with existing research on the prevalence of depression to understand the potential rates for comorbidity in people with T2DM and better inform the design of potential treatment modality in this population.

2.3 Methods

2.3.1 Search criteria

The inclusion and exclusion criteria for this review were deliberately kept broad, with the view to capture as many studies as possible within the emotional-DSD literature since this in this relatively new field of study and data was limited. Studies were selected, regardless of methods, if they reported a baseline measure of emotional-DSD within an adult population ($\geq$18 years) of people with T2DM. In studies where both T1DM and T2DM populations were present, studies with a majority of T2DM ($\geq$70%) were included. Studies were excluded if they were not reported in the English language.

2.3.2 Search strategy and selection

A range of bibliographic databases were searched using a combination of free-text and Medical Subject Heading (MeSh)/Thesaurus terms. These included:

- The Excerpta Medica Database (EMBASE)
- The Medical Literature Analysis and Retrieval System Online (MEDLINE)
- The Psychological Information Database (PsycINFO)

- The Cumulative Index to Nursing and Allied Health Literature (CINAHL)
- The Cochrane Library
- The Applied Social Sciences Index and Abstracts database (ASSIA)
- The Scopus database.

Initial scoping searches indicated that the existing data for emotional-DSD was limited, and due to the exploratory nature of this study, the search strategy was also kept broad so as to include all studies that could provide a baseline score for emotional-DSD and thus inform the understanding of prevalence rates in this population. The search strategy was circulated to members of the project team (KK, FS, MD) to advise on any potential missing terms and these were added to the search. The final search for this review (see Box 2-1) was conducted on 12th September 2015.

Box 2-1: Example of the search strategy used in a systematic review and meta-analyses to determine the prevalence of diabetes-specific emotional distress in people with Type 2 diabetes, terms varied slightly depending on individual databases medical subject headings and truncations

Database: MEDLINE <1946 to 2015 week 37> Search Strategy:

1. Type 2 diabetes.tw.
2. (T2DM OR DM2 OR NIDDM OR IIDM).tw.
3. diabetes mellitus non insulin dependent.tw.
4. diabetes non insulin dependent.tw.
5. insulin resistance.tw.
6. exp Insulin Resistance/
7. (adult$ onset OR matur$ onset OR late$ onset).tw.
8. (non insulin$ depend$ OR non-insulin$ depend).tw.
9. ((typ$ 2 OR typ$ II) adj10 (diabet$ OR DM)).tw.
10. Distress$.tw.
11. (symptom$ adj4 distress$).tw.
12. (emotion$ adj4 distress$).tw.
13. (emotion$ adj4 problem$).tw.
14. (psychosocial adj4 distress$).tw.
15. (psycholog$ adj4 distress$).tw.
16. (physical$ adj4 distress$).tw.
17. (mental$ adj4 distress$).tw.
18. (burn adj out).tw
19. Exp Adjustment Disorders/
20. (adjust$ adj disorder$).tw
21. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9
22. 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20
23. 21 and 22

limit 23 to (english language and humans)

Box 2-2: Example of paper-selection tick-sheet used to ensure clarity in a systematic review and meta-analyses to determine the prevalence of diabetes-specific emotional distress in people with Type 2 diabetes

Stage 1: Initial paper selection from titles and abstracts

Points to consider	Yes	No	Unclear	Notes
Is the study written in English				Exclude if 'No'
Is the study population majority people Type 2 diabetes? (≥70%)				Exclude if 'No' Include if 'Unclear'
Are the study participants adult? (≥18 years old)				Exclude if 'No' Include if 'Unclear'
Does the study include a baseline measure of diabetes-specific emotional distress?				Exclude if 'No' Include if 'Unclear'

Include		Exclude	

Other potential terminology for diabetes-specific emotional distress could be:

- Emotional distress
- Emotional problems
- Psychosocial distress
- Psychological distress
- Physical distress
- Mental distress
- Burn out
- Adjustment disorder

2.3.3 Data extraction

Data were extracted using a form designed specifically for the review (Appendix 1). The main outcome measure to be extracted was a measure of emotional-DSD, taken as the number and percentage of the overall population scoring over the threshold for significant distress, depending on the measure used. For studies reporting the Problem Areas in Diabetes (PAID) scale as their outcome measure, the cut-off point was set at 40 as this is deemed high and has discriminative validity (142,194). For studies reporting the PAID-5, a short-form version of the PAID, the cut off was ≥8

(195). For studies using the Diabetes Distress Scale (DDS), where the total is taken as an average, rather than cumulatively, with moderate distress considered as 2.0-2.9, the cut of was ≥2 for the purposes of this review (139). Further data extracted included: study design, outcome, location and year; sample size, distribution and population demographics; biomedical outcomes such as HbA1c and body mass index (BMI); and depression where relevant.

Data reported in the study text was checked against data in tables and where discrepancies were found the data was taken from the tables.

For articles where studies were eligible but data was missing, incomplete or unclear, the authors were contacted to request data and/or clarification. In cases where studies reported their methodology elsewhere, all papers related to a particular study (including original study papers and/or papers solely reporting design and methodology) were retrieved to extract data or clarify information. Where possible, missing data (if not received from authors) was calculated using appropriate equations or imputed from other scores (Appendix 2).

2.3.4 Meta-analyses

The primary outcome of interest for this meta-analysis was the mean overall percentage of people in each study demonstrating significant levels of emotional-DSD. From this percentage, the proportion was calculated, and then from this the standard error of emotional-DSD (Appendix 2). The proportion and standard error were used to calculate overall prevalence using a random-effects meta-analysis.

Publication bias is a prominent concern within meta-analyses, which refers to the tendency within empirical research for studies of greater significance, interest, of higher quality, and/or from larger and better-funded studies to be published, or published faster, than other less prominent research (196). In order to determine how robust the findings of this meta-analysis were, publication bias was assessed using funnel plots and Egger's test (197).

An I^2 statistic test of heterogeneity was conducted to establish whether variations between studies included in this meta-analysis were due to chance. The value is expressed as a percentage of the total variation across studies that is attributed to heterogeneity rather than chance, which was quantified

as low (25%), moderate (50%) and high (75%) using tentative cut-off points suggested by previous authors (198). Meta-regression analyses were used to identify any potential sources of heterogeneity between studies against the following confounders: year of study, location of study (Eastern vs. Western culture), ethnicity distribution (≥50% vs. ≤50% Caucasian), gender distribution (Male ≥50% vs. Female ≥50%), mean age, mean HbA1c, mean length of T2DM diagnosis, mean BMI, percentage of diabetes complications/comorbidities, and percentage of comorbid depression.

Secondary analyses were conducted with further random-effects meta-analyses to determine and compare the prevalence rates of emotional-DSD across the following variables: outcome measure used; study location region; study location culture; population age group; population gender majority; population ethnicity (Caucasian vs. Black Minority Ethnic (BME) population); mean population BMI; mean population HbA1c; means years diagnosed with T2DM; population with diabetes-related complications and/or comorbidities; and population comorbid depression rates.

Study location regions were grouped following the six regions stated by the World Health Organisation (WHO) (Appendix 3). For culture, populations were split into either Eastern or Western cultures; Western cultures were defined as cultures developing from Europe and the historic expansion of this into the Americas and Australasia. Diabetes complications and comorbidities were initially intended to be assessed separately, but many studies reported these as the same thing so they were combined for the purposes of the analyses also.

All analyses were performed in STATA version 13.1 with advice and guidance given by trained statisticians when needed (DB, LG, NA_1).

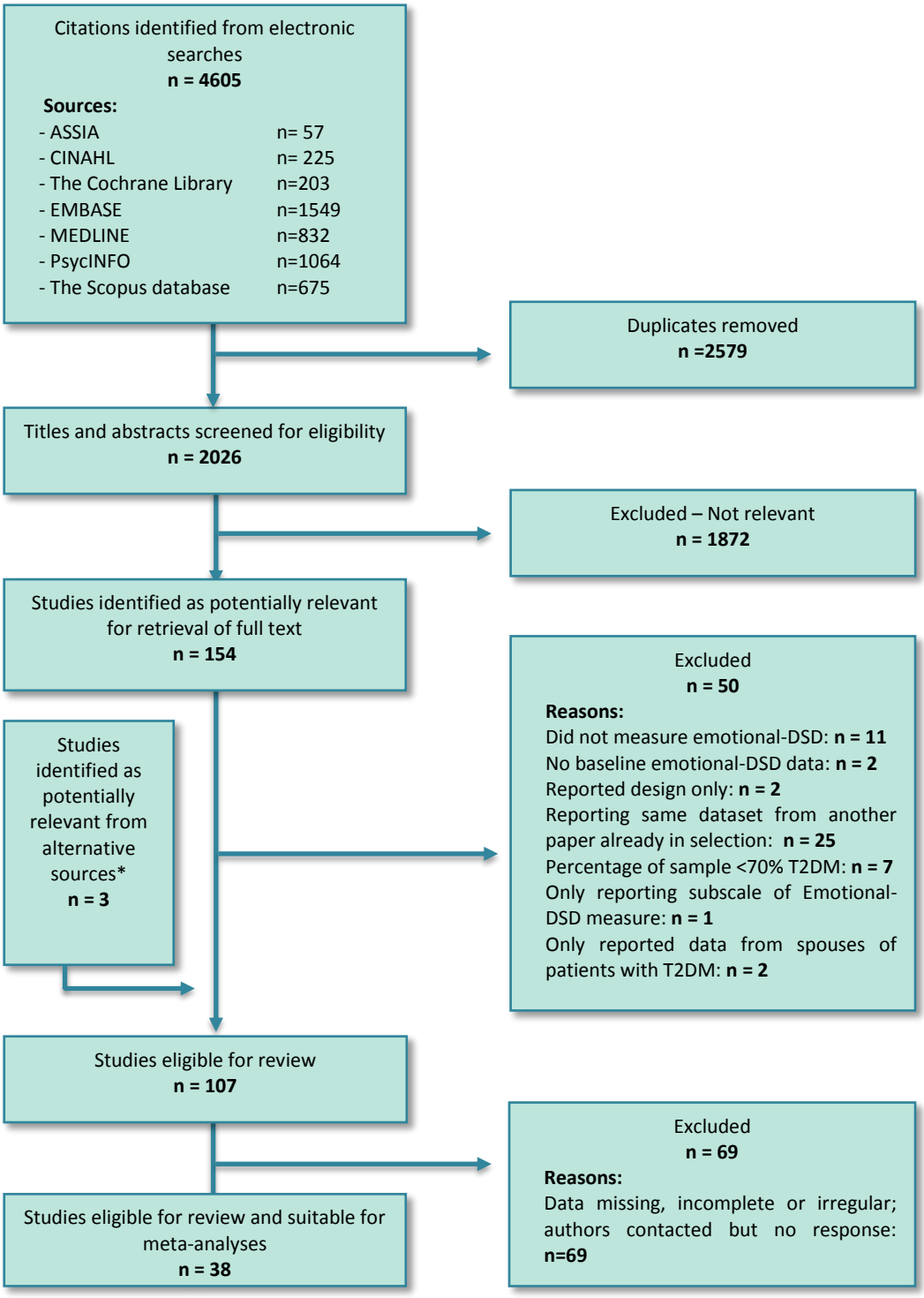
2.4 Results

2.4.1 Identification of studies

The process of identification and selection of eligible papers is summarised in Figure 2-1. Searches generated 4605 citations, of which 2026 abstracts were screened for eligibility following the removal of duplicates. Of these, 154 potentially relevant studies were selected for full text retrieval. Discussion with

field experts highlighted one study that was not on the databases searched (186) and this was included in the study. When requesting further information for two studies, authors directed me to other papers reporting the same data but in greater detail and these were used in the review instead: (199) directed to (200); (201) directed to (202). Of the 154 potential studies, plus the three directed from other sources, 107 were selected for inclusion within the review (135,136,148,149,156,171,173,174,186,200,202-298), of which thirty-eight were suitable for inclusion within the meta-analyses (135,136,149,174, 200,202-207,210,211,213-216,226,238,240,241,244,250,255,256,261,263, 266,268,272,274,276,278,285,291,293,297,298).

Figure 2–1: Consort flow diagram of the selection of studies, from initial searches to final inclusion, in a systematic review and meta-analyses to determine the prevalence of diabetes-specific emotional distress in people with Type 2 diabetes



*Identified from discussion with field experts or after direction from authors when contacted for further information
Abbreviations: ASSIA- The Applied Social Sciences Index and Abstract database; CINAHL - The Cumulative Index to Nursing and Allied Health Literature; EMBASE - The Exerpta Medica Database; Emotional-DSD – Diabetes-specific emotional distress; MEDLINE - The Medical Literature Analysis and Retrieval System Online; PsycINFO - The Psychological Information Database; T2DM – Type 2 diabetes

2.4.2 Summary of studies

Studies included in this systematic review and meta-analyses are summarised in Tables 2-1 and 2-2.

Of the thirty-eight studies included in the meta-analyses, studies were grouped by the measure of emotional-DSD they reported with twenty-two using the PAID scale, three using the short-form version PAID-5, and thirteen using the DDS. Studies were conducted within the last sixteen years, with data collected from the USA (n=18), the Netherlands (n=5), Australia (n=2), Canada (n=2), China (n=2), Germany (n=1), Indian (n=1), Iran (n=1), Japan (n=1), Norway (n=1) Serbia (n=1), Singapor (n=1), Slovenia (n=1), and one multi-national study.

The majority of studies in this review adopted a cross-sectional design (n=24). There were also RCTs (n=7), cohort studies (n=4), longitudinal studies (n=2) and one observational study. Samples sizes within the studies varied from 21 through to 8596.

The average age of participants in the studies was 57.11 years, with an even split of male and female genders (50.36% male). There was an average of 40.35% Caucasian ethnicity. Participants had been diagnosed with T2DM for an average of 10 years (range: 2.86-15.61 years) and had an average HbA1c was 8.02%. The average BMI in participants was 31.78.

Table 2-1: Studies included in a systematic review and meta-analyses to determine the prevalence of diabetes-specific emotional distress in people with Type 2 diabetes, authors A to M

Author	Study details		Sample		Sample demographics						Diabetes-specific emotional distress data				Comorbid depression data			
Aikens (2014)	Design	Observational	Total N	303	Age (M Yr)	66.60	HbA1c (M %)	-	BMI (M)	-	% DSD	04.00	Scale	PAID	% Dep	30.20	Scale	CES-D
	Location	USA	T2DM (%)	100	Male (%)	97.00	Duration (M Yr)	-	Caucasian (%)	92.90	M DSD	31.20	SD DSD	13.10	M D	02.50	SD D	02.37
Aikens (2012)	Design	Cross-sectional	Total N	253	Age (M Yr)	57.30	HbA1c (M %)	07.60	BMI (M)	-	% DSD	21.00	Scale	PAID	% Dep	50.00	Scale	PHQ-9
	Location	USA	T2DM (%)	100	Male (%)	50.00	Duration (M Yr)	01.60	Caucasian (%)	45.00	M DSD	22.10	SD DSD	19.00	M D	05.60	SD D	04.70
Ang-Co (2015	Design	Longitudinal	Total N	213	Age (M Yr)	45.00	HbA1c (M %)	08.30	BMI (M)	29.10	% DSD	31.92	Scale	PAID	% Dep	-	Scale	-
	Location	Singapore	T2DM (%)	100	Male (%)	63.40	Duration (M Yr)	09.30	Caucasian (%)	00.00	M DSD	29.03	SD DSD	21.91	M D	-	SD D	-
Baek (2014)	Design	Cross-sectional	Total N	119	Age (M Yr)	56.30	HbA1c (M %)	07.90	BMI (M)	-	% DSD	27.70	Scale	DDS	% Dep	-	Scale	-
	Location	USA	T2DM (%)	100	Male (%)	36.10	Duration (M Yr)	13.30	Caucasian (%)	25.40	M DSD	02.30	SD DSD	01.20	M D	-	SD D	-
Baradaran (2013)	Design	Cross-sectional	Total N	185	Age (M Yr)	56.06	HbA1c (M %)	08.03	BMI (M)	28.30	% DSD	35.00	Scale	PAID	% Dep	43.20	Scale	C.I.
	Location	Iran	T2DM (%)	100	Male (%)	48.00	Duration (M Yr)	09.70	Caucasian (%)	00.00	M DSD	-	SD DSD	-	M D	-	SD D	-
Baumeister (2014)	Design	RCT	Total N	145	Age (M Yr)	57.30	HbA1c (M %)	-	BMI (M)	-	% DSD	10.15	Scale	PAID	% Dep	41.50	Scale	PHQ-9
	Location	Germany	T2DM (%)	72	Male (%)	63.10	Duration (M Yr)	13.11	Caucasian (%)	-	M DSD	-	SD DSD	-	M D	-	SD D	-
Beverly (2013)	Design	RCT	Total N	134	Age (M Yr)	59.10	HbA1c (M %)	08.40	BMI (M)	34.20	% DSD	27.23	Scale	PAID	% Dep	-	Scale	BSI
	Location	USA	T2DM (%)	100	Male (%)	48.50	Duration (M Yr)	13.30	Caucasian (%)	71.60	M DSD	34.10	SD DSD	21.70	M D	49.70	SD D	10.40
Browne (2012)	Design	Cross-sectional	Total N	149	Age (M Yr)	32.33	HbA1c (M %)	-	BMI (M)	33.64	% DSD	63.00	Scale	PAID-5	% Dep	-	Scale	-
	Location	Australia	T2DM (%)	100	Male (%)	38.20	Duration (M Yr)	02.86	Caucasian (%)	-	M DSD	09.41	SD DSD	04.85	M D	-	SD D	-
Carper (2012)	Design	Cross-sectional	Total N	146	Age (M Yr)	56.01	HbA1c (M %)	08.25	BMI (M)	-	% DSD	79.5	Scale	DDS	% Dep	56.80	Scale	C.I.
	Location	USA	T2DM (%)	100	Male (%)	57.50	Duration (M Yr)	10.93	Caucasian (%)	82.00	M DSD	02.87	SD DSD	01.09	M D		SD D	-
Chen (2013)	Design	Cohort	Total N	1200	Age (M Yr)	-	HbA1c (M %)	-	BMI (M)	-	% DSD	65.50	Scale	PAID	% Dep	28.00	Scale	CES-D
	Location	China	T2DM (%)	100	Male (%)	100.0	Duration (M Yr)	-	Caucasian (%)	00.00	M DSD	-	SD DSD	-	M D		SD D	-
Chesla (2013)	Design	Cohort	Total N	178	Age (M Yr)	64.45	HbA1c (M %)	07.17	BMI (M)	-	% DSD	-	Scale	DDS	% Dep	48.00	Scale	CES-D
	Location	USA	T2DM (%)	100	Male (%)	41.00	Duration (M Yr)	07.91	Caucasian (%)	00.00	M DSD	02.59	SD DSD	02.38	M D	18.06	SD D	11.79
Delahanty (2007)	Design	Cross-sectional	Total N	815	Age (M Yr)	-	HbA1c (M %)	-	BMI (M)	-	% DSD	15.43	Scale	PAID	% Dep	-	Scale	-
	Location	USA	T2DM (%)	100	Male (%)	51.00	Duration (M Yr)	-	Caucasian (%)	85.33	M DSD	18.70	SD DSD	-	M D	-	SD D	-
Fisher (2010)	Design	Cross-sectional	Total N	463	Age (M Yr)	58.80	HbA1c (M %)	08.10	BMI (M)	34.80	% DSD	51.30	Scale	DDS	% Dep	15.30	Scale	PHQ-8
	Location	USA	T2DM (%)	100	Male (%)	48.50	Duration (M Yr)	-	Caucasian (%)	72.00	M DSD	-	SD DSD	-	M D	-	SD D	-
Gariepy (2013)	Design	Cross-sectional	Total N	600	Age (M Yr)	58.10	HbA1c (M %)	-	BMI (M)	-	% DSD	23.00	Scale	DDS	% Dep	-	Scale	-
	Location	Canada	T2DM (%)	100	Male (%)	46.30	Duration (M Yr)	11.50	Caucasian (%)	-	M DSD	01.60	SD DSD	00.70	M D	-	SD D	-
Ikeda (2014)	Design	Cross-sectional	Total N	199	Age (M Yr)	60.45	HbA1c (M %)	07.60	BMI (M)	27.13	% DSD	-	Scale	PAID	% Dep	-	Scale	-
	Location	Japan	T2DM (%)	100	Male (%)	58.50	Duration (M Yr)	10.58	Caucasian (%)	21.71	M DSD	28.57,	SD DSD	19.95	M D	-	SD D	-
Jansen (2014)	Design	Cohort	Total N	65	Age (M Yr)	60.00	HbA1c (M %)	08.90	BMI (M)	30.80	% DSD	73.85	Scale	PAID	% Dep	-	Scale	-
	Location	Netherlands	T2DM (%)	100	Male (%)	64.00	Duration (M Yr)	09.00	Caucasian (%)	95.00	M DSD	10.00	SD DSD	01.40	M D	-	SD D	-
Karlsen (2012)	Design	Cross-sectional	Total N	378	Age (M Yr)	58.10	HbA1c (M %)	07.10	BMI (M)	29.70	% DSD	22.00	Scale	PAID	% Dep	-	Scale	-
	Location	Norway	T2DM (%)	100	Male (%)	54.20	Duration (M Yr)	08.20	Caucasian (%)	100	M DSD	26.00	SD DSD	18.00	M D	-	SD D	-
LeBron (2014)	Design	Cross-sectional	Total N	157	Age (M Yr)	52.60	HbA1c (M %)	-	BMI (M)	-	% DSD	23.31	Scale	PAID	% Dep	13.41	Scale	PHQ-9
	Location	USA	T2DM (%)	100	Male (%)	29.30	Duration (M Yr)	-	Caucasian (%)	00.00	M DSD	25.00	SD DSD	01.76	M D	05.07	SD D	05.12
McEwen (2000)	Design	Cohort	Total N	21	Age (M Yr)	53.71	HbA1c (M %)	07.79	BMI (M)	35.26	% DSD	19.00	Scale	DDS	% Dep	-	Scale	-
	Location	USA	T2DM (%)	100	Male (%)	19.00	Duration (M Yr)	07.20	Caucasian (%)	-	M DSD	02.14	SD DSD	01.70	M D	-	SD D	-

Abbreviations: BMI – Body mass index (kg/m^2); BSI – Brief Symptom Inventory ; CES-D – Center for Epidemiological Studies Depression Scale ; C.I. – Clinical Interviews; D – Depression; DSD– Diabetes-specific emotional distress (% DSD is percentage of participants demonstrating significant levels of DSD); M – Mean; N – Number; PHQ-8 – Personal Health Questionnaire version 8 ; PHQ-9 – Personal Health Questionnaire version 9; SD – Standard Deviation; Yr – Years.

Table 2-2: Studies included in a systematic review and meta-analyses to determine the prevalence of diabetes-specific emotional distress in people with Type 2 diabetes, authors A to M

Author	Study details		Sample		Sample demographics						Diabetes-specific emotional distress data				Comorbid depression data			
Nichols	Design	Cross-sectional	Total N	924	Age (M Yr)	35.10	HbA1c (M %)	07.95	BMI (M)	32.85	% DSD	35.17	Scale	PAID	% Dep	-	Scale	-
(2000)	Location	USA	T2DM (%)	100	Male (%)	-	Duration (M Yr)	15.00	Caucasian (%)	-	M DSD	-	SD DSD	-	M D	-	SD D	-
Nicolucci	Design	Cross-sectional	Total N	8596	Age (M Yr)	57.00	HbA1c (M %)	-	BMI (M)	27.10	% DSD	44.60	Scale	PAID	% Dep	25.50	Scale	-
(2013)	Location	Multi-national	T2DM (%)	84	Male (%)	52.60	Duration (M Yr)	09.00	Caucasian (%)	-	M DSD	35.20	SD DSD	24.20	M D	-	SD D	-
Park	Design	Cross-sectional	Total N	155	Age (M Yr)	55.70	HbA1c (M %)	07.40	BMI (M)	33.00	% DSD	54.19	Scale	DDS	% Dep	24.5	Scale	*
(2015)	Location	USA	T2DM (%)	100	Male (%)	28.40	Duration (M Yr)	07.30	Caucasian (%)	40.60	M DSD	02.33	SD DSD	01.04	M D	-	SD D	-
Primozic	Design	Cross-sectional	Total N	98	Age (M Yr)	63.74	HbA1c (M %)	07.68	BMI (M)	30.15	% DSD	13.20	Scale	PAID	% Dep	-	Scale	HDI
(2012)	Location	Slovenia	T2DM (%)	100	Male (%)	49.00	Duration (M Yr)	15.61	Caucasian (%)	-	M DSD	15.09	SD DSD	12.78	M D	10.48	SD D	07.87
Rogvi	Design	Cross-sectional	Total N	2045	Age (M Yr)	64.30	HbA1c (M %)	07.60	BMI (M)	31.00	% DSD	29.05	Scale	PAID-5	% Dep	-	Scale	-
(2012)	Location	Netherlands	T2DM (%)	100	Male (%)	65.00	Duration (M Yr)	14.40	Caucasian (%)	-	M DSD	-	SD DSD	-	M D	-	SD D	-
Schiotz	Design	Cross-sectional	Total N	2572	Age (M Yr)	60.50	HbA1c (M %)	07.50	BMI (M)	30.80	% DSD	26.00	Scale	PAID-5	% Dep	-	Scale	-
(2011)	Location	Netherlands	T2DM (%)	100	Male (%)	66.00	Duration (M Yr)	10.00	Caucasian (%)	-	M DSD	-	SD DSD	-	M D	-	SD D	-
Sekhar	Location	RCT	Total N	546	Age (M Yr)	55.44	HbA1c (M %)	-	BMI (M)	-	% DSD	53.00	Scale	-	% Dep	-	Scale	-
(2013)	Location	India	T2DM (%)	100	Male (%)	56.00	Duration (M Yr)	06.14	Caucasian (%)	00.00	M DSD	-	SD DSD	-	M D	-	SD D	-
Sinclair	Design	RCT	Total N	65	Age (M Yr)	53.83	HbA1c (M %)	09.86	BMI (M)	36.83	% DSD	67.10	Scale	PAID	% Dep	-	Scale	-
(2013)	Location	USA	T2DM (%)	100	Male (%)	37.50	Duration (M Yr)	-	Caucasian (%)	00.00	M DSD	28.10	SD DSD	27.11	M D	-	SD D	-
Smith	Design	Cross-sectional	Total N	1787	Age (M Yr)	60.55	HbA1c (M %)	-	BMI (M)	-	% DSD	22.50	Scale	DDS	% Dep	13.38	Scale	PHQ-9
(2013)	Location	USA	T2DM (%)	100	Male (%)	48.5	Duration (M Yr)	-	Caucasian (%)	-	M DSD	-	SD DSD	-	M D	-	SD D	-
Spencer	Design	Cross-sectional	Total N	180	Age (M Yr)	56.63	HbA1c (M %)	08.39	BMI (M)	-	% DSD	25.10	Scale	PAID	% Dep	-	Scale	-
(2006)	Location	USA	T2DM (%)	100	Male (%)	25.55	Duration (M Yr)	-	Caucasian (%)	00.00	M DSD	23.93	SD DSD	21.81	M D	-	SD D	-
Stankoviv	Design	Cross-sectional	Total N	90	Age (M Yr)	55.75	HbA1c (M %)	08.90	BMI (M)	30.74	% DSD	67.80	Scale	PAID	% Dep	51.10	Scale	PHQ-9
(2011)	Location	Serbia	T2DM (%)	100	Male (%)	34.65	Duration (M Yr)	12.03	Caucasian (%)	-	M DSD	47.97	SD DSD	15.83	M D	10.54	SD D	07.86
Stoop	Design	Cross-sectional	Total N	1300	Age (M Yr)	65.00	HbA1c (M %)	07.03	BMI (M)	29.00	% DSD	10.00	Scale	PAID	% Dep	-	Scale	-
(2014)	Location	Netherlands	T2DM (%)	100	Male (%)	55.00	Duration (M Yr)	-	Caucasian (%)	94.00	M DSD	14.06	SD DSD	17.45	M D	-	SD D	-
Thom	Design	RCT	Total N	299	Age (M Yr)	55.19	HbA1c (M %)	09.99	BMI (M)	33.74	% DSD	60.96	Scale	DDS	% Dep	-	Scale	-
(2013)	Location	USA	T2DM (%)	100	Male (%)	47.80	Duration (M Yr)	08.90	Caucasian (%)	10.75	M DSD	02.42	SD DSD	00.97	M D	-	SD D	-
van Son	Design	RCT	Total N	139	Age (M Yr)	56.50	HbA1c (M %)	07.55	BMI (M)	-	% DSD	33.90	Scale	PAID	% Dep	-	Scale	HADS
(2013)	Location	Netherlands	T2DM (%)	70	Male (%)	50.50	Duration (M Yr)	-	Caucasian (%)	-	M DSD	36.05	SD DSD	18.30	M D	08.40	SD D	03.90
Wardian	Design	Cross-sectional	Total N	267	Age (M Yr)	57.97	HbA1c (M %)	-	BMI (M)	30.94	% DSD	59.93	Scale	DDS	% Dep	-	Scale	-
(2015)	Location	USA	T2DM (%)	100	Male (%)	44.00	Duration (M Yr)	05.06	Caucasian (%)	56.00	M DSD	02.40	SD DSD	00.99	M D	-	SD D	-
Welch	Design	RCT	Total N	46	Age (M Yr)	55.82	HbA1c (M %)	08.77	BMI (M)	34.71	% DSD	50.85	Scale	PAID	% Dep	66.10	Scale	PHQ-9
(2011)	Location	USA	T2DM (%)	100	Male (%)	35.05	Duration (M Yr)	11.90	Caucasian (%)	-	M DSD	49.68	SD DSD	23.82	M D	-	SD D	-
Wycherley	Design	RCT	Total N	84	Age (M Yr)	56.10	HbA1c (M %)	07.43	BMI (M)	35.32	% DSD	36.90	Scale	PAID	% Dep	-	Scale	-
(2014)	Location	Australia	T2DM (%)	100	Male (%)	58.30	Duration (M Yr)	-	Caucasian (%)	-	M DSD	31.90	SD DSD	19.30	M D	-	SD D	-
Zhang	Design	Cross-sectional	Total N	200	Age (M Yr)	59.60	HbA1c (M %)	-	BMI (M)	-	% DSD	64.00	Scale	DDS	% Dep	-	Scale	-
(2013)	Location	China	T2DM (%)	100	Male (%)	48.00	Duration (M Yr)	09.00	Caucasian (%)	00.00	M DSD	-	SD DSD	-	M D	-	SD D	-
Zulman	Design	Cross-sectional	Total N	1834	Age (M Yr)	70.00	HbA1c (M %)	-	BMI (M)	-	% DSD	62.00	Scale	PAID	% Dep	19.00	Scale	CES-D
(2012)	Location	USA	T2DM (%)	100	Male (%)	48.00	Duration (M Yr)	12.00	Caucasian (%)	76.00	M DSD	-	SD DSD	-	M D	-	SD D	-

Abbreviations: BMI – Body mass index (kg/m^2); CES-D – Center for Epidemiological Studies Depression Scale; D – Depression; DSD– Diabetes-specific emotional distress (% DSD is percentage of participants demonstrating significant levels of DSD); HADS – Hospital Anxiety and Depression Scale; M – Mean; N – Number; PHQ-9 – Personal Health Questionnaire version 9; SD – Standard Deviation; Yr – Years. * - No Scale given, described as "having regular MD".

2.4.3 Meta-analyses

A summary of the data for this meta-analyses to determine the prevalence of emotional-DSD in people with T2DM is shown in Table 2-3.

Table 2-3: Summary of data used in meta-analyses to determine the prevalence of diabetes-specific emotional distress in people with Type 2 diabetes

Author	(Year)	Outcome	Total N	N DSD	% DSD	Prop DSD	SE DSD
Aikens	(2012)	PAID	253	53	21.00	.210	.026
Aikens	(2014)	PAID	303	12	04.00	.040	.011
Ang Co	(2015)	PAID	213	68	31.92	.319	.032
Baek	(2014)	DDS	119	57	47.90	.479	.046
Baradaran	(2013)	DDS	185	65	35.00	.350	.035
Baumeister	(2014)	PAID	145	14	10.15	.101	.025
Beverly	(2013)	PAID	134	316	27.53	.275	.385
Browne	(2012)	PAID-5	149	88	63.00	.630	.040
Carper	(2012)	DDS	146	116	79.50	.795	.033
Chen	(2013)	PAID	1200	786	65.50	.655	.014
Chesla	(2013)	DDS	178	126	71.60	.716	.034
Delahanty	(2007)	PAID	815	126	15.43	.154	.013
Fisher	(2010)	DDS	463	238	51.30	.513	.023
Gariepy	(2013)	DDS	600	138	23.00	.230	.017
Ikeda	(2014)	PAID	199	66	33.00	.330	.033
Jansen	(2014)	PAID	65	48	73.85	.738	.055
Karlsen	(2012)	PAID	378	83	22.00	.220	.021
Le Bron	(2014)	PAID	157	38	23.31	.233	.034
McEwan	(2010)	DDS	21	84	19.00	.190	.856
Nichols	(2000)	PAID	924	325	35.17	.352	.016
Nicolucci	(2013)	PAID	8596	3486	44.60	.446	.005
Park	(2015)	DDS	155	84	54.19	.542	.040
Primozic	(2012)	PAID	98	15	13.20	.132	.034
Rogvi	(2012)	PAID-5	2045	314	29.05	.291	.010
Schiotz	(2011)	PAID-5	2572	657	26.00	.260	.008
Sekhar	(2013)	DDS	546	291	53.00	.530	.021
Sinclair	(2013)	PAID	65	55	67.10	.671	.058
Smith	(2013)	DDS	1787	457	22.50	.225	.010
Spencer	(2006)	PAID	180	45	25.10	.251	.032
Stankoviv	(2011)	PAID	90	61	67.80	.678	.049
Stoop	(2014)	PAID	1300	131	10.00	.100	.008
Thom	(2013)	DDS	299	182	60.96	.610	.028
van Son	(2013)	PAID	139	47	33.90	.339	.040
Wardian	(2015)	DDS	267	160	59.93	.599	.030
Welch	(2011)	PAID	46	23	50.85	.509	.074
Wycherley	(2014)	PAID	84	31	36.90	.369	.053
Zhang	(2013)	DDS	200	128	64.00	.640	.034
Zulman	(2012)	PAID	1834	1137	62.00	.620	.011

38 studies, with a total of 26,950 participants, reported the percentage of significant emotional-DSD and were included in a random-effects meta-analysis to determine the overall prevalence of emotional-DSD in people with T2DM (Table 2-4; Figure 2-2).

Table 2-4: Results of a pooled random effects meta-analysis to determine the overall prevalence of diabetes-specific emotional distress in people with Type 2 diabetes

Author	(Year)	Effect Size	95% Confidence Interval		% Weight
Aikens	(2012)	0.210	0.160	0.260	2.67
Aikens	(2014)	0.040	0.018	0.062	2.71
Ang Co	(2015)	0.319	0.257	0.382	2.65
Baek	(2014)	0.479	0.389	0.569	2.57
Baradaran	(2013)	0.350	0.281	0.419	2.63
Baumeister	(2014)	0.101	0.025	0.151	2.67
Beverly	(2013)	0.275	0.200	0.351	2.61
Browne	(2012)	0.630	0.552	0.708	2.61
Carper	(2012)	0.795	0.730	0.860	2.64
Chen	(2013)	0.655	0.628	0.682	2.71
Chesla	(2013)	0.716	0.650	0.782	2.64
Delahanty	(2007)	0.154	0.129	0.179	2.71
Fisher	(2010)	0.513	0.467	0.559	2.68
Gariepy	(2013)	0.230	0.196	0.264	2.70
Ikeda	(2014)	0.330	0.265	0.395	2.64
Jansen	(2014)	0.738	0.632	0.845	2.52
Karlsen	(2012)	0.220	0.178	0.262	2.69
LeBron	(2014)	0.233	0.167	0.299	2.64
McEwan	(2010)	0.190	0.022	0.358	2.27
Nichols	(2000)	0.352	0.321	0.383	2.70
Nicolucci	(2013)	0.446	0.435	0.457	2.72
Park	(2015)	0.542	0.463	0.620	2.61
Primozic	(2012)	0.132	0.065	0.199	2.64
Rogvi	(2012)	0.290	0.271	0.310	2.71
Schiotz	(2011)	0.260	0.243	0.277	2.71
Sekhar	(2013)	0.530	0.488	0.572	2.69
Sinclair	(2013)	0.671	0.557	0.785	2.49
Smith	(2013)	0.225	0.206	0.244	2.71
Spencer	(2006)	0.521	0.188	0.314	2.64
Stankoviv	(2011)	0.678	0.581	0.775	2.55
Stoop	(2014)	0.100	0.084	0.116	2.72
Thom	(2013)	0.610	0.554	0.665	2.66
Van Son	(2013)	0.339	0.260	0.418	2.61
Wardian	(2015)	0.599	0.540	0.658	2.65
Welch (ii)	(2011)	0.508	0.634	0.653	2.37
Wycherley	(2014)	0.369	0.266	0.482	2.53
Zhang	(2013)	0.640	0.57.	0.707	2.64
Zulman	(2012)	0.620	0.598	0.642	2.71
Pooled Effect Size		0.402	0.341	0.464	100

The overall effect size (ES) was 0.402 (95% CI = 0.341, 0.464). Heterogeneity was shown to be very high with I^2 = 99.2 with potential confounders identified through meta-regression analyses as the outcome measures used, mean Hba1c, and mean duration of T2DM diagnosis (Table 2-6 and 2-7). Eggers test (p=0.299) suggested that publication bias was absent, however the funnel plot demonstrated asymmetry, which could indicate the potential for publication bias.

Figure 2–2: Graph demonstrating the results of a pooled random effects meta-analysis to determine the overall prevalence of diabetes-specific emotional distress in people with Type 2 diabetes

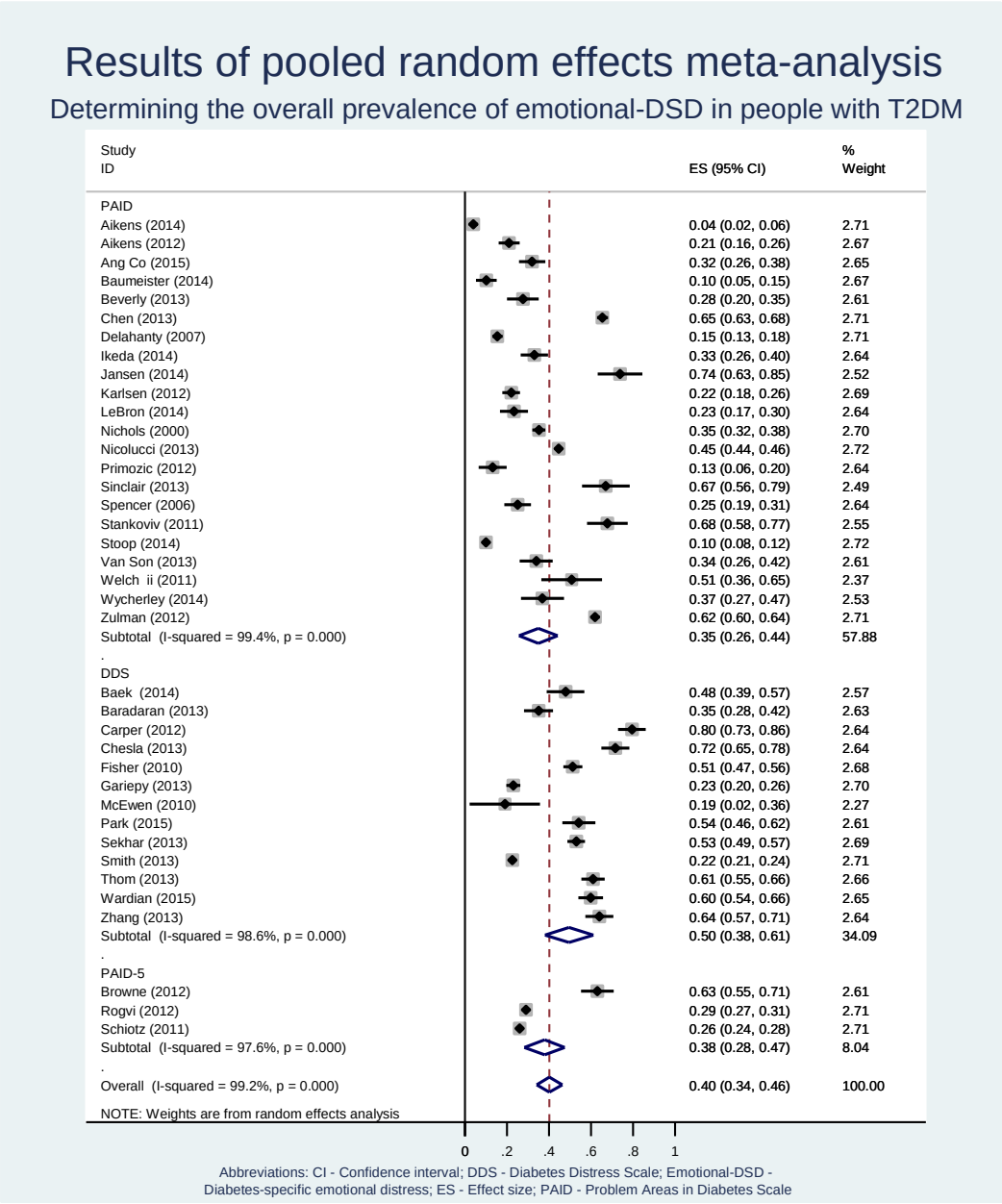
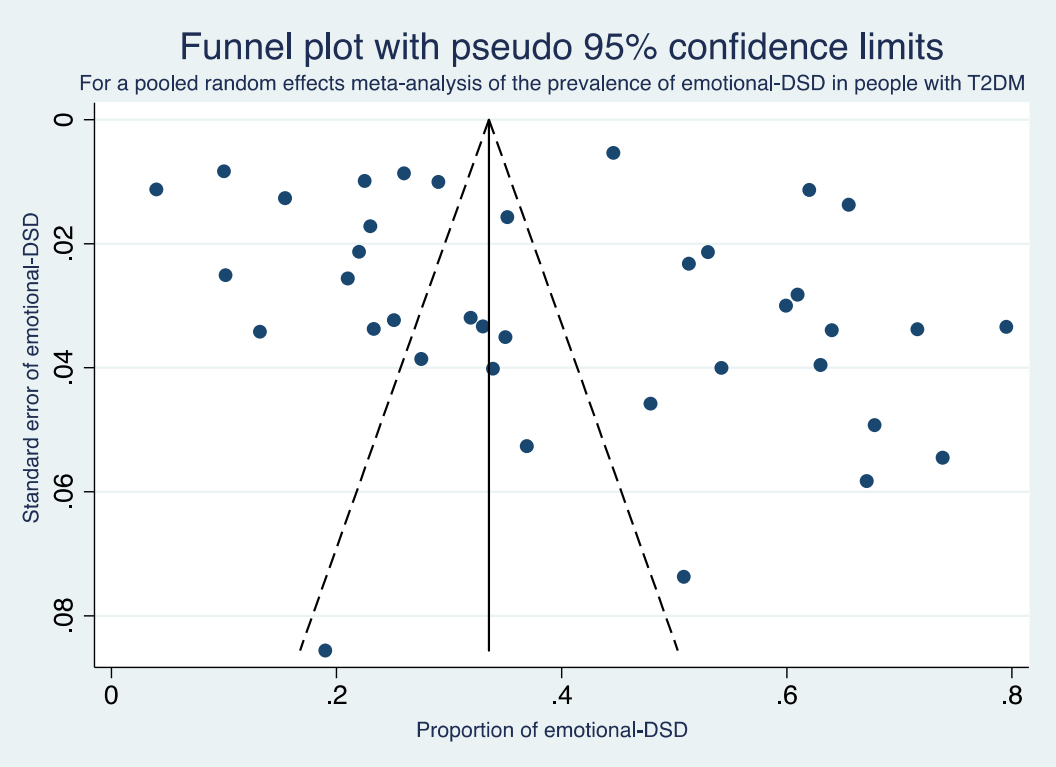


Figure 2–3: Funnel plot to determine potential publication bias in a pooled random effects meta-analysis to determine the overall prevalence of diabetes-specific emotional distress in people with Type 2 diabetes



Secondary analyses, to explore the prevalence of emotional-DSD across different variables to consider factors that significantly affect prevalence rates (Table 2-5 and 2-6), demonstrated that the prevalence of emotional-DSD was significantly influenced by the outcome measure used (p=0.045), mean HbA1c scores (p=0.003), and the mean duration of T2DM diagnoses (p=0.049). Prevalence rates were significantly higher in studies using the DDS (50%; ES=0.496) than those using the PAID or PAID-5 (35%; ES=0.349 and 38%; ES=0.378). Emotional-DSD was also significantly higher when the average HbA1c score was increased (32%; ES=0.317 for 7-7.9% HbA1c; 49%; ES=0.490 for 8-8.9% HbA1c; and 62%; ES=0.621 for 9-9.9% HbA1c, p=0.003). Lastly, significantly higher emotional-DSD was seen in those with more recently diagnosed T2DM, showing a reduction in rates as diagnosis duration increased (63%, ES=0.630 for 2-4 years; 60%, ES=0.599 for 4-6 years; 52%, ES=0.515 for 6-8 years; 43%. ES=0.430 for 8-10 years; 42%. ES=0.420 for 10-12 years; 43%. ES=0.430 for 12-14 years; and 27%. ES=0.265 for 14-16 years, p=0.049).

Table 2-5: Results of secondary pooled random effects meta-analyses and meta-regression to determine and compared the prevalence of diabetes-specific emotional distress in people with Type 2 diabetes across differing variables, part one.

Variables		N_S	Meta-analyses					Meta-regression				
			Prevalence (%)	ES	95% CI		Weight %	Co-Eff	SE	p-value	95% CI	
Outcome measure	DDS	13	50	0.496	0.380	0.611	34.09	0.723	0.351	**0.045**	0.002	0.144
	PAID	22	35	0.349	0.257	0.442	57.88					
	PAID-5	03	38	0.378	0.282	0.475	08.04					
Study year	2014-2015	11	35	0.346	0.234	0.458	28.90	0.009	0.012	0.471	-0.016	0.034
	2012-2013	19	45	0.450	0.374	0.527	50.46					
	2010-2011	05	43	0.433	0.256	0.609	12.58					
	Pre-2010	03	25	0.252	0.111	0.393	08.05					
Study location*	AMERICAS	20	41	0.410	0.310	0.511	52.39	0.057	0.039	0.152	-0.022	0.138
	EASTERN MEDITERANIAN	01	35	0.350	0.281	0.419	02.63					
	WESTERN PACIFIC	06	49	0.492	0.351	0.633	15.77					
	SOUTH EAST ASIA	01	53	0.530	0.488	0.572	02.69					
	EUROPEAN	09	31	0.306	0.224	0.389	23.81					
	Multinational	01	45	0.446	0.435	0.457	02.71					
Study location culture*	Western	31	38	0.387	0.319	0.455	81.33	-0.084	0.095	0.383	-0.276	0.109
	Eastern	06	47	0.472	0.345	0.599	15.95					
	Multinational	01	47	0.446	0.435	0.457	02.72					
Age group (years)	30 - 39	02	49	0.488	0.216	0.761	05.31	-0.005	0.005	0.262	-0.015	0.004
	40 - 49	01	32	0.319	0.257	0.382	02.65					
	50 - 59	23	43	0.425	0.359	0.490	59.92					
	60 - 69	10	29	0.290	0.211	0.368	26.70					
	70 - 79	01	62	0.620	0.598	0.642	02.71					
	Not reported	01	66	0.655	0.628	0.682	02.71					
Gender majority (%)	Female	20	46	0.455	0.362	0.548	52.02	-0.110	0.069	0.118	-0.249	0.029
	Male	17	35	0.345	0.253	0.437	45.28					
	Not reported	01	40	0.352	0.321	0.383	02.70					
Ethnicity majority (%)	Caucasian	10	40	0.404	0.240	0.568	26.64	-0.063	0.093	0.505	-0.257	0.130
	BME	14	47	0.466	0.368	0.564	36.87					
	Not reported	14	34	0.336	0.269	0.403	36.49					
Body Mass Index	25.0 - 29.9	06	29	0.294	0.123	0.465	16.04	0.022	0.015	0.154	-0.009	0.052
	30.0 - 34.9	14	44	0.443	0.364	0.523	36.73					
	35.0 - 39.9	03	42	0.415	0.155	0.675	07.28					
	Not reported	15	40	0.404	0.273	0.535	39.95					

Abbreviations: CI – Confidence interval; Co-Eff – Co-efficient; ES – Effect size; N_S – Number of studies; SE – Standard error

Table 2-6: Results of secondary pooled random effects meta-analyses and meta-regression to determine and compared the prevalence of diabetes-specific emotional distress in people with Type 2 diabetes across differing variables, part two.

Variables		N_S	Meta-analyses					Meta-regression				
			Prevalence (%)	ES	95% CI		Weight %	Co-Eff	SE	p-value	95% CI	
HbA1c (%)	7.0 - 7.9	13	32	0.317	0.229	0.406	33.98	0.148	0.045	**0.003**	0.054	0.242
	8.0 - 8.9	09	49	0.490	0.358	0.623	23.29					
	9.0 - 9.9	02	62	0.621	0.571	0.671	05.15					
	Not reported	14	39	0.392	0.294	0.490	37.58					
Years diagnosed with T2DM	2 - 4	01	63	0.630	0.552	0.708	02.61	-0.026	0.013	**0.049**	-0.052	-0.001
	4 - 6	01	60	0.599	0.540	0.658	02.65					
	6 - 8	04	52	0.515	0.378	0.652	10.20					
	8 - 10	07	43	0.430	0.267	0.594	18.49					
	10 - 12	05	42	0.420	0.264	0.577	13.06					
	12 - 14	05	43	0.430	0.181	0.679	13.12					
	14 - 16	03	27	0.265	0.183	0.347	08.05					
	Not reported	12	35	0.336	0.214	0.58	31.82					
Comorbidities/complications (%)	10 - 19	01	74	0.738	0.632	0.845	02.52	0.001	0.002	0.879	-0.004	0.005
	20 - 29	01	21	0.210	0.160	0.260	02.67					
	30 - 39	01	53	0.530	0.488	0.572	02.69					
	40 - 49	05	29	0.292	0.202	0.382	13.41					
	50 - 59	03	34	0.342	0.191	0.493	07.86					
	60 - 69	02	45	0.448	-0.232	1.128	05.31					
	70 - 79	05	33	0.332	0.123	0.541	13.37					
	80 - 89	03	36	0.631	0.126	0.597	08.02					
	90 - 100	01	68	0.678	0.581	0.775	02.55					
	Not reported	16	44	0.440	0.309	0.570	41.59					
Depression (%)	10 - 19	05	34	0.339	0.125	0.553	13.42	0.005	0.003	0.154	-0.002	0.123
	20 - 29	04	57	0.570	0.432	0.708	10.67					
	30 - 39	01	4	0.04	0.018	0.062	02.71					
	40 - 49	02	53	0.533	0.174	0.892	05.27					
	50 - 59	03	56	0.560	0.153	0.967	07.86					
	>60	01	51	0.508	0.364	0.653	02.37					
	Not reported	22	36	0.364	0.302	0.426	57.71					

Abbreviations: CI – Confidence interval; Co-Eff – Co-efficient; ES – Effect size; N_S – Number of studies; SE – Standard error

2.5 Discussion

2.5.1 Key findings

Thirty-eight studies, with a total of 26,950 participants, were included in meta-analyses to determine the overall prevalence of emotional-DSD in people with T2DM, with secondary analyses to examine how the prevalence varies across different variables. The overall prevalence of emotional-DSD in people with T2DM found in this review was 40% (ES=0.402). Secondary meta-analyses and meta-regression demonstrated that higher emotional-DSD was associated with use of the DDS scale, increased HbA1c, and newly diagnosed T2DM.

2.5.2 Strengths and limitations

This is the first known systematic review and meta-analyses of the existing literature to determine the prevalence of emotional-DSD in a T2DM population. As such, it provides novel information for a gap in the literature and offers validation to existing estimates. The methods used to carry out this review were robust, adopting strategies to gain all relevant outcome data available, even when not reported.

While it is a potential strength that this review is the first of its kind, it meant that the data available was limited, since the field of emotional-DSD is a relatively new one. This was further hindered by the vast majority of papers not reporting the data required for the analyses and despite extensive efforts to contact authors for any missing data or to clarify any discrepancies, this often proved unsuccessful, either due to contact details no longer being valid and/or receiving no reply.

Collating the data from multiple studies allows for increased power and precision, and the exploration of more conclusive interpretations that could not be demonstrated in a single study, such as specific population demographics that may influence upon prevalence rates. While there are potential strengths to meta-analyses, limitations also lie in the use of summary data only and the inability to alter or improve the quality of data from the original studies (299). Furthermore, there lies an inherent potential for

publication bias, as discussed with the funnel plot (Figure 2-3), where only studies with significant findings are likely to be published. This leaves the potential for studies with lower levels of DSD being missed from the analyses, and the potential inference that, had these studies been available for the analyses, then this may have altered the prevalence of emotional-DSD found in people with T2DM. Further statistical limitations should be considered in the use of meta-regression analyses in relation to the need to perform multiple tests and how this can increase the risk of false-positive assumptions (300). Caution should be taken when considering the significant findings in the current review, since the scale of analyses required multiple tests, with significance at the level of 0.05, denoting that one could expect 5% of tests to demonstrate a significant finding under the null hypothesis.

There was high heterogeneity between studies, another common limitation of meta-analyses, with particular concern lying in the reporting of emotional-DSD and the scales used. A number of studies that reported DDS scores conveyed the score as a cumulative rather than an average meaning that their results were dramatically higher than the majority of studies. As such, if authors did not respond to requests for an average score, these studies needed to be excluded so as not to impair the results. Similarly the reporting of comorbid depression was highly varied with ten different scales reported, two studies reporting diagnoses by clinical diagnostic interview and one study merely stating the percentage that has “regular MD” (major depression). While further heterogeneity between studies was evident in terms of study location and population demographics, this was useful in terms of understanding prevalence across such variables and provides insight into how emotional-DSD varies across such factors.

Analyses to determine if publication bias was evident offered debatable results. While the funnel plot shows asymmetry, Egger’s test deemed that publication bias was not present (p=0.229). It is possible that the distribution within the funnel plot, namely an excess of studies to the right of the plot, could suggest a bias in that studies with higher results of emotional-DSD are more likely to be published.

2.5.3 Surrounding evidence and implications

The results demonstrated an overall prevalence of 40% (ES=0.402). In chapter one varying estimates given by leading authors in the field were given at 18-35% for elevated DSD and 10-30% for severe DSD (134,139). While the current results are higher than the estimates given, this could be due to the fact that of the 107 relevant studies, only 38 were able to be included in the final analyses. The main reason for exclusion was that studies reported the average emotional-DSD score, but for the purposes of the analyses, the percentage of participants demonstrating significant emotional-DSD was needed, so that the proportion and standard error could be calculated from this. When looking anecdotally at the emotional-DSD scores of all the studies in the review, 71 of the 107 reported appropriate average emotional-DSD scores. Of these 26 scored over the threshold for significant distress, which is roughly 37%. One could hypothesise that, had all the studies that were relevant for this review (n=107) reported the appropriate data required for analyses, then perhaps the overall prevalence would have corroborated existing estimates, since only just over a third of relevant studies could be included in the meta-analyses.

Prevalence of emotional-DSD was higher in studies reporting the DDS compared to the PAID and the PAID-5 scales. A recent study comparing the DDS and PAID scales acknowledged that while both scales are excellent psychometric self-report measures, they bear fundamental differences in terms of the issues they address (301). For example, the authors noted that the PAID scale encapsulates a broader range of emotional concerns compared to the DDS, which is comprised of factors more closely linked to diabetes self-management. The paper concluded from their results that higher PAID scores were indicative of dysfunctional coping, quality of life and depression, whereas higher DDS scores were strongly associated with reduced self-care and metabolic control. This could explain the differences in prevalence between the measures found in the present findings, since the scales themselves explore fundamentally different aspects of emotional-DSD. This draws light upon the concerns, outlined in chapter one, about the disparity in defining and assessing DSD; since there is no one-single

definition or diagnostic criteria for DSD, this leaves open further obstacles in properly identifying, and thus treating, people with T2DM who are presenting with comorbid psychological difficulties.

The PAID scale appears to be the most prominent and more widely used scale (302), perhaps as it was the first scale designed to measure emotional-DSD or because it is functionally simpler and faster to deliver. The PAID can be used for both T1DM and T2DM populations, whereas the DDS offers a more comprehensive assessment, originally developed to overcome psychometric limitations of the PAID, and is specifically for people with T2DM (303). A large proportion of research combines T1DM and T2DM populations together when exploring DSD, however this can be problematic since the way in which emotional-DSD manifests in the two populations can be contextually different; such as fear of hypoglycaemia being a more prominent fear in patients with T1DM, or feelings of guilt/shame being more prominent in patients with T2DM. It has been previously emphasised that the information collected from patients with Type 1 DM using the PAID scale would likely differ from that found in people with Type 2 DM or a mixed Type 1 DM/Type 2 DM population (304), with leading authors recently developing a separate DDS scale for people with Type 1 DM, the T1-DDS (305).

The preference of the PAID, as corroborated by nearly 70% of the papers found to be eligible for this review using the scale, combined with the differences between how the PAID and DDS identify diabetes-specific concerns, further exacerbates issues in assessment and without proper understanding of the difference scales properties, leaves potential room for inappropriate use. Schmitt *et al* (301) concluded their comparative work with the recommendation that the DDS might be most appropriate when the intentions for use lie in measuring separate areas of emotional-DSD distinctly, appraising any associations between emotional-DSD and self-management and/or diabetes-outcomes, and/or making cross-cultural comparisons of DSD. They suggested that the PAID scale would be most suitable when the intentions for use are to assess the various aspects of emotional-DSD as a whole, to determine how DSD impacts on an individual's quality of life and/or depression status, and to make global comparisons of DSD.

The analyses demonstrated a higher prevalence of emotional-DSD in people with newly diagnosed T2DM (2-4 years diagnosed, 63%; ES=0.630), which steadily reduced across the sample the longer duration of T2DM was reported. This appears to suggest that people with T2DM adjust to their diagnosis and most likely learn to manage their conditions better over time resulting in a reduction in their levels of emotional-DSD. This is of particular interest since, as discussed in chapter one, rates of depression appear to be lower or not evident in newly diagnosed or undiagnosed people with T2DM but increase over time (33,66). One could infer that the impact of diagnosis could lead to an individual feeling overwhelmed with the reality of their situation, which could result in increased emotional-DSD that is a clear and distinct reaction to their diagnosis. However, should an individual go on to experience poor management, a difficulty in acceptance of their condition, and/or continue to feel burdened by their self-management, this could be identified as depression due to the chronicity of their affect, or issues that were originally diabetes-related may have developed into more engrained psycho-social concerns. This reiterates the differences between depression and DSD, and raises the question about appropriate diagnosis, highlighting a need to differentiate between the two to be able to provide individuals with adequate patient-centred support. Factors such as the appropriateness of treatment that targets general depression rather than focussing on T2DM management and acceptance, or treating diabetes-related concerns when wider psycho-social concerns may also need attention.

The prevalence of emotional-DSD was directly linked to HbA1c with a distinct and significant rise in prevalence as the blood glucose levels rose. The prevalence of emotional-DSD in the group whose average HbA1c was 7.0-7.9% was 32% (ES=0.317), which rose to 49% (ES=0.490) for those with an HbA1c of 8.0-8.9% and jumped to 62% (ES=0.621) for those with an HbA1c of 9.0-9.9%. It is reasonable to expect increased emotional-DSD alongside increased HbA1c since, by its very nature, emotional-DSD is directly linked to T2DM and poor management would increase distress related to this. As discussed in chapter one, this has been shown in numerous studies comparing the relationship between HbA1c and DSD and/or depression finding that DSD is clearly and bi-directionally linked to HbA1c.

When comparing the relationship between depression and glycaemic control, while a bi-directional relationship has been shown, the evidence of this is varied and unclear (140,142,156,157,171-174), with emotional-DSD standing as a mediator between depression and blood glucose (157,175,176). This again highlights the stark need to refine the profiles of patients presenting with T2DM and depression and/or DSD and to appropriately identify patients' needs to tailor care appropriately.

2.6 Conclusion and chapter summary

The findings of this review demonstrate that emotional-DSD is a prominent issue in people with T2DM that is significantly increased in those with more recently diagnosed T2DM and poorer glycaemic control. Emotional-DSD is also affected by the outcome measure used to assess DSD. These findings highlight important factors to consider when managing people with T2DM and emotional concerns, particularly when acknowledging their individual presentation and the means by which DSD is identified.

As discussed in chapter one, both depression and DSD are under-recognised and inadequately treated in T2DM (60,108,109,112), the findings of this review highlight the importance of identification and subsequent management of emotional-DSD and/or depression in people with T2DM. There is a stark need for better understanding and deciphering of the symptomatology presenting in an individual with T2DM and an appreciation of their wider-life circumstances so as to understand how best to support them.

The purpose of this review was to determine the 'extent of the problem' when understanding emotional-DSD in people with T2DM, and combining this with existing literature on the prevalence of depression (28), it emphasises the need for astute assessment and appropriate tailored holistic care to be able to treat these three comorbid and highly interlinked conditions.

This review alone does not provide adequate understanding to proceed with recommendations for an assessment and treatment protocol, so to further explore and gain understanding, a second systematic review was conducted

exploring the existing literature on interventions for emotional-DSD in people with T2DM, which is reported in chapter three.

Chapter 3 Effective interventions for the treatment of diabetes-specific emotional distress in people with Type 2 diabetes: A systematic review and meta-analysis

3.1 Chapter overview

In this chapter, I report the findings of a second systematic review and meta-analysis undertaken to explore the effect of existing interventions on diabetes-specific emotional distress (emotional-DSD) in people with Type 2 diabetes (T2DM). Firstly, the background and rationale for carrying out the systematic review and meta-analyses is given, stating the aims and objectives (section 3.2), Following this, the methods used to carry out the systematic review and meta-analyses are discussed (section 3.3), with further details given alongside the reporting of the results (section 3.4). Lastly, the key findings are discussed, reflecting upon the strengths and limitations of the review and its implications in relation to existing research and clinical practice (section 3.5), before concluding the chapter (section 3.6).

3.2 Introduction

3.2.1 Background and rationale

As discussed in chapters one and two, the increasing prevalence of depression and DSD in people with T2DM, combined with poor recognition and sub-optimal care, calls for further research into effective treatment for these three comorbid conditions. Treatments for depression are well established and researched, in areas such as pharmacotherapy (162-164), psychotherapy (166,167,178), and exercise (306,307). Systematic reviews and analyses of such interventions, evaluating their effect on depression and glycaemic control, have been conducted (155,308). However, interventions specifically designed to account for emotional-DSD are sparse and there is a need to better understand what interventions impact upon emotional-DSD in people with T2DM.

At the time of initially undertaking this review, there had been no review to date to determine effective interventions for the treatment of emotional-DSD. However, during the process of completion a paper was published (185) that sought to answer the same question. Since this body of work was already well underway, it was decided to complete the review and meta-analyses but to consider the results of the other study in relation to the findings within the discussion (section 3.5).

3.2.2 Aims and objectives

This systematic review and meta-analysis sought to determine existing interventions that have been successful in reducing emotional-DSD, as well as physiological measures such as glycated haemoglobin (HbA1c), in people with T2DM, with the additional aim of understanding the specific components within these interventions that proved successful.

The overarching aim was to use the data collected from this and the prior review (chapter two), combining this with and building upon existing research and theory, as well as data collected from a qualitative study (chapters four to six), to inform the design of comprehensive treatment approach for people with T2DM and coexisting depression and/or emotional-DSD, with a view to improve clinical outcomes and reduce the physical, psychological and financial costs of these three comorbid conditions.

3.3 Methods

3.3.1 Search criteria

The inclusion and exclusion criteria for this systematic review are outlined in Table 3-1; the criteria were developed alongside the review question using the PICOS approach (Population, Intervention, Comparators, Outcomes, Study Design) (309).

Table 3-1: Inclusion and exclusion criteria for a systematic review and meta-analyses to determine effective interventions for the treatment of diabetes-specific emotional distress in people with Type 2 diabetes

PICOS	Inclusion criteria	Exclusion criteria
P: Population	Adults ≥18 years Sample majority (≥70%) diagnosed with Type 2 diabetes	Children and adolescents Sample majority Type 1 diabetes
I: Intervention	Psychological/educational interventions	Pharmacological intervention only
C: Comparator	Usual or active controls 'Before and after' analysis Placebo	-
O: Outcomes	Changes in diabetes-specific emotional distress (Primary or secondary outcome measure)	No measure of diabetes-specific emotional distress
S: Study design	Randomised controlled trials Experimental studies Quasi-experimental studies Clinical trials Longitudinal studies Before and after evaluations Cohort trials Follow-up studies Intervention studies Retrospective studies	Qualitative studies
Additional	-	Not reported in English

Studies were included if they tested the impact of an intervention on emotional-DSD, either as a primary or secondary outcome, using a psychometrically validated tool, in adults with T2DM (>18 years). In studies were both T1DM and T2DM population were present, only studies with a majority of ≥70% T2DM were included. Studies were excluded if they were not reported in the English language.

3.3.2 Search strategy and selection

A range of bibliographic databases were searched using a combination of free-text and Medical Search Heading (MeSh)/Thesaurus terms. These included:

- The Excerpta Medica Database (EMBASE)
- The Medical Literature Analysis and Retrieval System Online (MEDLINE)
- The Psychological Information Database (PsycINFO)
- The Cumulative Index to Nursing and Allied Health Literature (CINAHL)
- The Cochrane Library

- The Applied Social Sciences Index and Abstracts database (ASSIA)
- The Scopus database.

Initial scoping searches indicated that the existing data was limited, due to this, and the exploratory nature of the study, the inclusion criteria and search strategy were kept broad to encapsulate as much data as possible. Due to the limited research in emotional-DSD it was decided to include both randomized controlled trials (RCTs) and cohort studies within the search. The search strategy was sent to members of the project team (KK, FS, MD) to advise on any potential missing terms and these were added to the search. The final search for this review (see Box 3-1) was conducted on the 12th September 2015.

As with the prevalence review in chapter two, the help of another reviewer was enlisted (NA_2) to ensure inter-rater reliability. Abstracts and titles were independently assessed for eligibility and potentially relevant articles were retrieved for full-text review. The initial paper-selection tick-sheet from the previous review was adapted for the current to encourage mutual understanding of the relevance of papers (see Box 3-2). Once abstracts were reviewed independently, any inconsistencies in opinion were resolved through discussion without the need to seek a third reviewer opinion.

Box 3-1: Example of the search strategy used in a systematic review and meta-analyses to determine effective interventions for the treatment of diabetes-specific emotional distress in people with Type 2 diabetes, terms varied slightly depending on individual databases medical subject headings and truncations

Database: MEDLINE <1946 to 2015 week 37> Search Strategy:

24. Type 2 diabetes.tw.
25. (T2DM OR DM2 OR NIDDM OR IIDM).tw.
26. diabetes mellitus non insulin dependent.tw.
27. diabetesnon insulin dependent.tw.
28. insulin resistance.tw.
29. exp Insulin Resistance/
30. (adult$ onset OR matur$ onset OR late$ onset).tw.
31. (non insulin$ depend$ OR non-insulin$ depend).tw.
32. ((typ$ 2 OR typ$ II) adj10 (diabet$ OR DM)).tw.
33. Distress$.tw.
34. (symptom$ adj4 distress$).tw.
35. (emotion$ adj4 distress$).tw.
36. (emotion$ adj4 problem$).tw.
37. (psychosocial adj4 distress$).tw.
38. (psycholog$ adj4 distress$).tw.
39. (physical$ adj4 distress$).tw.
40. (mental$ adj4 distress$).tw.
41. (burn adj out).tw
42. Exp Adjustment Disorders/
43. (adjust$ adj disorder$).tw
44. exp Research/
45. Observation$.tw
46. exp Randomized Controlled Trials as Topic/
47. RCT.tw
48. (random$ adj control$ adj trial$).tw
49. (experiment$ adj4 stud$).tw.
50. (quasiadj experiment$).tw.
51. trial$.tw.
52. Exp Clinical Trial/
53. (Time-series or time series).tw.
54. (cross$ adj section$).tw.
55. (cross$ adj section$ adj stud$).tw.
56. exp Longitudinal Studies/
57. (longitudinal adj4 stud$).tw.
58. exp Placebos/
59. Placebo$.tw.
60. Random$.tw.
61. exp Control Groups/
62. Group$.tw.
63. (before adj2 after).tw
64. exp Cohort Studies/
65. (cohortadj stud$).tw.
66. exp Follow-Up Studies/
67. ((follow up adj stud$) or (follow-up stud$)).tw.
68. exp Intervention Studies/
69. Intervention stud$.tw
70. Exp Retrospective Studies/
71. Restrospective.tw.
72. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9
73. 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20
74. 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49
75. 49 and 50 and 51

limit 52 to (english language and humans)

Box 3-2: Example of paper-selection tick-sheet used to ensure clarity in a systematic review and meta-analyses to determine effective interventions for the treatment of diabetes-specific emotional distress in people with Type 2 diabetes

Stage 1: Initial paper selection from titles and abstracts

Points to consider	Yes	No	Unclear	Notes
Is the study written in English				Exclude if 'No'
Is the study population majority people Type 2 diabetes? (≥70%)				Exclude if 'No' Include if 'Unclear'
Are the study participants adult? (≥18 years old)				Exclude if 'No' Include if 'Unclear'
Does the study include interventions with an outcome measure of diabetes-specific emotional distress?				Exclude if 'No' Include if 'Unclear'

Include		Exclude	

Other potential terminology for diabetes-specific emotional distress could be:

- Emotional distress
- Emotional problems
- Psychosocial distress
- Psychological distress
- Physical distress
- Mental distress
- Burn out
- Adjustment disorder

3.3.3 Data extraction

Data were extracted using a form designed specifically for this review (see Appendix 4). The main outcome measure to be extracted was a measure of emotional-DSD at baseline and post-intervention at the furthest point of follow-up.

Further data extracted included study design, outcome, location and year; sample size, distribution and population demographics; intervention and control group details; and length of follow-up. Where possible, physiological

outcome data for HbA1c, body mass index (BMI), blood pressure, and cholesterol was also recorded.

Data reported in the study text was checked against data in tables and where discrepancies were found the data was taken from the tables.

For articles where studies were eligible but data was missing, incomplete or unclear, the authors were contacted to request data and/or clarification. In cases where studies reported their methodology elsewhere, all papers related to a particular study (including original study papers and/or papers solely reporting design and methodology) were retrieved to extract data or clarify information. Where possible, missing data (if not received from authors) was calculated using appropriate equations or imputed from other scores (Appendix 2). In cases where studies reported more than one intervention arm, the most intensive and/or comprehensive intervention arm data was taken and compared to the control with the other arms being excluded from the analyses.

3.3.4 Quality assessment

The quality of studies was evaluated using the Effective Public Health Practice Project (EPHPP) 'Quality assessment for quantitative studies' (310). The decision was made to use this tool as it allows for the assessment of both RCTs as well as non-RCT studies. For the EPHPP scale, a score of one is given from 'strong', two for 'moderate', and three for 'weak'. The EPHPP sections on selection bias, study design, data collection methods and withdrawals/drop-outs were included in the assessment, with quality assessed across sections separately. Sections on confounders and blinding were omitted, as they were not relevant to this review. With the assistance of a second reviewer (SB), quality assessment was performed independently and any discrepancies resolved through discussion.

3.3.5 Meta-analyses

The primary outcome of interest for the analyses was the mean emotional-DSD score at the end of follow-up in intervention groups compared to control groups (if relevant). End of follow-up was defined as the last point of follow-up and split into either under or over twelve months. The results from different

studies were combined using a random effects meta-analysis, which assumed that underlying effect sizes differ across studies. Standardisation, which allows for combinations of measurements from different scales, was used to combine scores from studies using the Problem Areas in Diabetes (PAID) scale and studies using the Diabetes Distress Scale (DDS). Further non-standardised meta-analyses were also conducted to explore the impact of interventions separately for studies assessing emotional-DSD with either the PAID or DDS.

Funnel plots and Egger's test (197) were used to determine whether publication bias was present. Heterogeneity was assessed using the I^2 statistic, as discussed in chapter two, whereby the higher a I^2 value indicates higher heterogeneity with cut-offs defined as low (25%), moderate (50%) and high (75%). Meta-regression analyses were performed to identify any potential sources of heterogeneity between studies against the following confounders: length of follow-up, gender, mean age, ethnicity, mean BMI, mean HbA1c, mean years diagnosed with T2DM, year of study and country within which the study was conducted.

Further standardised random effects meta-analyses were conducted to assess how specific intervention characteristics impact on DSD, comparing the effect sizes and significance of studies using a particular method against those that did not. In order to include studies that did not have a control group, further random effects meta-analyses were performed on treatment arms only. To account for this inclusion of both RCT and non-RCT studies in this review, sensitivity analyses were performed to assess whether the same analyses using only RCTs would have yielded different results.

The above processes were repeated for HbA1c and BMI scores. While data was extracted for blood pressure and cholesterol, due to the low numbers reported, these could not be not analysed.

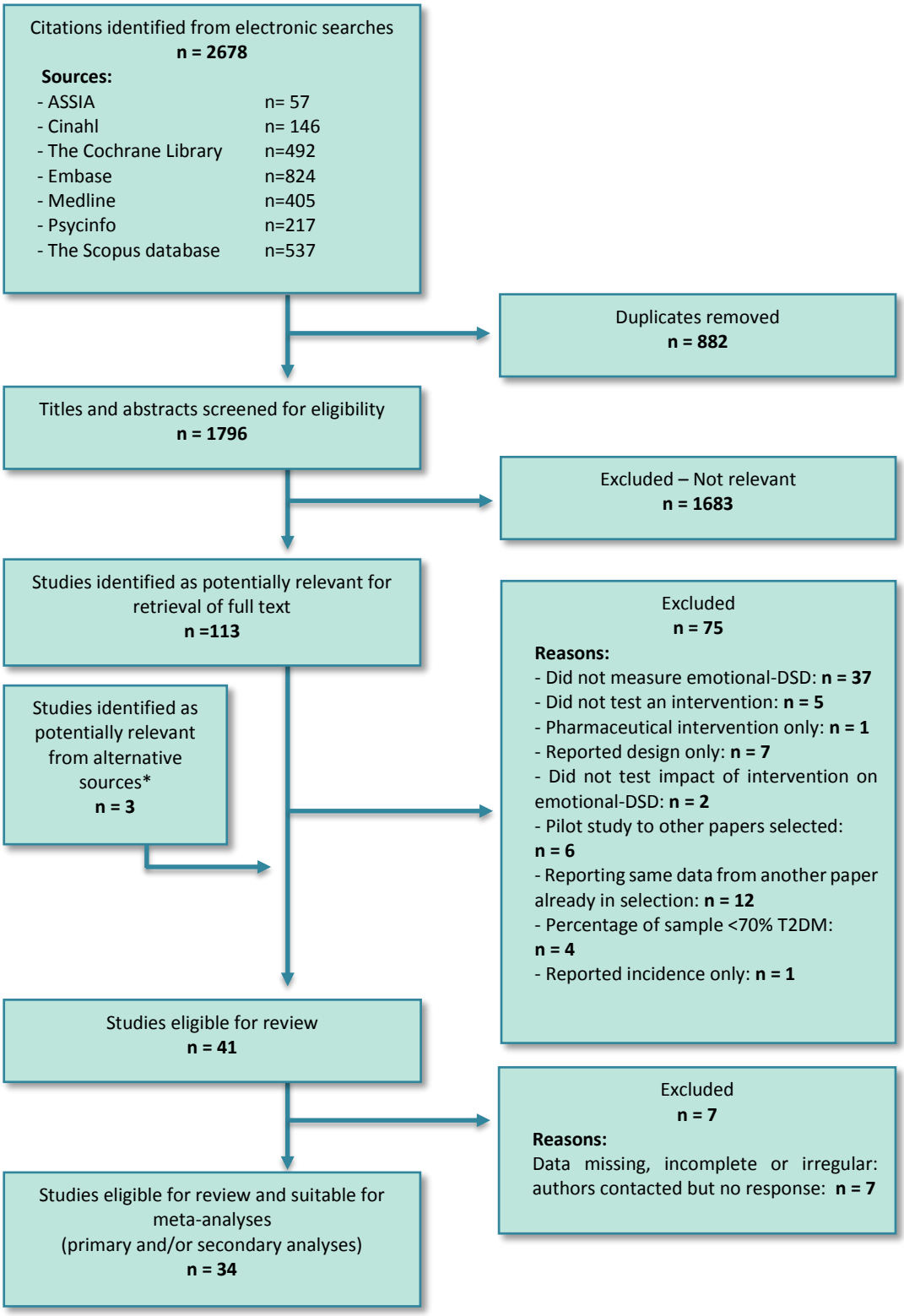
All analyses were performed in STATA version 13.1, with advice and guidance given by trained statisticians when needed (DB, LG).

3.4 Results

3.4.1 Identification of studies

The process of identification and selection of eligible papers is summarised in Figure 3-1. Searches generated 2678 citations, of which 1796 were screened for eligibility following the removal of duplicates. Of these, 113 were selected for full text retrieval. Studies that did not meet the criteria but discussed research that was of potential for inclusion yielded one result to be included in the review (311). Discussions with field experts highlighted one study that was not on the databases searched (186), and when requesting further information for one paper (201), authors directed to another paper that reported more data so this was included in the review instead (202). Of the 113 potentially relevant studies, and the three directed from other sources, forty-one were selected for inclusion within the review (186,202,208,209,211,216,218,220,221,224,225,230-232,243,245,250,251,253,262,264,265,269-273,275,277,279,284,289,292,293,295-297,311-314), of which thirty-four were eligible for use within the meta-analyses either in the primary and/or the secondary analyses (186,202,208,209,211,216,218,221,224,225,230-232,243,250,251,253,262,264,265,269,271,272,275,279,284,289,292,293,295,297,311,312,314).

Figure 3–1: Consort flow diagram of the selection of studies, from initial searches to final inclusion, in a systematic review and meta-analyses to determine effective interventions for the treatment of diabetes-specific emotional distress in people with Type 2 diabetes



*Identified from discussion with field experts or after direction from authors when contacted for further information
Abbreviations: ASSIA- The Applied Social Sciences Index and Abstract database; CINAHL - The Cumulative Index to Nursing and Allied Health Literature; EMBASE - The Exerpta Medica Database; Emotional-DSD – Diabetes-specific emotional distress; MEDLINE - The Medical Literature Analysis and Retrieval System Online; PsycINFO - The Psychological Information Database; T2DM – Type 2 diabetes

3.4.2 Summary of studies

Studies included in this review and meta-analysis are summarised in Tables 3-2 to 3-5.

Of the thirty-four eligible for inclusion within the meta-analyses, studies were grouped by the measure of emotional-DSD they reported, twenty-three studies used the PAID scale and thirteen used the DDS. Twenty-six studies were randomized controlled trials and eight were cohort studies. Studies were conducted in the USA (n=25), the Netherlands (n=3), the UK (n=3), Australia (n=1), Belgium (n=1), Germany (n=1) and Turkey (n=1). Studies were conducted from 2004 to 2015, with follow-up periods ranging from three months to 4.5 years.

Six studies reported more than one intervention arm (262,270,271,273, 277,292), from which the most comprehensive arm was used for analyses.

Interventions characteristics were established during data extraction and studies grouped into those that were delivered individually, either in part or in full (n=24) or those solely delivered in a group format (n=10). Further intervention characteristics included studies that adopted the following factors: use of a collaborative care approach (n=8); use of a cognitive behavioral approach (n=7); use of a mindfulness based-approach (n=2); use of a self-efficacy/empowerment based approach (n=18); use of a mobile-phone-based interface (n=1); use of a computer/web-based interface (n=6); use of social/peer support (n=13); use of motivational interviewing (n=7); use of self-management education (n=31); monitoring of physical activity (n=22); monitoring of nutritional intake (n=25); self-monitoring of blood glucose (n=15); use of individualised goal setting (n=29); use of educational materials (n=15); use of accountability through self-reported feedback (n=16); use of telephone support and/or feedback (n=15); use of coping skills training (n=10); and use of problem solving training, including the identification of barriers (n=18). Studies included varying combinations of the above characteristics, with analyses comparing the effectiveness of those that adopted an approach compared to those that did not.

Table 3-2: Overview of studies included in a systematic review and meta-analyses to determine effective interventions for the treatment of diabetes-specific emotional distress in people with Type 2 diabetes. Study details, authors B to H.

Author (Year)	Study design	Location	Intervention characteristics																		Control	Scale used	Follow-up (months)
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19			
Basak (2014)	RCT	Turkey	Health coaching intervention, use to facilitate individuals to transform cognitive and emotional functioning to adopt positive health behaviours.																			Formal health education	PAID	16
			x				x						x	x		x			x					
Bastiaens (2009)	Cohort	Belgium	Self-management education programme recognising people with diabetes as the experts of their own lives and healthcare professionals as facilitators/coaches																				PAID	18
				x			x			x	x	x	x	x		x	x	x		x	x			
Beverly (2013)	RCT	USA	Educator facilitated patient group discussions using the US Diabetes Conversation Maps programme.																			2 x classes on dyslipidemia & hypertension	PAID	12
												x		x	x	x								
Chesla (2013)	Cohort	USA	Specific culturally adapted coping skills training programme																				DDS	6
			x		x		x			x		x								x	x			
D'Eramo -Melkus (2010)	RCT	USA	Nurse-led culturally relevant, cognitive-behavioural, self-management and coping skills training intervention																			Conventional diabetes group education	PAID	24
				x	x		x			x		x	x	x	x	x	x	x		x	x			
Fisher (2013)	RCT	USA	Web-based diabetes self-management improvement programme plus diabetes-specific problem solving training																			Computer-based minimal intervention	DDS	12
			x						x			x	x	x		x	x	x	x		x			
Fisher (2011)	Cluster RCT	USA	Collaborative structured self-monitoring of blood-glucose protocol																			Enhanced usual care	DDS	12
			x	x								x	x	x	x	x		x						
Gabbay (2013)	RCT	USA	Nurse case-management intervention with behavior change counselling																			Usual care	PAID	24
			x								x	x				x			x					
Gabbay (2006)	RCT	USA	Nurse case-management intervention including self-management education																			Usual care	PAID	12
			x	x								x				x			x					
Heisler (2014)	RCT	USA	Community health worker led self-management support delivered using tablet computers tailored for low literacy																			As intervention, using untailored print materials	DDS	3
			x				x		x		x	x				x	x	x			x			
Heisler (2010)	RCT	USA	Reciprocal peer support intervention with training and self-management education																			Enhanced usual care nurse case-management	DDS	6
							x			x		x				x	x		x					
Hermanns (2012)	RCT	Germany	Self-management education and intensive insulin treatment.																			Didactic diabetes education	PAID	6
							x			x		x	x	x	x	x	x	x			x			

KEY: 1 = Delivered individually (in full or in part); 2 = Use of collaborative care approach; 3 = Use of cognitive behavioual approach; 4 = Use of a mindfulness based approach; 5 = Use of self-efficacy/empowerment based approach; 6 = Use of mobile-phones-based interface; 7 = Use of computer/web-based interface; 8 = Use of social/peer support; 9 = Use of motivational interviewing; 10 = Use of self-management education; 11 = Use of physical activity; 12 = Monitoring of nutritional intake; 13 = Self-monitoring of blood glucose; 14= Use of individualised goal setting; 15 = Use of educational materials; 16 = Use of accountability through self-reported feedback; 17 = Use of telephone support and/or feedback; 18 = Use of coping skills training; 19 = Use of problem solving training (including identification of barriers). Abbreviations: DDS – Diabetes Distress Scale PAID – Problem Areas in Diabetes scale; RCT – Randomised Controlled Trial

Table 3-3: Overview of studies included in a systematic review and meta-analyses to determine effective interventions for the treatment of diabetes-specific emotional distress in people with Type 2 diabetes. Study details, authors K to S.

Author (Year)	Study design	Location	Intervention characteristics																		Control	Scale used	Follow-up (months)
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19			
Khunti (2012)	Cluster RCT	UK	Structured group education programme for newly diagnosed people with T2DM promoting a non-didactic approach.																			Enhanced usual care	PAID	36
							x					x	x	x	x	x	x				x			
Lamers (2011)	RCT	Nether-lands	Nurse-administered minimal psychological intervention including self-management education.																			Usual care	PAID	9
			x		x							x				x		x						
McEwen (2010)	Cohort	USA	Culturally tailored diabetes self-management social support intervention.																				DDS	6
			x							x		x	x	x		x		x						
Mc-Mahon (2012)	RCT	USA	Telephone-based self-management support intervention with case-management support and training.																			Online-training alone	PAID	12
			X									x		x	x	x			x					
Naik (2012)	Cohort	USA	Behavioural health coaching intervention for rural-dwelling older adults.																				PAID	6
			x		x	x						x	x	x		x	x	x	x	x	x			
Quinn (2011)	Cluster RCT	USA	Patient coaching system with clinical decision support using analysed patient data linked to standards of care and evidence-based guidelines																			Usual care	DDS	12
			x	x				x	x	x		x			x	x		x	x					
Ruggiero (2014)	Cohort	USA	Virtual world self-care educational intervention																				DDS	6
			x				x		x	x		x	x	x		x								
Sabourin (2011)	Cohort	USA	Brief psychosocial self-management education intervention for behavior modification, motivation maintenance and emotion management																				DDS	3
					x							x	x	x		x	x	x			x			
Siminerio (2013)	RCT	USA	Educator-led diabetes self-management support intervention																			Usual care self-management support	PAID	6
			x		x		x					x				x			x		x			
Simmons (2015)	RCT	UK	Group diabetes education workshop followed by 1:1 individual and group peer support																			Usual care	DDS	12
			x				x			x		x	x	x	x		x				x			
Sinclair (2013)	RCT	USA	Culturally-adapted diabetes self-management intervention																			Delayed intervention	PAID	3
							x			x		x	x	x	x	x				x	x			

KEY: 1 = Delivered individually (in full or in part); 2 = Use of collaborative care approach; 3 = Use of cognitive behavioual approach; 4 = Use of a mindfulness based approach; 5 = Use of self-efficacy/empowerment based approach; 6 = Use of mobile-phones-based interface; 7 = Use of computer/web-based interface; 8 = Use of social/peer support; 9 = Use of motivational interviewing; 10 = Use of self-management education; 11 = Use of physical activity; 12 = Monitoring of nutritional intake; 13 = Self-monitoring of blood glucose; 14= Use of individualised goal setting; 15 = Use of educational materials; 16 = Use of accountability through self-reported feedback; 17 = Use of telephone support and/or feedback; 18 = Use of coping skills training; 19 = Use of problem solving training (including identification of barriers). Abbreviations: DDS – Diabetes Distress Scale PAID – Problem Areas in Diabetes scale; RCT – Randomised Controlled Trial

Table 3-4: Overview of studies included in a systematic review and meta-analyses to determine effective interventions for the treatment of diabetes-specific emotional distress in people with Type 2 diabetes. Study details, authors S to W.

Author (Year)	Study design	Location	Intervention characteristics																		Control	Scale used	Follow-up (months)
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19			
Spencer (2011)	RCT	USA	Community health-worker led intervention using community based participatory research principles																			Delayed intervention	PAID	6
			x	x			x				x	x	x	x		x			x					
Sturt (2008)	Cluster RCT	UK	Nurse-led self-management education programme																			Delayed intervention	PAID	6
			x				x					x	x	x	x	x	x	x	x	x				
Tang (2012)	Cohort	USA	Culturally designed diabetes self-management education intervention																				DDS	36
							x			x		x				x	x	x		x	x			
Thom (2013)	RCT	USA	Peer health coaching intervention																			Usual care	DDS	6
			x							x		x			x	x			x				
van der Wulp (2012)	RCT	Nether-lands	Peer-led self-management coaching intervention																			Usual care	PAID	6
			x				x			x	x	x	x	x		x			x		x			
van Son (2014)	RCT	Nether-lands	Mindfulness based cognitive therapy																			Usual care	PAID	6
					x	x								x			x	x		x				
Wallace (2008)	Cohort	USA	Literacy-appropriate self-management education and brief counseling intervention																				DDS	3
			x		x		x					x	x	x	x	x	x	x	x		x			
Welch (2011) (I)	RCT	USA	Structured self-management education with motivational interviewing plus web-based tool																			Self-manage-ment education with web tool	PAID	6
			x				x		x		x	x	x	x	x	x				x	x			
Welch (2011) (II)	RCT	USA	Comprehensive diabetes management programme																			Self-management education	PAID	12
			x	x					x			x	x	x	x						x			
Whittemore (2004)	RCT	USA	Nurse coaching intervention plus standard diabetes care																			Usual care	PAID	6
			x	x							x	x	x	x		x			x	x	x			
Wycherley (2014)	PAID	Australia	Structure hypocaloric diet with exercise																			As intervention without exercise	PAID	4
			x										x	x				x						

KEY: 1 = Delivered individually (in full or in part); 2 = Use of collaborative care approach; 3 = Use of cognitive behavioual approach; 4 = Use of a mindfulness based approach; 5 = Use of self-efficacy/empowerment based approach; 6 = Use of mobile-phones-based interface; 7 = Use of computer/web-based interface; 8 = Use of social/peer support; 9 = Use of motivational interviewing; 10 = Use of self-management education; 11 = Use of physical activity; 12 = Monitoring of nutritional intake; 13 = Self-monitoring of blood glucose; 14= Use of individualised goal setting; 15 = Use of educational materials; 16 = Use of accountability through self-reported feedback; 17 = Use of telephone support and/or feedback; 18 = Use of coping skills training; 19 = Use of problem solving training (including identification of barriers). Abbreviations: DDS – Diabetes Distress Scale PAID – Problem Areas in Diabetes scale; RCT – Randomised Controlled Trial

Table 3-5: Overview of studies included in a systematic review and meta-analyses to determine effective interventions for the treatment of diabetes-specific emotional distress in people with Type 2 diabetes. Study population demographics.

Author (year)	Population number			% T2DM	Mean HbA1c (%)	Mean years T2DM	Mean BMI	Mean age (years)	Gender (% Male)	Ethnicity (% C)
	Total	Int.	Cont.							
Basak (2014)	186	77	109	100	07.68	11.75	30.60	N.R.	N.R.	N.R.
Bastiaens (2009)	44	44		100	07.40	05.00	28.60	66.00	53.00	N.R.
Beverly (2013)	134	67	67	100	08.40	13.00	34.20	59.00	49.00	75.00
Chesla (2013)	145	145		100	07.17	N.R.	N.R.	64.45	41.00	00.00
D'Eramo Melkus (2010)	109	57	52	100	08.10	03.70	34.30	48.50	00.00	00.00
Fisher (2013)	424	146	96	100	N.R.	07.03	33.59	55.53	57.20	38.60
Fisher (2011)	483	256	277	100	08.90	N.R.	35.10	55.80	53.20	63.10
Gabbay (2013)	545	232	313	100	08.95	N.R.	34.50	58.00	41.50	46.5
Gabbay (2006)	332	150	182	95	07.40	09.40	33.50	64.70	54.00	90.00
Heisler (2014)	188	93	35	100	08.23	09.08	N.R.	51.50	29.00	06.50
Heisler (2010)	244	119	125	N.R.	08.00	N.R.	N.R.	62.00	100	82.00
Hermanns (2012)	167	85	82	100	08.35	13.90	33.35	63.50	55.00	N.R.
Khunti (2012)	824	437	387	100	08.10	00.00	32.30	59.50	55.00	94.00
Lamers (2011)	208	105	103	100	07.40	09.00	N.R.	70.20	49.00	N.R.
McEwen (2010)	21	21		100	07.79	07.20	35.26	53.71	81.00	00.00
McMahon (2012)	100	51	49	100	10.00	N.R.	33.95	58.70	96.95	71.95
Naik (2012)	8	8		100	09.73	17.40	34.10	62.10	86.00	57.00
Quinn (2011)	118	62	56	100	09.57	08.58	35.09	52.57	50.00	54.65
Ruggiero (2014)	41	41		100	07.40	N.R.	39.30	55.20	29.00	00.00
Sabourin (2011)	15	15		100	N.R.	N.R.	N.R.	66.00	80.00	93.00
Sigurdardottir (2009)	53	28	25	100	08.00	08.50	32.10	61.10	68.00	N.R.
Siminerio (2013)	70	38	32	100	08.50	N.R.	35.15	60.00	44.50	82.45
Simmons (2015)	644	322	322	100	07.30	N.R.	32.10	64.95	59.00	N.R.
Sinclair (2013)	65	35	30	100	09.90	N.R.	37.00	54.00	37.00	00.00
Spencer (2011)	164	72	92	100	08.55	08.50	34.50	52.50	29.00	00.00
Sturt (2008)	245	114	131	100	08.85	07.90	31.70	62.00	60.50	80.00
Tang (2012)	52	52		100	07.90	11.80	N.R.	63.10	27.00	00.00
Thom (2013)	299	148	151	100	09.99	08.90	33.75	55.20	47.80	10.75
van der Wulp (2012)	119	59	60	100	N.R.	08.00	N.R.	61.00	54.60	N.R.
van Son (2014)	139	70	69	70	07.55	N.R.	N.R.	56.50	50.50	N.R.
Wallace (2008)	250	250		100	08.60	09.00	34.70	56.00	35.00	22.00
Welch (2011) (I)	119	61	58	100	08.85	08.40	34.50	56.65	41.85	81.35
Welch (2011) (II)	39	51	18	100	08.70	12.10	34.30	56.10	35.00	00.00
Whittemore (2004)	49	26	23	100	07.70	02.70	35.90	57.60	00.00	89.00
Wycherley (2014)	84	65	41	100	07.43	N.R.	35.32	56.10	56.10	N.R.

Abbrevaiatons: C – Caucasian; Cont. – Control; HbA1c – Glycated Haemoglobin; Int. – Intervention; T2DM – Type 2 diabetes

3.4.3 Study quality

Details of study quality are shown in Table 3-6.

Table 3-6: Results of quality assessment of studies included in a systematic review and meta-analyses to determine effective interventions for the treatment of diabetes-specific emotional distress in people with Type 2 diabetes. Study population demographics

Author	Year	Selection bias	Study design	Data collection methods	Withdrawals/ drop-outs
Basak	2014	1	1	1	1
Bastiaens	2009	2	2	1	3
Beverly	2013	2	1	1	1
Chesla	2013	1	2	1	1
D'Eramo Melkus	2010	1	1	1	2
Fisher	2013	1	1	1	1
Fisher	2011	2	1	1	2
Gabbay	2013	2	1	1	1
Gabbay	2006	2	1	1	3
Heisler	2014	2	1	1	1
Heisler	2010	3	1	1	1
Hermanns	2012	2	1	1	1
Khunti	2012	2	1	1	2
Lamers	2011	1	1	1	2
McEwan	2010	3	2	1	1
McMahon	2012	1	1	1	1
Naik	2012	3	2	1	1
Quinn	2011	1	1	1	1
Ruggiero	2014	1	2	1	3
Sabourin	2011	2	2	1	1
Sigurdardottir	2009	2	1	1	1
Simmons	2015	3	1	1	2
Sinclair	2013	2	1	1	1
Spencer	2011	2	1	1	2
Sturt	2008	2	1	1	2
Tang	2012	2	2	1	3
Thom	2013	1	1	1	1
van der Wulp	2012	3	1	1	1
van Son	2014	3	1	1	2
Wallace	2008	2	2	1	1
Welch (i)	2011	3	1	1	1
Welch (ii)	2011	1	1	1	1
Whittemore	2004	2	1	1	1
Wycherley	2014	3	1	1	2

The majority of studies (47%) scored 'moderate' for selection bias, however this was often due to a lack of reporting of percentages of approached individuals who declined to participant. Seventy-seven percent reported 'strong' for study design with the remaining scoring 'moderate', demonstrating that the likelihood for bias due to allocation processes was small. All studies scored 'strong' for data collection methods as they used either the PAID or DSS scales which have been previously reported as

reliable and valid. The majority of studies scored ‘strong’ for withdrawals and/or dropouts (71%) and a just under a quarter of studies were ‘moderate’ and only four studies scored as ‘weak’.

3.4.4 Meta-analyses

Primary analyses: Impact of interventions upon diabetes-specific emotional distress

A summary of the data used in the primary analyses to assess the effect of interventions on emotional-DSD is shown in Table 3-7.

Table 3-7: Summary of data used in unadjusted random effects meta-analyses to determine the effect of interventions upon diabetes-specific emotional distress in people with Type 2 diabetes

Author	Year	Outcome	Group	N	Baseline		Follow-up		Change	
					M DSD	SD DSD	M DSD	SD DSD	M DSD	SD DSD
Basak	2014	PAID	Intervention	77	39.80	10.50	49.80	11.20	10.00	09.72
			Control	109	38.90	13.50	45.80	14.90	06.90	12.76
Bastiaens	2009	PAID	Intervention	44	26.00	18.20	21.00	17.50	-05.00	15.98
			Control	-	-	-	-	-	-	-
Beverly	2013	PAID	Intervention	67	33.30	20.30	25.00	16.00	-08.30	16.68
			Control	67	34.80	23.10	25.70	22.70	-09.10	20.49
Chesla	2013	DDS	Intervention	145	02.59	02.38	02.33	01.05	-00.26	01.94
			Control	-	-	-	-	-	-	-
D'Eramo Melkus	2010	PAID	Intervention	57	54.00	31.00	38.00	17.50	-16.00	24.84
			Control	52	60.00	30.00	47.00	17.00	-13.00	24.02
Fisher	2013	DDS	Intervention	146	02.38	00.89	01.92	00.75	-00.46	00.74
			Control	96	02.48	00.95	01.98	00.88	-00.50	00.82
Fisher	2011	DDS	Intervention	256	02.44	01.44	01.79	01.28	-00.65	01.22
			Control	227	02.21	01.05	01.93	01.21	-00.28	01.02
Gabbay	2013	PAID	Intervention	232	29.00	23.00	23.00	21.00	-06.00	19.76
			Control	313	29.00	24.00	29.00	27.00	00.00	22.97
Gabbay	2006	PAID	Intervention	150	23.00	18.20	10.00	17.50	-13.00	15.98
			Control	182	-	-	-	-	-	-
Heisler	2010	DDS	Intervention	125	26.50	16.40	22.80	17.20	-03.70	15.04
			Control	119	26.40	19.80	20.80	18.80	-05.60	17.29
Hermanns	2012	PAID	Intervention	85	52.50	09.20	49.10	09.70	-03.40	08.46
			Control	82	47.60	09.60	48.00	11.20	00.40	09.41
Lamers	2011	PAID	Intervention	105	22.60	20.50	18.49	13.90	-04.11	16.48
			Control	103	23.40	19.50	22.89	13.40	-00.51	15.69
McEwen	2010	DDS	Intervention	21	02.14	01.70	01.95	02.30	-00.19	01.87
			Control	-	-	-	-	-	-	-
McMahon	2012	PAID	Intervention	51	24.50	20.00	18.30	15.70	-06.20	16.42
			Control	49	29.00	19.60	19.50	14.80	-09.50	15.97
Naik	2012	PAID	Intervention	8	46.80	06.29	20.40	20.70	-26.40	17.66
			Control	-	-	-	-	-	-	-
Quinn	2011	DDS	Intervention	62	02.60	00.90	02.30	00.80	-00.30	00.77
			Control	56	02.40	00.90	02.30	00.90	-00.10	00.80
Ruggiero	2014	DDS	Intervention	41	02.40	00.96	01.90	10.25	-00.50	09.70
			Control	-	-	-	-	-	-	-
Sabourin	2011	DDS	Intervention	15	32.42	12.43	29.26	09.35	-03.16	10.12
			Control	-	-	-	-	-	-	-
Sigurdardottir	2009	PAID	Intervention	28	24.10	14.50	19.10	12.90	-05.00	12.34
			Control	25	15.80	14.50	13.80	12.60	-02.00	12.24
Sinclair	2013	PAID	Intervention	35	31.00	31.00	20.00	22.00	-11.00	14.79
			Control	30	24.00	23.00	23.00	21.00	-01.00	19.76
Spencer	2011	PAID	Intervention	72	11.90	17.50	08.70	13.90	-03.20	12.30
			Control	92	13.80	20.30	12.90	20.10	-00.90	18.01
Sturt	2008	PAID	Intervention	114	21.00	15.00	17.00	14.00	-04.00	13.00
			Control	131	21.00	15.00	22.00	17.00	01.00	14.42
Tang	2012	DDS	Intervention	52	30.20	15.70	26.80	11.60	-03.40	12.75
			Control	-	-	-	-	-	-	-
Thom	2013	DDS	Intervention	148	02.44	00.96	02.27	00.93	-00.17	00.85
			Control	151	02.40	00.99	02.27	00.90	-00.13	00.85
van der Wulp	2012	PAID	Intervention	59	16.65	18.95	12.74	14.02	-03.91	15.39
			Control	60	14.48	15.50	11.09	14.99	-03.39	13.64
van Son	2014	PAID	Intervention	70	35.50	17.80	25.00	19.70	-10.50	16.86
			Control	69	36.60	18.90	32.80	20.10	-03.80	17.47
Wallace	2008	DDS	Intervention	250	36.44	16.99	31.29	13.64	-05.15	14.77
			Control	-	-	-	-	-	-	-
Welch (ii)	2011	PAID	Intervention	21	54.20	24.00	37.40	26.40	-16.80	22.64
			Control	18	44.30	23.00	52.70	26.30	08.40	22.24
Whittemore	2004	PAID	Intervention	26	59.90	22.00	46.90	23.00	-13.00	20.14
			Control	23	42.30	14.00	42.90	19.00	00.60	15.42
Wycherley	2014	PAID	Intervention	65	29.40	17.90	20.40	17.10	-09.00	15.67
			Control	41	35.70	21.00	23.70	19.30	-12.00	18.09

Abbreviations: DSD – Diabetes-specific emotional DSD; M – Mean; N – Number; SD – Standard deviation

Twenty-one studies, with a total of 3814 participants, used a control group and reported baseline and follow-up data for emotional-DSD. These were included in an unadjusted random effects meta-analysis comparing intervention groups against control groups for reducing emotional-DSD (Table 3-8 and Figure 3-2).

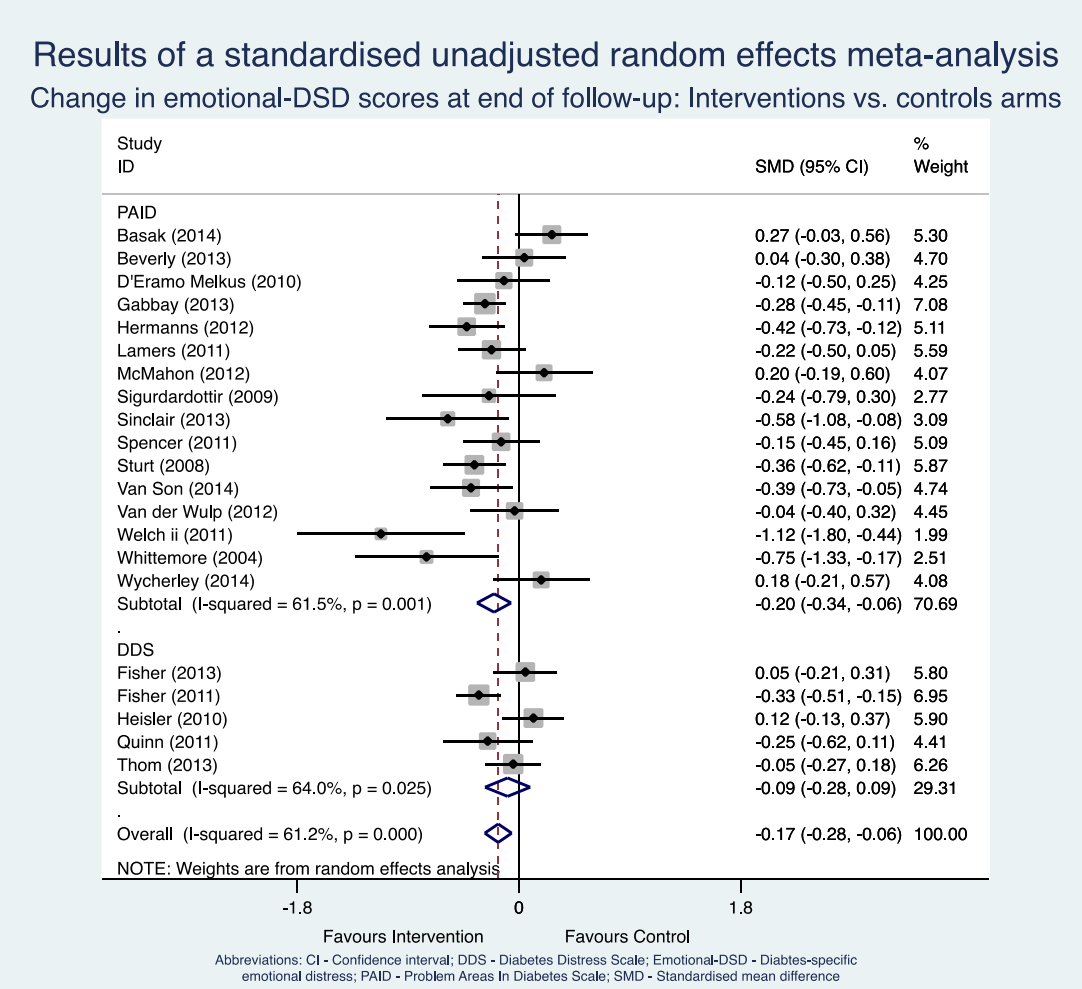
Overall emotional-DSD scores were lower in the intervention groups with a greater change from baseline at the end of follow-up compared to the control groups, with an overall standardised mean difference of -0.169 (95% CI = -0.278, -0.059), which was significant (p = 0.003).

Table 3-8:Results of an unadjusted random effects meta-analyses to determine the effect of interventions upon diabetes-specific emotional distress in people with Type 2 diabetes, comparing mean change from baseline to furthest follow-up point in interventions against control groups

Study	Year	SMD	95% CI		% Weight
Basak	2014	0.267	-0.026	0.560	05.30
Beverly	2013	0.043	-0.296	0.381	04.70
D'Eramo Melkus	2010	-0.123	-0.499	0.253	04.25
Fisher	2013	0.052	-0.206	0.309	05.80
Fisher	2011	-0.326	-0.506	-0.147	06.95
Gabbay	2013	-0.277	-0.448	-0.106	07.08
Heisler	2010	0.117	-0.134	0.369	05.90
Hermanns	2012	-0.425	-0.732	-0.118	05.11
Lamers	2011	-0.224	-0.496	0.049	05.59
McMahon	2012	0.204	-0.189	0.597	04.07
Quinn	2011	-0.255	-0.618	0.108	04.41
Sigurdardottir	2009	-0.244	-0.785	0.297	02.77
Sinclair	2013	-0.580	-0.078	-0.081	03.09
Spencer	2011	-0.146	-0.454	0.163	05.09
Sturt	2008	-0.636	-0.616	-0.110	05.87
Thom	2013	-0.047	-0.274	0.180	06.26
van der Wulp	2012	-0.036	-0.395	0.324	04.45
van Son	2014	-0.390	-0.726	-0.055	04.74
Welch (ii)	2011	-1.122	-1.801	-0.443	01.99
Whittemore	2004	-0.752	-1.333	-0.171	02.51
Wycherley	2014	0.180	-0.211	0.572	04.08
Overall Pooled SMD		-0.169	-0.278	-0.059	100.00

Abbreviations: CI – Confidence Interval; SMD – Standardised Mean Difference

Figure 3–2: Graph demonstrating results of an unadjusted random effects meta-analyses to determine the effect of interventions upon diabetes-specific emotional distress in people with Type 2 diabetes, comparing mean change from baseline to furthest follow-up point in interventions against control groups



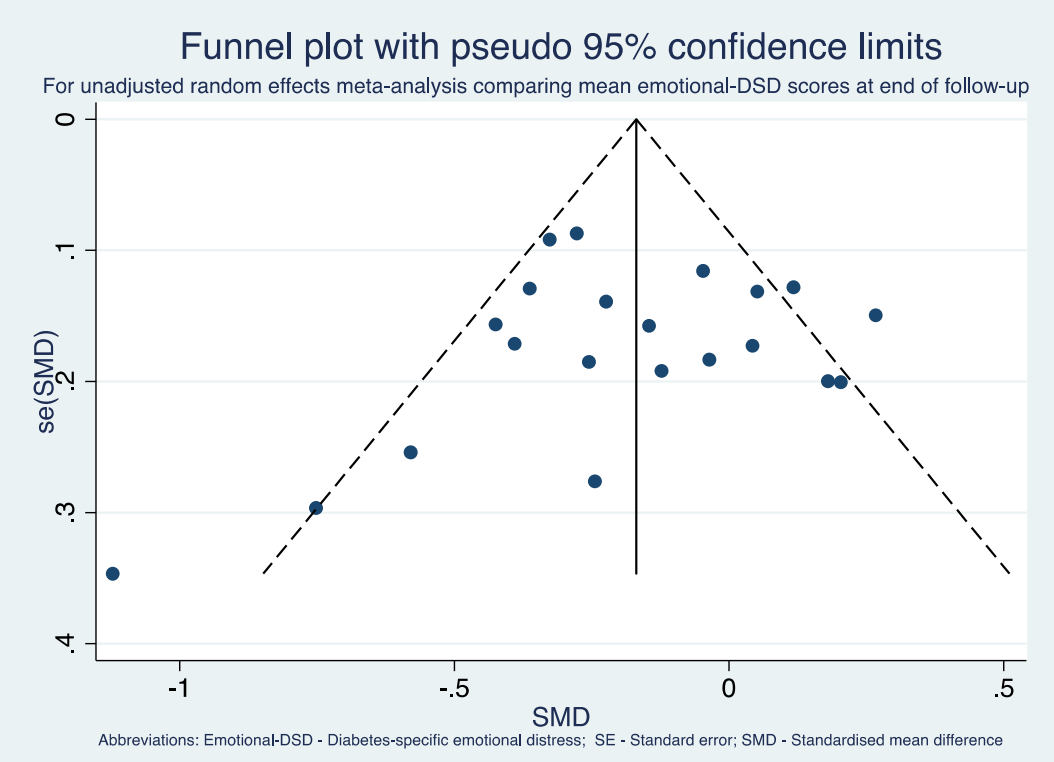
Heterogeneity was shown to be moderate with I^2 = 61.2%, however this was not explained by any of the potential confounders considered in the meta-regression analyses (Table 3-9). Non-standardised meta-analyses performed to assess the impact of interventions by the scales used demonstrated that interventions in studies using the PAID scale significantly reduced emotional-DSD compared to controls (WMD -3.233, 95% CI = -5.511, -0.956, p=0.005) but this was not seen in studies using the DDS (WMD -0.134, 95% CI = -0.324, -0.055, p=0.164).

Table 3-9: Results of meta-regression analyses to assess in confounders explained heterogeneity in an unadjusted random effects meta-analyses to determine the effect of interventions upon diabetes-specific emotional distress in people with Type 2 diabetes

Variable	Co-efficient	Standard Error	p>[t]	95% Confidence Interval	
Year of study	0.055	0.028	0.064	-0.004	0.114
Length of follow up (<1 yr. vs. >1 yr.)	0.088	0.126	0.492	-0.175	0.351
Study location (Western vs. Eastern)	-0.458	0.253	0.086	-0.987	0.072
Ethnicity (Caucasian <50% vs. ≥50%)	0.057	0.164	0.736	-0.300	0.413
Gender (Male <50% vs. ≥50%)	0.108	0.120	0.380	-0.144	0.361
Mean age (years)	-0.001	0.013	0.966	-0.028	0.026
Mean HbA1c (%)	-0.030	0.083	0.722	-0.206	0.146
Years diagnosed with T2DM	0.009	0.028	0.764	-0.053	0.070
Mean BMI (kg/m^2)	-0.071	0.049	0.165	-0.174	0.032

The funnel plot (Figure 3-3) and Eggers test (p=0.673) suggested that publication bias was absent.

Figure 3–3: Funnel plot to determine if publication bias was present in an unadjusted random effects meta-analyses to determine the effect of interventions upon diabetes-specific emotional distress in people with Type 2 diabetes



Further meta-analyses and meta-regression analyses conducted to assess and compare the effect of different intervention characteristics on emotional-DSD are shown in Table 3-10. Analyses demonstrated near-significant reductions in emotional-DSD in interventions utilising coping skills training when compared to interventions that did not (SMD = -0.378 vs. -0.109,

p=0.054). Although non-significant, substantial effects were also seen in interventions that utilised a collaborative care approach compared to those that did not (SMD = -0.343 vs. -0.108, p=0.092).

Table 3-10: Results of multiple unadjusted random effects meta-analyses to determine the effects of specific intervention characteristics upon diabetes-specific emotional distress in people with Type 2 diabetes

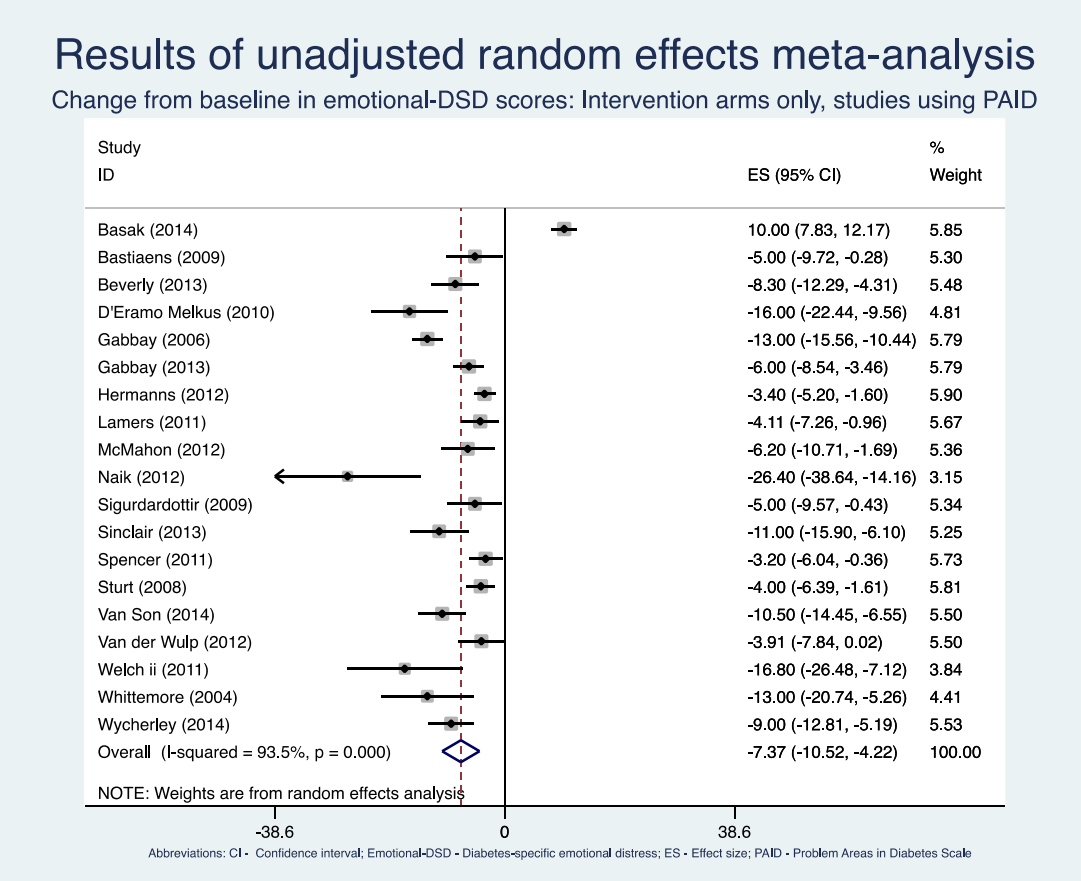
Intervention component	Used	N	SMD	95% CI		MA p-value	MR p-value	I^2 (%)
Delivered to individual (Either in part or in full)	Yes	15	-0.159	-0.288	-0.029	0.016	0.790	63.20
	No	6	-0.200	-0.428	0.027	0.085		63.00
Use of a mobile phone interface	Yes	1	-0.255	-0.618	0.108	0.168	0.774	-
	No	20	-0.165	-0.279	-0.051	0.004		63.00
Use of a web-based interface	Yes	3	-0.353	-0.881	0.175	0.190	0.599	81.00
	No	18	-0.157	-0.269	-0.046	0.006		58.50
Collaborative care approach	Yes	6	-0.343	-0.550	-0.136	0.001	0.092	49.30
	No	15	-0.108	-0.232	0.015	0.085		60.30
Use of motivational interviewing	Yes	4	-0.240	-0.436	-0.045	0.016	0.544	36.90
	No	17	-0.152	-0.281	-0.023	0.021		64.70
Cognitive behavioural approach	Yes	3	-0.250	-0.434	-0.065	0.008	0.609	00.00
	No	18	-0.157	-0.282	-0.032	0.014		65.70
Use of social/peer support	Yes	7	-0.154	-0.324	0.016	0.076	0.932	48.40
	No	14	-0.175	-0.318	-0031	0.017		66.80
Use of mindfulness approach	Yes	1	-0.390	-0.726	-0.055	0.023	0.435	-
	No	20	-0.158	-0.271	-0.045	0.006		61.90
Self-efficacy/empowerment	Yes	9	-0.148	-0.329	0.033	0.110	0.756	62.20
	No	12	-0.185	-0.328	-0.043	0.011		62.80
Self-management education	Yes	18	-0.197	-0.306	-0.088	<0.001	0.216	55.10
	No	3	-0.020	-0.397	0.436	0.926		78.00
Use of physical activity component	Yes	13	-0.220	-0.386	-0.055	0.009	0.425	67.10
	No	8	-0.115	-0.254	0.025	0.106		50.30
Monitoring of eating behavior	Yes	16	-0.188	-0.334	-0.042	0.012	0.725	65.10
	No	5	-0.136	-0.290	0.018	0.083		49.20
Self-monitoring of blood glucose	Yes	11	-0.245	-0.395	-0.095	0.001	0.218	54.90
	No	10	-0.093	-0.250	0.063	0.424		64.10
Individualised goal setting	Yes	18	-0.151	-0.258	-0.044	0.006	0.431	35.70
	No	3	-0.390	-1.009	0.229	0.217		82.80
Use of educational materials	Yes	7	-0.184	-0.368	-0.000	0.050	0.862	58.70
	No	14	-0.162	-0.304	-0.021	0.025		64.90
Accountability (self-reported feedback)	Yes	9	-0.226	-0.352	-0.099	<0.001	0.437	41.60
	No	12	-0.135	-0.305	0.034	0.118		67.40
Telephone support and/or feedback	Yes	12	-0.096	-0.231	0.040	0.167	0.154	59.30
	No	9	-0.275	-0.446	-0.104	0.002		56.60
Coping skills training	Yes	5	-0.378	-0.539	-0.216	<0.001	0.054	00.10
	No	16	-0.109	-0.230	0.012	0.077		62.40
Problem solving training	Yes	8	-0.331	-0.573	-0.089	0.007	0.145	63.50
	No	13	-0.113	-0.235	0.009	0.069		61.40

Abbreviations: CI – Confidence interval; MA – Meta-analysis; MR – Meta-regression; N – Number of interventions using approach; SMD – Standardised mean difference (negative number indicates that studies using method have greater reduction in diabetes-specific emotional distress compared to those that do not

To include data from cohort studies, analyses were performed to assess the change in emotional-DSD scores from baseline in treatment arms only, with analyses performed for studies using the PAID and those using the DDS

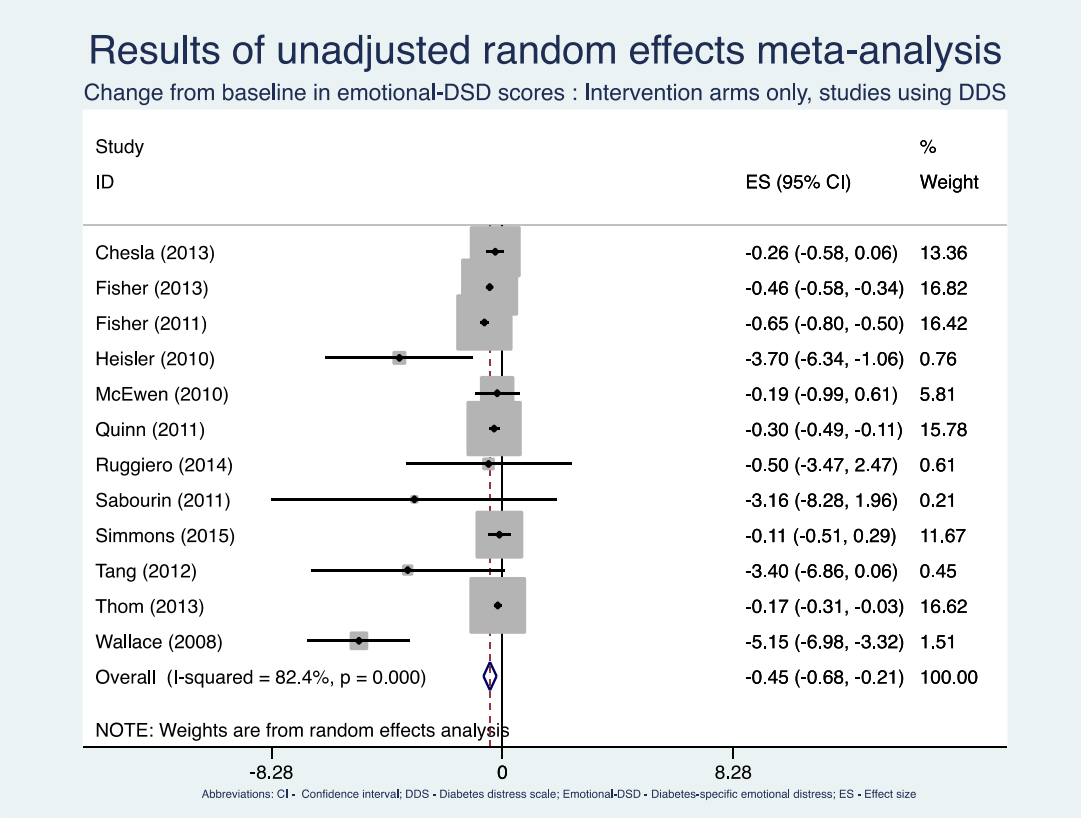
conducted separately. Results for studies using the PAID (Figure 3-4) demonstrated a mean change of -7.370 (95% CI = -10.521, -4.219), which was significant (p<0.001) and there was high heterogeneity between studies with I^2 = 93.5%.

Figure 3–4: Graph demonstrating the results of an unadjusted random effects meta-analyses to determine the effects of interventions upon diabetes-specific emotional distress in people with Type 2 diabetes, comparing mean change from baseline to furthest follow-up point in treatment arms only in studies using the Problem Areas in Diabetes Scale



Results for studies using the DDS (Figure 3-5) demonstrated a mean change of -0.449 (95% CI = -0.684, -0.214), which was also significant (p=0.001) with high heterogeneity between studies (I^2 = 82.4%). Sensitivity analyses, performed to see if different results would be found if only RCT's were included, demonstrated that the effect sizes were still significant but slightly less for both studies using the PAID (SMD = -6.850, 95% CI = -10.134, -3.565, p=<0.001), and again for studies using the DDS (SMD = -0.379, 95% CI = -0.588, -0.171, p=<0.001).

Figure 3–5: Graph demonstrating the results of an unadjusted random effects meta-analyses to determine the effects of interventions upon diabetes-specific emotional distress in people with Type 2 diabetes, comparing mean change from baseline to furthest follow-up point in treatment arms only in studies using the Diabetes Distress Scale



Secondary analyses: Impact of interventions upon physiological measures

HbA1c

A summary of the data used in the secondary analyses to assess intervention effects on HbA1c is shown in Table 3-11.

Table 3-11: Summary of data used in unadjusted random effects meta-analyses to determine the effect of interventions upon glycated haemoglobin in people with Type 2 diabetes

Author	Year	Outcome	Group	N	Baseline		Follow-up		Change	
					M DSD	SD DSD	M DSD	SD DSD	M DSD	SD DSD
Basak	2014	PAID	**Intervention**	77	07.50	01.50	06.90	01.30	-00.60	01.50
			Control	109	07.80	01.60	07.80	01.60	00.00	01.75
Bastiaens	2009	PAID	**Intervention**	44	07.40	01.30	07.30	00.80	-00.10	01.20
			Control	-	-	-	-	-	-	-
Beverly	2013	PAID	**Intervention**	67	08.50	01.40	08.20	0140	-00.30	01.50
			Control	67	0830	01.00	08.10	01.50	-00.20	01.43
Chesla	2013	DDS	**Intervention**	145	07.17	01.28	07.09	01.19	-00.08	01.40
			Control	-	-	-	-	-	-	-
D'Eramo Melkus	2010	PAID	**Intervention**	57	08.00	02.10	07.20	02.15	-00.80	02.30
			Control	52	08.30	02.20	08.00	02.41	-00.30	02.53
Gabbay	2013	PAID	**Intervention**	232	08.80	02.40	07.80	01.70	-1.00	02.30
			Control	313	09.10	02.30	08.00	01.80	-01.10	02.28
Gabbay	2006	PAID	**Intervention**	150	07.46	01.40	07.45	01.40	-00.01	01.50
			Control	182	07.36	01.50	07.40	01.80	00.04	01.82
Heisler	2014	DDS	**Intervention**	93	08.20	01.90	07.80	01.70	-00.40	02.00
			Control	95	08.30	02.20	07.90	01.90	-0.40	02.26
Heisler	2010	DDS	**Intervention**	125	07.93	01.40	08.22	01.74	-00.29	01.40
			Control	119	08.02	01.32	07.73	01.32	00.29	01.74
Hermanns	2012	PAID	**Intervention**	85	08.50	01.50	07.90	01.20	-00.60	01.50
			Control	82	08.20	01.10	07.80	01.50	-00.40	01.46
Khunti	2012	PAID	**Intervention**	437	08.30	02.20	-	-	-1.32	02.72
			Control	387	07.90	02.00	-	-	-0.81	02.61
Lamers	2011	PAID	**Intervention**	105	07.50	01.20	07.30	00.90	-00.20	01.20
			Control	103	07.20	01.40	07.80	00.80	00.60	01.31
McEwen	2010	DDS	**Intervention**	21	07.79	02.40	07.91	02.70	00.12	02.80
			Control	-	-	-	-	-	-	-
McMahon	2012	PAID	**Intervention**	51	09.75	01.12	08.40	01.37	-01.40	01.60
			Control	49	10.10	01.40	08.40	01.70	-01.70	01.72
Naik	2012	PAID	**Intervention**	8	09.73	02.62	08.89	03.35	-00.84	03.30
			Control	-	-	-	-	-	-	-
Quinn	2011	DDS	**Intervention**	62	09.90	02.10	07.90	01.70	-02.00	02.10
			Control	56	09.20	01.70	08.50	01.80	-00.70	01.92
Ruggiero	2014	DDS	**Intervention**	41	07.40	01.34	07.10	01.41	-00.30	01.50
			Control	-	-	-	-	-	-	-
Sigurdardottir	2009	PAID	**Intervention**	28	08.09	00.95	08.01	01.16	-00.08	09.10
			Control	25	07.88	00.89	07.76	00.81	-00.12	00.93
Simmons	2015	DDS	**Intervention**	322	07.30	01.30	07.50	-	-00.29	13.60
			Control	322	07.30	01.30	-	-	-	-
Sinclair	2013	PAID	**Intervention**	35	09.70	02.10	08.20	01.10	-01.50	01.90
			Control	30	09.80	02.30	09.40	02.20	-00.40	02.47
Spencer	2011	PAID	**Intervention**	72	08.60	08.23	07.80	08.44	-00.80	09.10
			Control	92	08.50	02.69	08.50	02.69	00.00	02.95
Sturt	2008	PAID	**Intervention**	114	08.90	01.40	08.40	01.40	-00.50	01.50
			Control	131	08.70	01.40	08.40	01.40	-00.30	01.53
Tang	2012	DDS	**Intervention**	52	07.90	01.70	07.10	01.40	-00.80	01.70
			Control	-	-	-	-	-	-	-
Thom	2013	DDS	**Intervention**	148	10.05	02.00	08.98	01.99	-01.07	02.20
			Control	151	09.85	01.99	09.55	02.33	-00.30	02.38
van Son	2014	PAID	**Intervention**	70	07.50	01.20	07.60	01.20	00.10	01.30
			Control	69	07.60	01.20	07.70	01.50	00.10	01.50
Welch (i)	2011	PAID	**Intervention**	61	08.80	01.00	-	-	-00.32	01.40
			Control	58	08.90	01.20	-	-	-	-
Welch (ii)	2011	PAID	**Intervention**	21	09.00	01.20	07.40	01.40	-01.60	01.40
			Control	18	08.50	01.00	07.90	01.40	-00.60	01.36
Whittemore	2004	PAID	**Intervention**	26	07.70	01.00	07.50	01.00	-00.20	01.10
			Control	23	07.60	01.00	07.50	01.00	-00.10	01.10
Wycherley	2014	PAID	**Intervention**	65	07.20	01.60	06.00	01.00	-01.20	01.50
			Control	41	07.80	01.50	06.50	00.90	-01.30	01.41

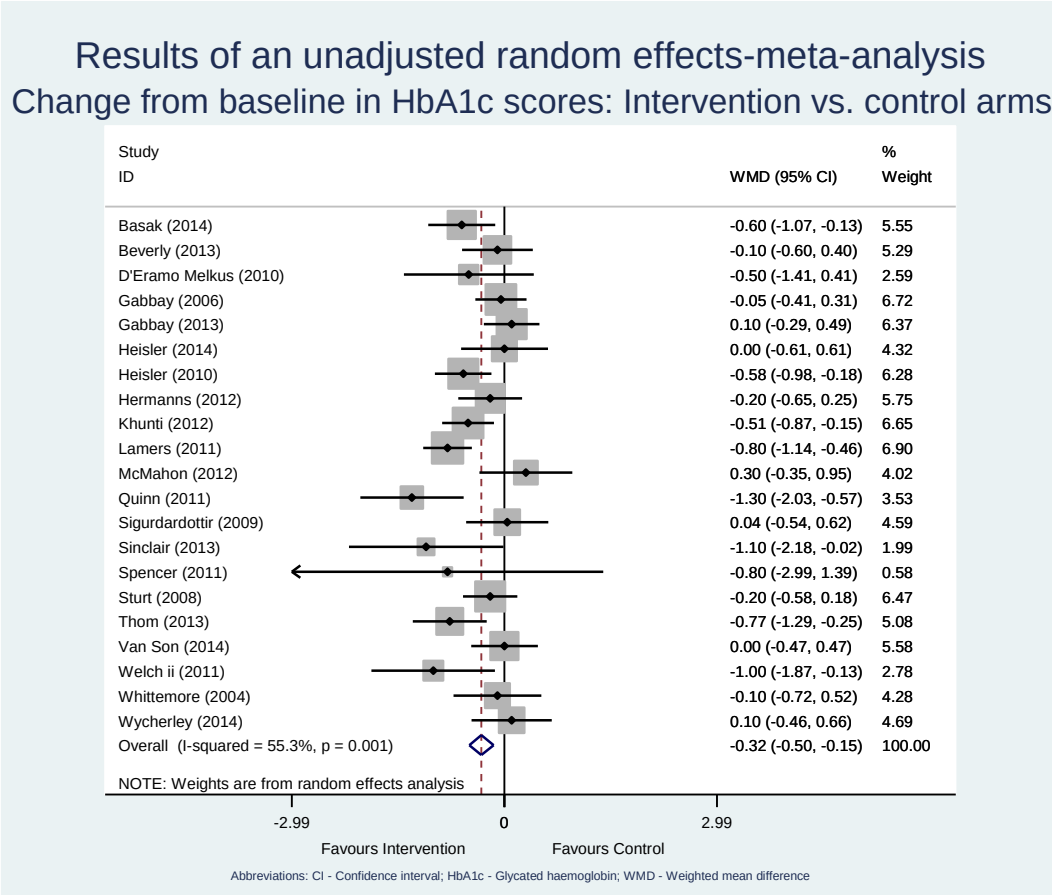
Abbreviations: DSD – Diabetes-specific emotional DSD; M – Mean; N – Number; SD – Standard deviation

Twenty-one studies, with a total of 4314 participants, used a control group and reported baseline and follow-up data for HbA1c. These were included in an unadjusted random effects meta-analysis comparing interventions against controls for reducing HbA1c (Table 3-12, Figure 3-6). Overall HbA1c scores were lower in the intervention groups with a greater change from baseline at the end of follow-up compared to the control groups with an overall weighted mean difference of -0.323 (95% CI = -0.495, -0.152) and this difference was significant (p<0.001).

Table 3-12:Results of an unadjusted random effects meta-analyses to determine the effect of interventions upon glycated haemoglobin in people with Type 2 diabetes, comparing mean change from baseline to furthest follow-up point in interventions against control groups

Study	Year	WMD	95% CI		% Weight
Basak	2014	-0.600	-1.070	-0.130	05.55
Beverly	2013	-0.100	-0.597	0.397	05.29
D'Eramo Melkus	2010	-0.500	-1.411	0.411	02.59
Gabbay	2013	-0.050	-0.408	0.308	06.72
Gabbay	2006	0.100	-0.289	0.489	06.37
Heisler	2014	0.000	-0.610	0.610	04.32
Heisler	2010	-0.580	-0.978	-0.182	06.28
Hermanns	2012	-0.200	-0.649	0.249	05.75
Khunti	2012	-0.510	-0.874	-0.146	06.65
Lamers	2011	-0.800	-1.141	-0.459	06.90
McMahon	2012	0.300	-0.351	0.951	04.02
Quinn	2011	-1.300	-2.025	-0.575	03.53
Sigurdardottir	2009	0.040	-0.536	0.616	04.59
Sinclair	2013	-1.100	-2.184	-0.016	01.99
Spencer	2011	-0.800	-2.987	1.387	00.58
Sturt	2008	-0.200	-0.581	0.181	06.47
Thom	2013	-0.770	-1.290	-0.250	05.08
van Son	2014	0.000	-0.467	0.467	05.58
Welch (ii)	2011	-1.000	-1.867	-0.133	02.78
Whittemore	2004	-0.100	-0.716	0.516	04.28
Wycherley	2014	0.100	-0.464	0.664	04.69
Overall Pooled WMD		-0.323	-0.495	-0.152	100.00
Abbreviations: CI – Confidence Interval; WMD – Weighted Mean Difference					

Figure 3–6: Graph demonstrating results of an unadjusted random effects meta-analyses to determine the effect of interventions upon glycated haemoglobin in people with Type 2 diabetes, comparing mean change from baseline to furthest follow-up point in interventions against control groups



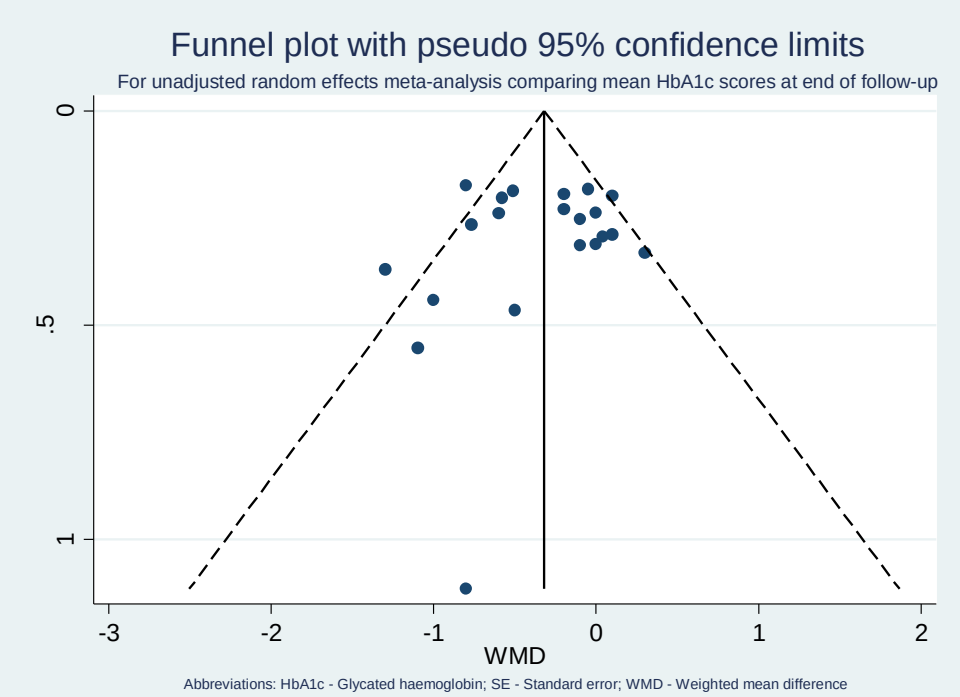
Heterogeneity was shown to be moderate $I^2 = 55.3\%$, however this was not explained by any of the potential confounders considered in the meta-regression analyses (Table 3-13).

Table 3-13: Results of meta-regression analyses to assess in confounders explained heterogeneity in an unadjusted random effects meta-analyses to determine the effect of interventions upon glycated haemoglobin in people with Type 2 diabetes

Variable	Co-efficient	Standard Error	p>[t]	95% Confidence Interval	
Year of study	-0.009	0.034	0.799	-0.080	0.062
Length of follow up (<1 yr. vs. >1 yr.)	-0.018	0.186	0.925	-0.408	0.372
Study location (Western vs. Eastern)	0.292	0.397	0.470	-0.538	1.123
Ethnicity (Caucasian <50% vs. ≥50%)	0.136	0.244	0.588	-0.392	0.664
Gender (Male <50% vs. ≥50%)	0.181	0.190	0.354	0.218	0.579
Mean age (years)	0.002	0.020	0.920	-0.039	0.043
Mean HbA1c (%)	-0.097	0.112	0.399	-0.332	0.138
Years diagnosed with T2DM	0.004	0.026	0.895	0.054	0.061
Mean BMI (kg/m^2)	-0.009	0.071	0.905	-0.160	0.143

The funnel plot (Figure 3-7) and Egger's test (p=0.606) suggested publication bias was absent.

Figure 3–7: Funnel plot to determine if publication bias was present in an unadjusted random effects meta-analyses to determine the effect of interventions upon glycated haemoglobin in people with Type 2 diabetes



Further meta-analyses and meta-regression analyses conducted to assess and compare the effect of different intervention characteristics on HbA1c are shown in Table 3-14. Analyses demonstrated significant reductions in HbA1c when comparing interventions that utilised a mobile phone interface against those that did not (WMD = -1.300 vs. -0.287, p=0.038), and in those including social and/or peer support (WMD = -0.652 vs. -0.210, p=0.029). Although non-significant, substantial effect sizes were also seen in interventions utilising a computer/web-based interface (WMD = -0.739 VS. -0.280, p=0.161)

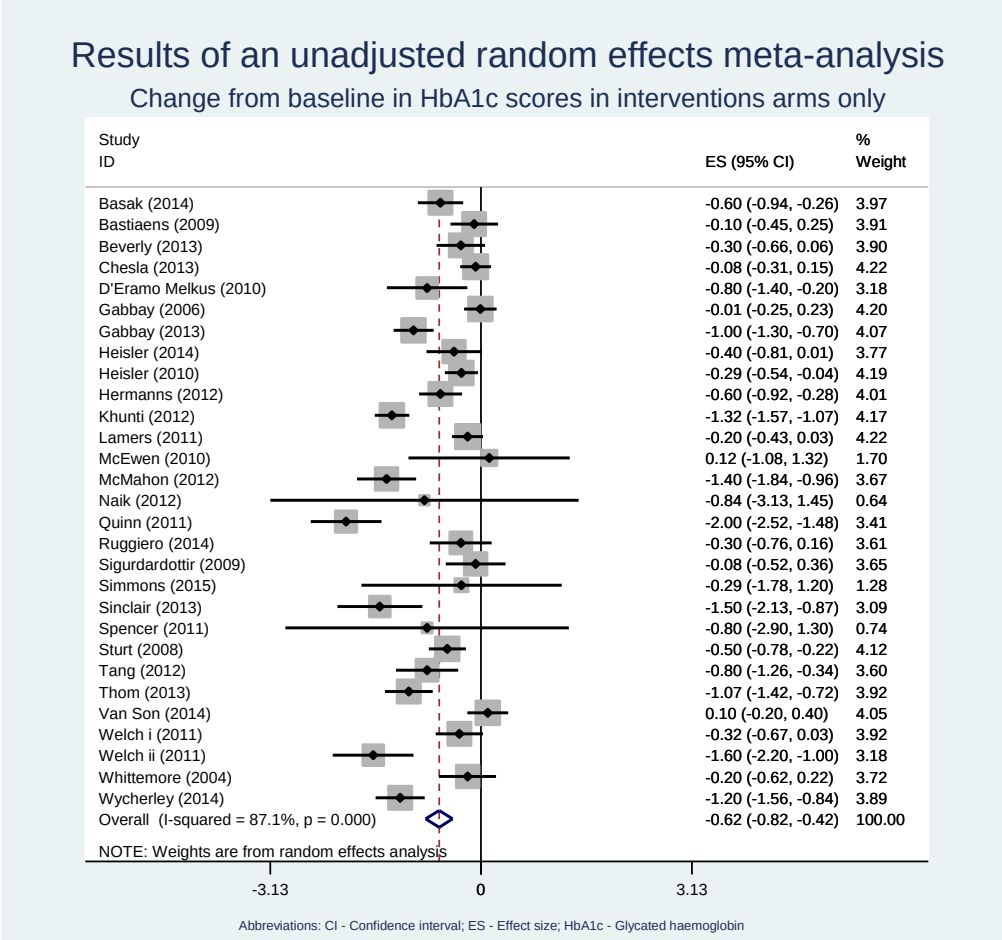
Table 3-14: Results of multiple unadjusted random effects meta-analyses to determine the effects of specific intervention characteristics upon glycated haemoglobin in people with Type 2 diabetes

Intervention component		N	WMD	95% CI		MA p-value	MR p-value	I^2 (%)
Delivered to individual (in part or in full)	Yes	14	-0.310	-0.552	-0.069	0.012	0.793	64.90
	No	7	-0.351	-0.563	-0.138	0.001		20.30
Use of a mobile phone interface	Yes	1	-1.300	-2.025	-0.575	0.000	0.038	00.00
	No	20	-0.287	-0.450	-0.124	0.001		49.50
Use of a computer/web-based interface	Yes	3	-0.739	-1.584	0.106	0.086	0.161	75.20
	No	18	-0.280	-0.448	-0.112	0.001		50.20
Collaborative care approach	Yes	6	-0.533	-1.011	-0.055	0.029	0.362	59.50
	No	15	-0.283	-0.471	-0.095	0.003		56.80
Use of motivational interviewing	Yes	4	0.019	-0.268	0.306	0.898	0.140	00.00
	No	17	-0.380	-0.569	-0.191	<0.001		57.60
Cognitive behavioural approach	Yes	3	-0.440	-1.020	0.139	0.136	0.563	72.80
	No	18	-0.298	-0.478	-0.119	0.001		51.10
Use of social/peer support	Yes	6	-0.652	-0.961	0.343	<0.001	0.029	36.70
	No	15	-0.210	-0.397	-0.023	0.028		51.80
Use of mindfulness approach	Yes	1	0.000	-0.467	0.467	1.000	0.394	00.00
	No	20	-0.343	-0.521	-0.165	<0.001		55.70
Self-efficacy/empowerment	Yes	10	-0.371	-0.535	-0.206	<0.001	0.654	02.30
	No	11	-0.295	-0.580	-0.010	0.042		71.30
Self-management education	Yes	18	-0.351	-0.542	-0.161	<0.001	0.502	56.80
	No	3	-0.181	-0.616	0.254	0.416		56.30
Use of physical activity component	Yes	11	-0.326	-0.514	-0.139	0.001	0.853	15.80
	No	10	-0.310	-0.593	-0.127	0.032		72.60
Monitoring of eating behavior	Yes	14	-0.240	-0.412	-0.068	0.006	0.296	22.80
	No	7	-0.455	-0.805	-0.106	0.011		76.50
Self-monitoring of blood glucose	Yes	11	-0.408	-0.661	-0.154	0.002	0.381	53.40
	No	10	-0.245	-0.490	-0.001	0.049		60.20
Individualised goal setting	Yes	18	-0.345	-0.528	-0.162	<0.001	0.543	55.60
	No	3	-0.200	-0.745	0.346	0.473		58.30
Use of educational materials	Yes	8	-0.274	-0.447	-0.102	0.002	0.493	08.00
	No	13	-0.392	-0.666	-0.118	0.005		67.40
Accountability (self-reported feedback)	Yes	8	-0.338	-0.646	-0.030	0.031	0.919	65.50
	No	13	-0.313	-0.526	-0.100	0.004		50.50
Telephone support and/or feedback	Yes	11	-0.301	-0.549	-0.053	0.017	0.778	60.30
	No	10	-0.352	-0.599	-0.105	0.005		51.90
Coping skills training	Yes	5	-0.197	-0.445	0.052	0.121	0.687	00.00
	No	16	-0.344	-0.551	-0.137	0.001		62.30
Problem solving training	Yes	8	-0.323	-0.562	-0.083	0.008	0.923	21.10
	No	13	-0.320	-0.553	-0.086	0.007		66.60

Abbreviations: CI – Confidence interval; MA – Meta-analysis; MR – Meta-regression; N – Number of interventions using approach; WMD – Weighted mean difference.

To include data from cohort studies, analyses were performed to assess the change from baseline in treatment arms only, demonstrating an overall effect size of -0.622 (95% CI = -0.820, -0.423) and this effect was significant ($p<0.001$).

Figure 3–8: Graph demonstrating the results of an unadjusted random effects meta-analysis to determine the effects of interventions upon glycated haemoglobin in people with Type 2 diabetes in intervention arms only



Sensitivity analyses, performed to see if different results would be found if only RCT's were included, demonstrated that there was very little difference in the findings (ES = -0.636, 95% CI = -0.853, -0.420, p<0.001).

Body Mass Index

A summary of the data used in the secondary analyses to assess the effect of interventions on BMI is shown in Table 3-15.

Table 3-15: Summary of data used in unadjusted random effects meta-analyses to determine the effect of interventions upon body mass index in people with Type 2 diabetes

Author	Year	Outcome	Group	N	Baseline		Follow-up		Change	
					M DSD	SD DSD	M DSD	SD DSD	M DSD	SD DSD
Basak	2014	PAID	Intervention Control	77 109	30.10 31.00	05.30 06.10	34.00 30.80	32.30 15.20	03.90 -00.20	29.43 12.53
Bastiaens	2009	PAID	Intervention Control	44 -	28.60 -	18.00 -	28.07 -	05.80 -	-00.53 -	12.30 -
Beverly	2013	PAID	Intervention Control	67 67	34.60 33.70	07.00 07.10	34.40 33.40	07.50 06.40	-00.02 -01.30	06.50 06.07
McEwen	2010	DDS	Intervention Control	21 -	35.26 -	05.50 -	35.14 -	06.00 -	-00.12 -	05.16 -
McMahon	2012	PAID	Intervention Control	51 49	34.05 34.20	06.70 07.00	34.40 34.30	03.60 06.40	00.60 00.10	06.57 06.02
Ruggiero	2014	DDS	Intervention Control	41 -	39.30 -	10.25 -	38.60 -	10.63 -	-00.70 -	09.34 -
Sigurdardottir	2009	PAID	Intervention Control	28 25	31.54 32.71	05.10 05.00	31.20 32.70	04.30 04.90	-00.34 -00.01	01.00 04.43
Spencer	2011	PAID	Intervention Control	72 92	32.70 34.10	08.23 08.56	33.00 33.70	08.44 08.81	00.30 -00.40	07.46 07.77
Tang	2012	DDS	Intervention Control	52 -	34.70 -	07.30 -	34.40 -	06.50 -	-00.30 -	06.21 -
Thom	2013	DDS	Intervention Control	148 151	35.18 32.81	08.27 08.67	35.02 32.64	08.17 08.45	-00.16 -00.22	07.35 07.66
Welch (ii)	2011	PAID	Intervention Control	21 18	33.80 35.80	07.80 14.00	33.80 32.60	06.90 06.30	00.00 -03.20	01.40 04.13
Whittemore	2004	PAID	Intervention Control	26 23	36.50 34.80	07.00 07.00	36.80 35.10	06.00 07.00	00.30 00.30	01.40 04.13
Wycherley	2014	PAID	Intervention Control	65 41	35.20 35.50	04.40 04.80	31.30 32.50	03.90 04.40	-03.90 -00.30	01.90 04.13

Abbreviations: DSD – Diabetes-specific emotional DSD; M – Mean; N – Number; SD – Standard deviation

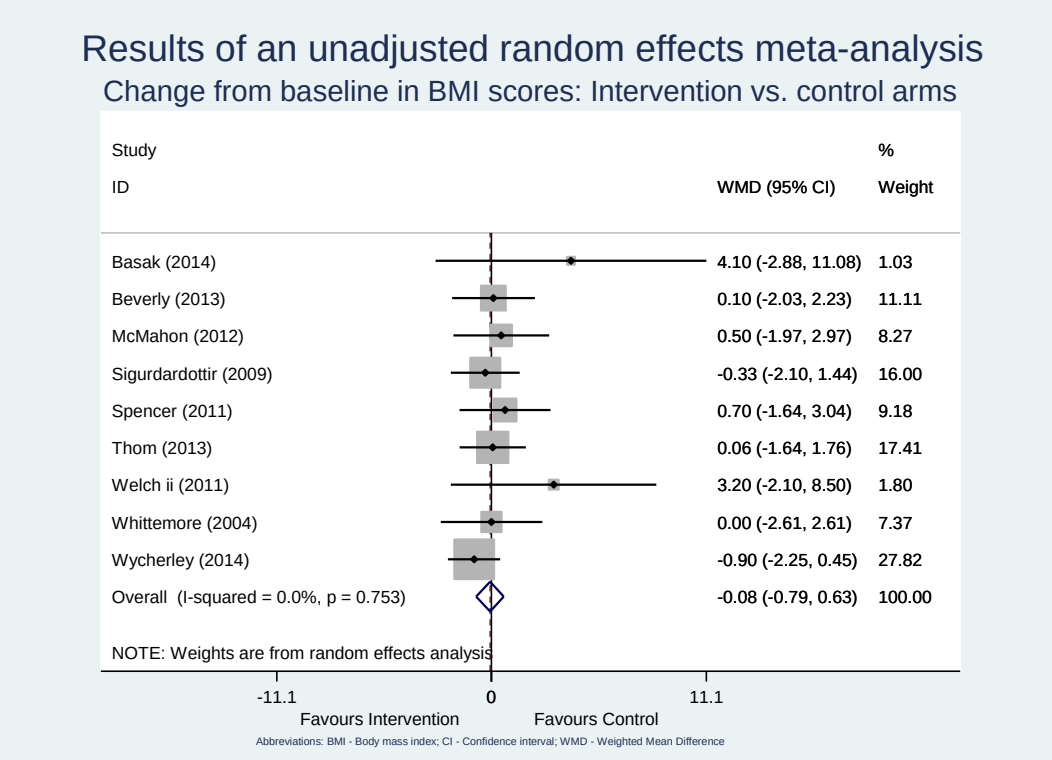
Nine studies, with a total of 1130 participants, used a control group and reported data for BMI and these were included in an unadjusted random effects meta-analysis comparing interventions against controls for reducing BMI (Table 3-16, Figure 3-10).

Table 3-16:Results of an unadjusted random effects meta-analyses to determine the effect of interventions upon body mass index in people with Type 2 diabetes, comparing mean change from baseline to furthest follow-up point in interventions against control groups

Study	Year	WMD	95% CI		% Weight
Basak	2014	4.100	-2.881	11.081	01.03
Beverly	2013	0.100	-2.029	2.229	11.11
McMahon	2012	0.500	-1.969	2.969	08.27
Sigurdardottir	2009	-0.330	-2.105	1.445	16.00
Spencer	2011	0.700	-1.643	3.043	09.18
Thom	2013	0.060	-1.642	1.762	17.41
Welch (ii)	2011	3.200	-2.098	8.498	01.80
Whittemore	2004	0.000	-2.615	2.615	07.37
Wycherley	2014	-0.900	-2.245	0.446	27.82
Overall Pooled SMD		-0.076	-0.786	0.634	100.00

Abbreviations: CI – Confidence Interval; WMD – Weighted Mean Difference

Figure 3–9: Graph demonstrating results of an unadjusted random effects meta-analyses to determine the effect of interventions upon body mass index in people with Type 2 diabetes, comparing mean change from baseline to furthest follow-up point in interventions against control groups

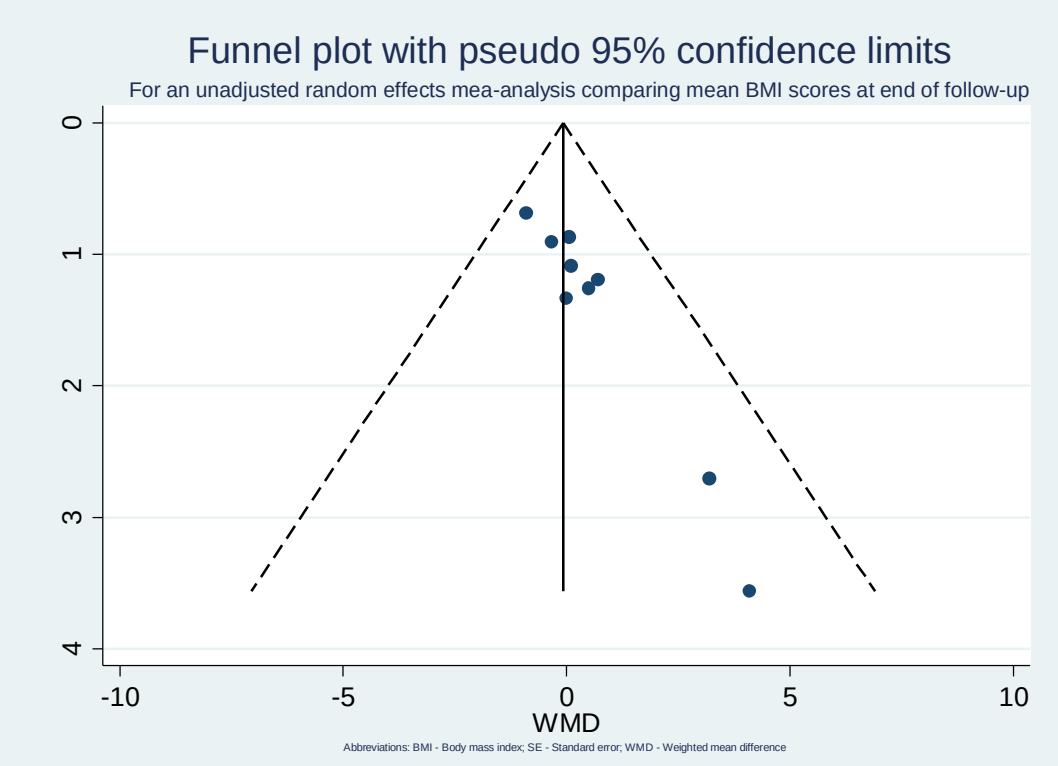


Overall BMI scores were lower in the intervention groups with a greater change from baseline at the end of follow-up compared to the control groups with an overall weighted mean difference of -0.076 (95% CI = -0.786, 0.634), which was non-significant (p=0.833). The I^2 statistic demonstrated no heterogeneity and no confounders were identified in the meta-regression analyses (Table 3-17). The funnel plot (Figure 3-11) and Egger's test (p=0.774) suggested that publication bias was absent.

Table 3-17: Results of meta-regression analyses to assess in confounders explained heterogeneity in an unadjusted random effects meta-analyses to determine the effect of interventions upon body mass index in people with Type 2 diabetes

Variable	Co-efficient	Standard Error	p>[t]	95% Confidence Interval	
Year of study	-0.050	0.131	0.714	-0.361	0.260
Length of follow up (<1 yr. vs. >1 yr.)	0.979	0.871	0.298	-1.081	3.040
Study location (Western vs. Eastern)	-4.220	3.580	0.277	-12.686	4.246
Ethnicity (Caucasian <50% vs. ≥50%)	-0.270	0.976	0.796	-2.979	0.440
Gender (Male <50% vs. ≥50%)	-0.808	0.729	0.310	-2.593	0.976
Mean age (years)	-0.041	0.147	0.789	0.401	0.319
Mean HbA1c (%)	0.352	0.365	0.368	-0.512	1.216
Years diagnosed with T2DM	0.070	0.162	0.685	-0.346	0.486
Mean BMI (kg/m²)	-0.216	0.301	0.497	-0.927	0.496

Figure 3–10: Funnel plot to determine if publication bias was present in an unadjusted random effects meta-analyses to determine the effect of interventions upon body mass index in people with Type 2 diabetes



Further meta-analyses and meta-regression analyses conducted to assess and compare the effect of different intervention characteristics on BMI demonstrated no significant effects (Table 3-18).

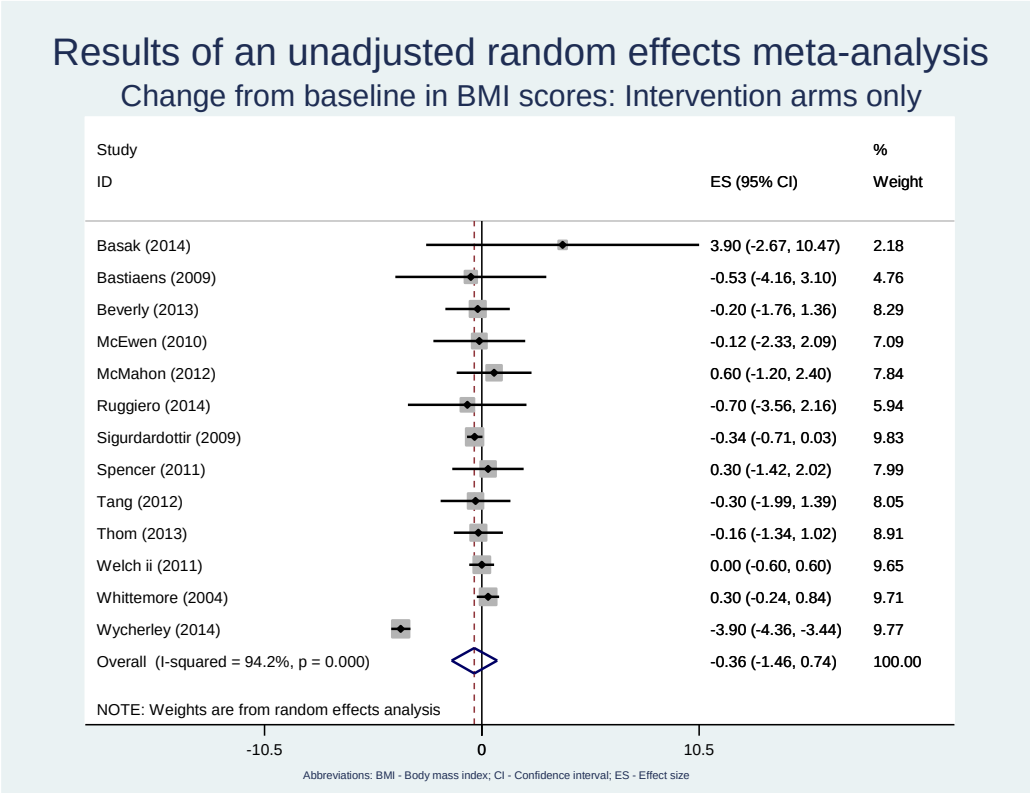
Table 3-18: Results of multiple unadjusted random effects meta-analyses to determine the effects of specific intervention characteristics upon body mass index in people with Type 2 diabetes

Intervention component		N	WMD	95% CI		MA p-value	MR p-value	I^2 (%)
Delivered to individual (in part or in full)	Yes	8	-0.098	-0.851	0.655	0.798	0.868	00.00
	No	1	0.100	-2.029	2.229	0.927		00.00
Use of a computer/web-based interface	Yes	1	3.200	-2.098	8.498	0.236	0.261	00.00
	No	8	-0.136	-0.852	0.580	0.710		00.00
Collaborative care approach	Yes	3	0.663	-0.994	2.321	0.433	0.365	00.00
	No	6	-0.242	-1.028	0.543	0.545		00.00
Use of motivational interviewing	Yes	2	0.388	-1.357	2.133	0.663	0.586	00.00
	No	7	-0.168	-0.945	0.609	0.671		00.00
Use of social/peer support	Yes	1	0.060	-1.642	1.762	0.945	0.868	00.00
	No	8	-0.105	0.886	0.676	0.792		00.00
Self-efficacy/empowerment	Yes	3	0.206	-1.181	1.592	0.771	0.657	00.00
	No	6	-0.176	-1.003	0.650	0.676		00.00
Self-management education	Yes	7	0.185	-0.656	1.027	0.666	0.294	00.00
	No	2	0.379	-3.897	4.654	0.862		47.40
Use of physical activity component	Yes	6	-0.220	-1.113	0.673	0.629	0.619	00.00
	No	3	0.171	-0.999	1.341	0.775		00.00
Monitoring of eating behavior	Yes	8	-0.105	-0.886	0.676	0.792	0.868	00.00
	No	1	0.060	-1.642	1.762	0.945		00.00
Self-monitoring of blood glucose	Yes	5	0.124	-0.837	1.085	0.801	0.564	00.00
	No	4	-0.305	-1.375	0.765	0.576		01.30
Individualised goal setting	Yes	7	0.166	-0.680	1.012	0.701	0.337	00.00
	No	2	0.316	-3.354	3.987	0.866		53.70
Use of educational materials	Yes	1	-0.330	-2.105	1.445	0.716	0.769	00.00
	No	8	-0.028	0.802	0.747	0.944		00.00
Accountability (self-reported feedback)	Yes	1	-0.900	-2.246	0.446	0.190	0.201	00.00
	No	7	0.241	-0.594	1.077	0.571		00.00
Telephone support and/or feedback	Yes	6	0.178	-0.744	1.101	0.705	0.425	00.00
	No	2	-3.03	-1.694	1.088	0.669		20.30
Coping skills training	Yes	1	0.000	-2.615	2.615	1.000	0.954	00.00
	No	7	-0.082	-0.820	0.655	0.827		00.00
Problem solving training	Yes	3	0.019	-1.397	1.434	0.980	0.884	00.00
	No	6	-0.108	-0.929	0.713	0.796		00.00

Abbreviations: CI – Confidence interval; MA – Meta-analysis; MR – Meta-regression; N – Number of interventions using approach; SMD – Standardised mean difference (negative number indicates that studies using method have greater reduction in diabetes-specific emotional distress compared to those that do not

To include data from cohort studies, analyses were performed to assess the change from baseline in treatment arms only, demonstrating an overall effect size of -0.359 (95% CI = -1.458, 0.740) and this effect was non-significant (p=0.522). Sensitivity analyses, performed to see if different results would be found if only RCTs were included demonstrated similar findings (ES = -0.341, 95% CI = -1.659, 0.977, p=0.612).

Figure 3–11: Graph demonstrating the results of an unadjusted random effects meta-analyses to determine the effects of interventions upon body mass index in people with Type 2 diabetes, comparing mean change from baseline to follow-up point in intervention arms only



3.5 Discussion

3.5.1 Key findings

Thirty-four studies, with a total of 6497 participants, were included in meta-analyses to determine the effect of interventions on emotional-DSD in people with T2DM, with secondary analyses determining the effects upon HbA1c and BMI.

The primary meta-analyses of existing RCTs looking at the effects of existing interventions on emotional-DSD included twenty-one studies with a total of 3814 participants, showing a significant overall effect of interventions on emotional-DSD compared to controls (p=0.003). Sub-group analyses assessing intervention components that might mediate this effect, demonstrated near-significant effects for interventions that utilised coping-skills training (p=0.054) compared to those that did not. Promise was also seen in interventions that utilised a collaborative care approach. To include data from cohort studies, change from baseline analyses were performed for

intervention arms only and these also yielded significant results (p<0.001 for studies using the PAID, p=0.001 for studies using the DDS).

The same analyses for HbA1c scores, which included twenty-one studies with a total of 4314 participants, also yielded positive results with interventions demonstrating a significant reduction in HbA1c compared to controls when comparing changes from baseline (p<0.001). Subgroup analyses, as with the primary analyses, showed significantly reduced HbA1c scores when interventions used a mobile phone-based interface (p=0.038), and interventions that included social and/or peer support (p=0.029). Although non-significant, promise was also seen in interventions that utilised a computer/web-based interface. Once again, to include data from cohort studies change from baseline analyses were performed for intervention arms only and this also yielded significant results (p<0.001).

Lastly, the same analyses for BMI scores included nine RCTs with a total of 1130 participants showed no overall significant effects of interventions on BMI scores (p=0.833), with sub-group analyses and analyses to include cohort data also demonstrating no significant findings.

In summary, existing interventions reported in this review have a positive effect on reducing emotional-DSD and HbA1c, but not BMI. There appears to be merit in interventions that include digital platforms, such as mobile phone or web-based interfaces, include coping skills training, social and/or peer support, and/or a collaborative care approach.

3.5.2 Strengths and limitations

At the time of undertaking this thesis, this was the first known systematic review and meta-analyses of the existing literature examining interventions that impact on emotional-DSD in T2DM, augmented by an additional focus on specific intervention characteristics that mediate the effect. As such, it addressed a gap in the literature with novel information. However, during the process of completion, another study by Sturt *et al (*185) was published which also sought to determine the effect of interventions on emotional-DSD, although there were differences between our approach and findings.

The overall aim of this thesis was to inform the design of a potential intervention for people with T2DM with depression and/or DSD, as such, the

search criteria were kept specific to T2DM, and if studies included both T1DM and T2DM then a proportion of >70% T2DM was required for inclusion. Sturt *et al*, however, included both T1DM and T2DM populations. As discussed in chapter two, a large proportion of research combines T1DM and T2DM populations together when exploring DSD, which can be problematic since DSD can likely manifest differently in the two populations. Again, to keep within the overarching thesis aims, interventions were broken down into more specific categories, so that information could be gained from this to inform the potential designs for potential treatment pathways. Sturt *et al*, kept their categories much broader such as 'psycho-education interventions' and 'generalist interventionist'. Similarly, the current review included any intervention regardless of study design whereas Sturt *et al* included only RCTs. Due to the scope of the work and the main thesis interest lying within health psychology, interventions that were solely pharmacotherapy based were excluded. Sturt *et al* included these in their study, whereas the current review sought to understand the benefits of psychosocial and/or educational interventions, that may or not include pharmacotherapy within their protocol. As such, the overall search numbers were larger in the Sturt *et* al review and they reported a number of studies that were ineligible for the current review either due to the proportion of T1DM participants or due to the pharmacotherapeutic design.

Sturt *et al* stated that they only contacted authors once for further information, however, in this meta-analysis data was chased two to three times depending on the responses. Similarly to the 3D-study approach, Sturt split studies with multiple intervention arms into the most intensive arm and the control.

Of particular interest was the fact that Sturt *et al* reported studies that could have been eligible for this review, but that did not appear in the current findings, and vice versa. Sturt reported eleven studies(113,315-325) that appeared to be eligible for this review. It is unclear why they did not appear in the current searches although a number of studies were from members of the review team and two papers were stated as 'in press' and 'author reported', suggesting that Sturt *et al* may have had access to potential 'grey literature' and/or data that was not available to the current review. Also two

papers reported by Sturt *et al* appeared to only be the baseline data and/or the protocol/design of an intervention (113,326), one of which appeared in the current searches but was excluded due to a lack of follow-up data. The current review reported twenty-one studies, of which thirteen were RCTs that were not reported by Sturt *et al* (202,208,225,230,231,245,270-273,277,296,297). Without seeing their specific search terms, it is unclear as to why studies were missed on both sides, but it would be interesting in the future to include the missing studies in analyses and see if this impacts the results and findings in any way.

A strength in the current work is that the methods used to carry out the review and analyses were robust, and strategies were adopted to gain all relevant outcome data that were available, even when not reported. In spite of this, a number of hurdles were encountered, and although the best efforts were taken to obtain missing data from authors, it was not always possible. Where possible, data was imputed from existing data or calculated from alternative data given by studies.

As discussed in chapter two, there are both strengths and limitations to the use of meta-analyses and meta-regression analyses to explore research questions. Collating the data from multiple studies allows for increased power to understand the effect of interventions on emotional-DSD. However, the use of aggregate data and the inability to alter or improve the quality of data from the original studies stands as a limitation (299). The use of multiple tests, as performed to explore and compare the effect of specific intervention characteristics, can increase the risk of false positives and caution should be taken when interpreting the findings (300).

The standardising of the emotional-DSD meta-analyses to determine an overall effect also warrants caution in interpretation; particularly since the findings of the analyses in chapter two demonstrated an influence of the scale used upon emotional-DSD scores suggesting a difference in how the scales conceptualise and determine emotional-DSD. Sensitivity analyses to explore the effect of interventions specifically by the scale demonstrated significant findings for interventions in studies using the PAID (p=0.005) compared to controls, but not in studies using the DDS (p=0.164). One could argue that the proportionally lower number of studies using the DDS is not enough to

conclude a significant effect, but one could also consider the findings in chapter two, and how the DDS is a more comprehensive scale and appeared to demonstrate higher rate of emotional-DSD compared to the PAID scale. As such the combination of studies using either the PAID or the DDS to produce an overall standardised mean difference warrants cautious interpretation of any definitive conclusions in the current findings.

A further limitation is that the studies included in this review were very heterogeneous across multiple variables, another common limitation of meta-analyses. Twenty-three studies used the PAID scale and thirteen used the DDS, with a number of studies reporting outcomes differently even if the same scale was used, resulting in a number of exclusions. The locations of the studies also varied considerably, both globally and locally, as did the length of follow-up, both of which could impact the validity of the outcomes. The majority of the analyses were performed on data from RCTs, of which there were thirty-three but only twenty-one could be included in the meta-analyses. Data from cohort studies were included but external validity of these findings is limited. While overall quality of the studies included was moderate, there was considerable variation between studies at an individual level. Although data was extracted for other bio-medical outcomes, such as blood pressure and cholesterol, it was not possible to analyse these as too few studies reported them. Lastly, all except one of the studies reported emotional-DSD as a secondary outcome, meaning that interventions were not necessarily designed with emotional-DSD in mind and as such the results of this review should be interpreted with caution.

3.5.3 Surrounding evidence and implications

The purpose of this review was to identify interventions that improved emotional-DSD so as to inform the potential design of a comprehensive intervention for people with T2DM and depression and/or DSD, as such it is important not only compare the results to existing evidence surrounding DSD and HbA1c, but also to consider depression when interpreting the findings.

While the overall finding of the current review demonstrated that interventions successfully reduce emotional-DSD compared to controls, the only significant finding demonstrated in the subgroup meta-analyses and

meta-regression analyses to explore what intervention characteristics might mediate this effect was the use of coping-skills training. Coping skills training is a method grounded in cognitive behavioural theory that aims to improve competence and mastery by retraining inappropriate or unhelpful coping behaviours into more constructive and useful ones (327). A great deal of the literature for coping skills training in diabetes focuses on T1DM, particularly in youth and adolescence, but in more recent years both T1DM and T2DM have been considered in the evidence (328). A prominent study to include coping skills training within T2DM was the Pathways Study by Katon *et al* (159), although this did not measure emotional-DSD, it demonstrated positive results in improving depression scores. The study also included problem solving training as part of its design, a component assessed in the current review that demonstrated a nearly three-times greater effect on DSD when compared to studies that did not use it, although this difference was non-significant. Problem solving and coping skills training are often combined in interventions but due to some studies having one or the other these were separated them for the 3D-study analyses. While coping skills training focuses on an individual's reaction to a situation with a view to ensure that the coping mechanisms used are constructive, problem solving therapy endeavors to work with individuals to establish the fundamental issues that underlie their main symptoms or concerns (329). The Sturt *et al* review highlighted three studies that used problem solving in their intervention design that did not come forward in the searches for this review (232,315,318), which showed positive results in their effects on emotional-DSD, with mixed or no results for impacting HbA1c. It would be advantageous for any intervention targeted at T2DM, depression and/or DSD to include both problem solving and coping skills training to ensure appropriate identification of the origin and reasons for an individual's presenting concerns, and to encourage appropriate and constructive reactions to this in order to overcome and improve overall outcomes.

An important mediator in an individual's ability to cope with their T2DM, depression and/or DSD is the social support they receive, either from peers, relatives and/or friends, which was shown to positively influence glycaemic control but not emotional-DSD in the current findings. Increased social

support, particularly that specific to illness, is associated with better self-management outcomes in many chronic conditions, including T2DM (330-332). Positive outcomes have been observed not only for those receiving the support, but also in the peers providing it (333). One study that appeared in this review's searches but was ineligible, due to its reporting of association rather than the impact of an intervention, demonstrated that good social support significantly correlated with positive health-promotion and well-being among individuals with T2DM, finding that a poor functional social network increased emotional-DSD and decreased self-care behaviours (266). This particular study looked at support from family and friends, but the study of specific peer-support in T2DM has also shown improved nutritional intake, increased physical activity and more regular self-monitoring of blood glucose (334). Adequate support, provided either through social and/or peer avenues, is important for people with T2DM to be able to feel confident in their own ability to self-manage, particularly if comorbidities exist such as depression and/or emotional-DSD. A recent study looking into the management of T2DM and how family support impacts on care demonstrated that not only did involvement of families in T2DM care improve outcomes, but also reduced the risk of development in family members (335)

Although non-significant, substantial effects were seen for interventions adopting a collaborative care model (CCM) for the reduction of emotional-DSD with a more than three-times greater reduction in DSD compared to interventions that did not adopt a CCM. The CCM can be defined as structured care involving a large number of non-medical specialists working together with a primary care physician and mental health professionals to deliver interventions, of varying intensity, with the overall aim of improving patient outcomes (336). A recent systematic review and meta-analysis of the literature surrounding interventions for depression in patients with T2DM (155), demonstrated that interventions were effective at reducing symptoms, with particular merit given to the CCM. This review found, however, that improvement of glycaemic control required further research as treatments targeted at depression alone did not improve diabetes outcomes. This corroborates other findings that interventions targeted at treating depression alone fail to improve physical outcomes, or vice versa (159,167,337). A

prominent study that utilised the CCM for the treatment of people with diabetes was, again, the Pathways study (159,178), which incorporated a motivational interviewing counseling style approach within their programme to support patients with problem solving and goal setting for people with comorbid diabetes and depression. The study demonstrated significantly greater improvements in depressive symptoms over 12 months, but lacked in statistically significant reductions in HbA1c. A later study looking at the effects of a CCM intervention on depression but also including a measure of DSD found that the CCM was effective in reducing both depression and DSD but again showed no significant effects on HbA1c (338), warranting a call for further research into for the management of these comorbid conditions, and consider factors that could be combined to improve glycaemic control as well as psychological outcomes. Advocating approaches that encourage a patient-centred approach using a collaborative model that includes not only practitioners and patients, but also their social support or a peer-support network, could allow for both effective and cost-effective treatment (339).

Lastly, notable findings were observed for interventions utilising digital platforms, such as mobile-phone or web-based interfaces, in reducing HbA1c compared to interventions that did not. Interventions adopting a mobile-phone interface significantly reduced HbA1c, while interventions adopting a computer-based interface demonstrated a nearly three times greater reduction in HbA1c compared to those that did not, although this difference was non-significant. No discernable effects were seen in the reduction of emotional-DSD. A recent systematic review and meta-analysis of web-based interventions for the management of T2DM demonstrated favourable outcomes for e-interventions in improving diabetes-related outcomes (340). The review identified goal setting, personalised coaching and interactive feedback and/or peer-support as among the most successful approaches included in web-based intervention design. The authors noted that interventions to improve knowledge and understanding were more promising than behavioural e-interventions, and acknowledged the improved strength of interventions when a care-coordinator was included to manage to the intervention, similarly to the CCM approach, further corroborating the findings in the current review.

Of the studies included in the analyses, only four studies adopted digital platforms with only the Reducing Distress and Enhancing Effect Management (REDEEM) study (186) being specifically designed for emotional-DSD, which, combined with the low numbers reporting digital-platform interventions, could potentially explain the lack of effect upon emotional-DSD. With as much as 17% of the UK's National Health Service's (NHS) budget anticipated to be attributable to diabetes care (1), and the burgeoning cost of diabetes in the US showing a 41% increase from $174 billion in 2007 to $245 billion in 2012 (341), there continues to be a pressing need to find cost-effective interventions offering patient-centred and tailored care; such cost-effective potential could be realised in the use of digital platforms. Despite an increasing call for such interventions, data is limited for web-based and mobile-based interventions, specifically when considering DSD in people with T2DM. A number of studies had to be excluded from the review due to an over-representation of T1DM or due to only reporting the effect of interventions upon depression. One study assessed the efficacy of a web-based intervention with mobile phone support for treating depression in people with T1DM and T2DM and found that significantly reduced depressive symptoms and emotional-DSD in the intervention group compared to the control group (342). A recent study that was published after the completion of searches for this review demonstrated positive results for depression, as well as anxiety and emotional-DSD in people with diabetes using a mobile and web-based Cognitive Behavioural Therapy (CBT) intervention (343). A further study, that was excluded due to over-representation of T1DM, tested a web-based CBT programme for patients with diabetes, depression and DSD showed promising results with reductions in both depressive symptoms ($p<0.001$) and emotional-DSD ($p<0.001$), but not HbA1c, although this could be explained by reasonable glycemic control at baseline (344). It is possible that, had these studies been available and/or eligible for the current review, this may have led to more favourable results. However, further research would be needed to discern this and any interpretations should be taken tentatively.

3.6 Conclusion

This systematic review and meta-analyses of the literature for interventions that impact on emotional-DSD, with secondary bio-medical analyses to account for any impact on glycaemic control and BMI, found that interventions had significant effects on emotional-DSD and Hba1c but not BMI. Targeted analyses demonstrated merit in interventions that included coping-skills training, adopted a collaborative care approach, and incorporated the use of digital platforms, although these effects were mixed in their improvement of emotional-DSD and/or HbA1c.

While there were areas showing promise in the results of this study, the findings should be interpreted tentatively, particularly when interpreting the results where only a small number of studies were able to provide data for analyses and consider the small number of studies specifically designed for emotional-DSD. The purpose of this review and analyses was to inform, in part, the development of a potential intervention for the treatment of depression and/or emotional-DSD in people with T2DM. Combining the results of this review with the existing literature on depression, it is clear there is a gap in the literature regarding interventions that improve depression, DSD and glycaemic control in people with T2DM. The findings suggested that collaborative care, and facets within this including problem solving and coping skills training, is a promising approach for its impact on depression (159,178) and its merit in both this review and others (155,185,308).

The number of studies that came forward in this review shows promise for the recognition of DSD as a construct and its importance within diabetes literature. While it is important to consider depression and DSD as distinct constructs when considering approaches to treatment and comorbidity with T2DM, as discussed in chapter one, it is also crucial not to entirely separate the two or treat them in isolation of one another. Treatment should be tailored to each individual, using realistic goal setting and collaborative decision making between healthcare professionals and patients, appreciating individual wider-life circumstances and providing methods that are both accessible and cost-effective.

3.7 Chapter summary

The information gained from this review and the prevalence review in chapter two, as well as the existing parallel data on the prevalence and treatment of depression in T2DM (28,155,308) offers potential insight into how best to treat depression and/or DSD in people with T2DM. It is, however, insufficient to inform the design of a complex intervention alone. To build on this information a qualitative study was conducted to explore the perceptions, understanding and experiences of both HCPs and patients, in the context of living with T2DM or providing healthcare for people with this condition and/or depression/DSD, which is reported in the following three chapters (chapters four to six).

Chapter 4 A qualitative study to elicit and explore the understanding, perceptions and experiences of Type 2 diabetes, depression and/or diabetes-specific distress

4.1 Chapter overview

In this chapter, I discuss the premise for and the methods used to conduct a qualitative interview study including healthcare professional (HCPs) and patient participants, supplemented by field-notes from wider discussions with other professionals, such as researchers and practitioners involved in the study and/or management of people with diabetes. The study sought to explore the perceptions and experiences individuals in relation to Type 2 diabetes (T2DM), depression and diabetes-specific distress (DSD). Firstly, the background and rationale for the study is given, followed by the aims and objectives (section 4.2). Following this, the methods used are discussed, including the processes of recruitment, data collection and data analyses (section 4.3). Lastly, the preliminary outcomes are discussed, outlining the recruitment process and sample demographics, before defining the key themes that emerged from the analyses (section 4.4). In-depth analysis of these findings are then reported across chapters five and six.

While this thesis is mostly reported in a passive voice, due to the nature of this qualitative study and the analyses being interpretative, the narrative in places is written in the first person (section 4.3.3).

4.2 Introduction

4.2.1 Background and rationale

As outlined in the preceding chapters, there is a substantial overlap between depression and DSD in patients with T2DM. This is not only due to their high comorbidity, but also the complexities that lie in defining, assessing and understanding the conditions, both separately and in conjunction with one another (36). Research has repeatedly demonstrated that individuals with

T2DM who displayed depressive symptoms, when assessed in further detail, were often not clinically depressed (117,156,182). In some cases, these individuals demonstrated generalised or diabetes-specific distress, emphasising the insufficiency of generically labelling the culprit of their symptomatology as depression. Fisher *et al* (156) emphasised a need for qualitative research into patients' experiences of DSD in order to better appreciate the emotional constructs that influence poor behavioral disease management. The review of the existing literature (chapter one) and further systematic reviews and meta-analyses (chapters two and three) reiterated that, while treatments exist and can be helpful, results of how these impact upon T2DM, depression and/or DSD are inconsistent. Current understanding, recognition, and consequential treatment of these three comorbid disorders still remain inadequate, demonstrating a need for better understanding and qualitative research to explore this.

4.2.2 Aims and objectives

The over-arching aim of this thesis was to inform potential treatment pathways that can adequately identify and manage depression and/or DSD in people with T2DM. While the views and experiences of patients in this context was vital, so were those of the HCPs involved in providing their care. Speaking to both patients and HCPs, as well as researchers and practitioners, allowed the appreciation of both sides of the therapeutic process and better understanding of what is considered useful or successful in current practice. It also offered the identification of potential areas that are lacking in existing provision, giving prospective insight into how care may be improved from both a professional and patient perspective.

With these factors in mind, this qualitative study sought to explore and understand the views of HCPs and patients in the context of living with T2DM, or providing healthcare for people with this condition, and potentially comorbid depression and/or DSD:

- For HCPs, the aims were to explore their knowledge, understanding and experience of depression and/or DSD in the context of T2DM; their views on screening methods and the practicalities and benefits of screening or depression and/or DSD; and their views and experience

of interventions for treating depression and/or DSD following assessment.

- For patients, the aims were to explore their knowledge and understanding of depression and/or DSD, including their perceptions/experiences of the impact of diagnosis on health, wellbeing and functioning. It also sought to understand their experiences of living with T2DM and depression and/or DSD, as well as any experiences of screening for depression and/or DSD; and lastly their views on interventions for treatment depression and/or DSD following potential identification.
- For researchers and other professionals involved in investigations, development and delivery of interventions for people with T2DM, the aims were to explore what lessons could be learnt from prior interventions, both in terms of planning and effectiveness, and areas for improvement to optimise success for these patients.

4.3 Methods

4.3.1 Design and recruitment

Ethical approval was obtained from the NHS National Research Ethics Service (NRES) East Midlands Committee on the 11th October 2011 (Appendix 5), with a minor amendment made and approved on the 3rd November 2011 (Appendix 6), and with all site-specific approvals received between the 1st November and the 16th March 2012 (Appendix 7-10).

Recruitment of general practices

Recruitment was executed within a diverse sample of ten practices from the Leicester City Primary Care Trust (PCT), the Leicester County and Rutland PCT, and NHS Northamptonshire between January and August of 2012 (PCTs were public authorities in England, which, at the time of this study, had responsibility for funding NHS services in a defined geographical area). This mix of PCTs was chosen to allow for a spread of both rural and urban areas from which recruitment could occur. When applying for approval it was advised that applications to the University Hospitals of Leicester NHS

trust would also be needed since some HCPs may be employed by the trust even though recruitment would not occur within the hospitals themselves.

Each practice was sent an invitation pack, which included an invitation letter, information sheet and reply slip (Appendix 11). Once reply slips were returned, practices were contacted by telephone and an introductory meeting with the practice manager was arranged to explain the study in further detail. Here they had the opportunity to ask any questions they might have and were provided with the necessary instructions and materials for recruitment to begin.

Recruitment of healthcare professionals

Recruitment was targeted at HCPs who were directly involved in the care of people with T2DM and/or psychological ill health, these included general practitioners GPs, nurses, and specific mental-health practitioners. A purposive sampling method was used to classify potential participants by their job roles, the practice within which they worked, and their personal demographics such as age, gender and years of professional experience. This information was collected at the point when HCPs responded with their initial expression of interest and entered it into a purposive sampling framework developed for purpose (Appendix 12). The framework provided a visual demonstration of the different demographics and their proportion within the sample, which was used to identify areas where there may be an over-representation of a particular demographic. From the information collected, it could be determined whether a participant should be taken forward for interview, or be excluded from the final sample and thanked for their time.

HCPs were initially approached by their practice managers, who were given a pack that included an information sheet giving them guidance for the recruitment process, as well as a study information sheet and an ‘initial expression of interest’ reply slip to give to any HCPs they approached to recruit (Appendix 13). HCPs were staff members who either worked within, or were linked to, the practice. While practice managers were asked to approach *all* relevant HCPs, there remained the potential for ‘gate keeping’, where practice managers may have only approached those they considered useful and/or willing to participate. HCPs were asked to return the slip indicating their

interest in participating and giving permission to be contacted to arrange a mutually convenient date and time for the interview.

Recruitment of patients

The initial intention for the recruitment of patients was to offer either researcher-led recruitment, such as attending practices during pre-agreed times such as when diabetes clinics were running, and/or for practice staff to approach patients during pre-planned appointments (Appendix 14). During the acquisition of ethical approval, however, it had been agreed that due to the nature of the study, privacy would be required to protect patients from having to discuss potentially sensitive subjects in open or shared areas such as waiting rooms. Further to this, during the initial meetings with practice managers, it became apparent that the vast majority of practices were unable to provide such a private space to allow for contained recruitment. Furthermore, a number of practice managers expressed a concern that many potential participants could be missed due to the sporadic nature of appointments clashing with the capacity to only recruit at set times. As such, the decision was made for practice staff to use their in-house systems, such as their patient registers or computerised systems, to identify potential patients using the eligibility criteria provided in a pre-made pack, which also included an information sheet for the practice staff who would be recruiting patients (Appendix 15). Once identified, participants were approached by their usual HCPs during pre-planned appointments. Although this again created the potential for 'gate-keeping', it was felt that this was the most pragmatic approach to reach the most participants and to ensure that those approached were given appropriate privacy and had their welfare protected during the recruitment process.

HCPs provided potential patients with a copy of the patient information sheet and an 'initial expression of interest' reply slip similar to that given to potential HCP-participants (Appendix 16). Posters advertising the study were also placed around the practice to increase awareness and reach more potential participants, for example should a person be eligible but not in the practice for their own appointment, or if an ineligible patient saw the poster

and passed on the information to potentially eligible friends or family (Appendix 17).

Once patients expressed an interest in participating in the study, a purposive sampling framework was again utilised to ensure that an even spread of patient demographics was achieved; classifying participants by their age, gender and whether or not they held a history of depression, either previously, recently, or never (Appendix 12).

Identification of other professionals

In order to supplement the interview data, individuals such as researchers and practitioners involved in, or with an interest in, current research and practice in T2DM and psychological health were approached. The aim in doing so was to seek out advice and/or knowledge in any areas that could be of use to the study, such as opinions of the work conducted thus far and how this corroborates or builds upon existing research and/or treatment for people with T2DM and comorbid depression and/or DSD.

To identify the most relevant researchers and practitioners, the PhD supervisory team were initially approached to ascertain suitable candidates to contact. This led to meeting these individuals and engaging in a 'snowballing' process by asking them to suggest further key people to approach and so on. This process ran from March 2012 to January 2013. The intentions for this exercise were initially solely to improve understanding in the field and to facilitate learning and, as such, this was not included in the original ethics committee application. However, the process grew in a methodical and organic manner, and before-long, it was recognised that the information being collected in the field-notes was valuable and had the potential to be used constructively to supplement the interview data. The ethics committee were contacted to discuss if it was possible to include this data within the study and, if so, what procedure should be followed in order to gain approval to do so. The ethics committee chair advised on 6th February 2014 over the telephone that under new guidelines, HCPs were no longer required to provide written consent, meaning that as long as the data were anonymised, this would be able to be included in the study without needing to reapply to the committee.

4.3.2 Data collection and recording

Interviews were semi-structured and informed by topic-guides developed through discussion with members in the immediate research group (Boxes 4.1 and 4.2).

Box 4-1: Topic guide for interviews with healthcare professionals in a qualitative study to elicit and explore the understanding, perceptions and experiences of Type 2 diabetes, depression and/or diabetes-specific distress

Healthcare Professional (HCP) Topic Guide

1. ***HCP's knowledge, understanding and experience of depression and/or distress, particularly in the context of type 2 diabetes:***

Possible questions include:

- What is your experience of treating depression in people with Type 2 diabetes?
- To what extent do you feel that patients of yours with diabetes are affected by depression and/or diabetes-specific distress?
- Are you aware of a relationship between depression and diabetes?
- What is your understanding of the term 'diabetes-specific distress'?
- Are you aware of the treatments available for people with depression/distress and diabetes?

2. ***HCP's views on screening methods, and practicalities and benefits of screening for depression/distress:***

Possible questions include:

- What are your thoughts on screening people with Type 2 diabetes for depression and/or diabetes-specific distress?
- What do you think would be the advantages and disadvantages of screening people at general practices?
- Are you aware of any tools that practices can use to screen people for depression and/or distress?
- What is your experience of using such tools?

3. ***HCP's understanding of treatment guidelines:***

Possible questions include:

- Are you aware of the NICE clinical guidance for managing depression in patients with diabetes?
- What is your understanding of 'collaborative care'?
- What factors are important for managing depression/distress in people with diabetes in general practices?
    - *Are there barriers? If so, how can they be addressed?*
    - *What would be helpful for healthcare professionals to know regarding management of people with diabetes and depression/distress?*
    - *What are the related training needs for these healthcare professionals?*

Box 4-2: Topic guide for interviews with patients in a qualitative study to elicit and explore the understanding, perceptions and experiences of Type 2 diabetes, depression and/or diabetes-specific distress

Patient Topic Guide

1. ***Patient knowledge, understanding and experience of depression and/or distress related to their diabetes:***

Lets start by talking about your diabetes:
Possible questions include:

- Can you tell me briefly about your diagnosis?
  Example probes:
  What was your reaction to your diagnosis?
  How did it affect your daily life?
- Can you tell me a bit about how you manage your diabetes day to day?
  Example probes:
  Can you tell me about the medication you use?
  And your diet and activity levels?
  Have you made any changes since being diagnosed?
  Have you ever had any problems with your diabetes and its management?
- How did other people feel about your diagnosis?
  - *To what extent did this affect how your feel about your diabetes?*
- How much would you say that you understand your diabetes?
  - *What information have you received?*

Now thinking about how your diabetes has affected you:

- Can you tell me whether your diabetes has ever gotten you down at all?
  Example probes:
  If so, have you ever seen your doctor about this?
  If yes, can you tell me a bit about that?
  If no, can you tell me why you did not go?
- Have you ever been diagnosed with depression?
  - *(If yes) Can you tell me about how you were diagnosed?*
  Example probes
  What made you go to the doctor?
  What symptoms did you have?
  Can you tell me a bit about the consultation – was there understanding? What did they recommend in terms of dealing with depression?
  How did you feel afterwards?
  How did your friends and family react; did you tell them?
- Were you diagnosed before your diabetes or after?
- Do you think that there is a relationship between your depression and your diabetes?

2. ***Patient's perceptions of screening, including methods, acceptability, utility and impact:***

Possible questions include:

- Have you ever been assessed at your general practice for depression?
  - *If so, what did you have to do?*
  Example probes:
  How did it make you feel?
  What happened after you were measured?
- If not, how would you feel about being screened for depression when you visit your practice?
  Example probes:
  Would you find it helpful or unhelpful?
  How do you think you would feel if you were found to have some for the characteristics of depression?
- What about distress specific to your diabetes – how would you feel about being measured for that at your practice?
  (Example probes as above)

3. ***Patient's views on interventions for treating depression/distress following diagnosis:***

Possible questions include:

- Are you aware of any treatments for depression?
  - *What do you think about them?*
  Example probes:
  Have you any experience of such treatments?
  What time of treatment would appeal to you?

With the predominant aim of this thesis being to better understand, and inform the design of a potential treatment pathway for people with, T2DM with depression and/or DSD, the topic guides were developed to provide broad areas of exploration. This went across participants understanding and experience of the T2DM, depression and DSD, and their views and experiences of assessment and treatment for these conditions. The question themes were similar in both HCP and patients; however, for HCPs a further focus on current guidelines and collaborative care was included to understand professional opinion and practice in relation to these.

The topic guides were used flexibly, modifying them as the study progressed and new areas of interest emerged, or if areas were not being covered and needed extra promotion within the discussions. For example, some participants would speak in great depth and cover a number of areas fluidly; as such there was not a strong need to follow the guide so closely since the discussions developed naturally and without much need for questioning. In other instances, some participants were very difficult to engage in conversation and needed a great deal of prompting with the topic guide to encourage discussion. One area that emerged was the impact of psychological health on patient family and friends; while the original topic guide asked about family and friend's reactions to diagnoses of both T2DM and depression, it did not discuss the on-going experience and impact upon patients and their social-support structures, particularly the stigma involved. This emerged as a particularly productive area of exploration in both HCP and patient interviews and as such, the topic guide was adjusted to include this going forward, alongside other wider-life context discussions. A reflective diary was used to inform such modifications, this process allowed engagement in evaluation and consideration through the progression of the qualitative study. Within this process, the interviews were appraised and discussed during reflexive meetings with the supervisory team.

Prior to conducting any interviews, training in encouraging open and non-judgmental discussion was undertaken, as well as engaging in mock interviews with a colleague prior to the study commencing. Interviews were conducted between June and December 2012. Patient interviews were conducted in their homes, with one exception, whom requested to be

interviewed in their place of work. HCP interviews were conducted in the general practices where they worked or with which they were affiliated. Detailed written consent was taken at the time of interview using pre-established forms (Appendix 18 and 19).

Immediately prior to recording, patients were informed about the limits of confidentiality should any disclosures suggesting severe distress and/or immediate risk of harm to themselves or others be disclosed. They were informed that, should such an instance arise, obligations existed to take action and inform relevant agencies. Following each interview patients were provided with a sheet thanking them for their participation and providing information about whom they could contact, such as The Samaritans and other relevant agencies, should discussions during the interview have raised any concerns for them (Appendix 20). HCP-participants were similarly informed that, should any disclosures or suspicions of malpractice be disclosed, such that could be considered to put a patient in immediate harm, then obligations existed to inform members of the supervisory team. The supervisory team included clinically qualified practitioners who took responsibility for assessing any potential need to take action. There was one instance where a disclosure was made about a past event that was felt to raise concern, and this was discussed with a member of the team; however, it was agreed that there was no immediate risk to the patient or anyone else, as such no further action was necessary.

Safeguarding procedures were put in place for when interviews were conducted, particularly when in patient's homes. In this process, two colleagues were provided with the interview time, location and the contact details of the participant. They were given contact details, with the proviso that a call would be made upon arrival, prior to the interview taking place, and then again following completion. It was agreed that if they had not received the follow up call within an hour and thirty minutes of the first phone call, they would make contact and continue to do so to ensure safety.

Data collected to supplement the interviews were collected in a variety of different settings including observations, one-to-one meetings and group meetings; with a final group meeting where all professionals that had been previously liaised with were invited. The aim of the final meeting was to

present the findings to date and engage in a 'brain-storming' development process to inform the potential design of a treatment pathway.

4.3.3 Data analyses

Theory

To analyse the data collected, the principles of Grounded Theory, more specifically facilitated by a Constant Comparative approach, were drawn upon to identify themes that emerged from the data, incorporated within a Framework Analysis method to aid exploration and interpretation within the themes identified.

Grounded Theory was developed by Glaser and Strauss (345), who undertook a piece of research with no preconceived hypotheses, continually comparing data during their analysis and building theory as they progressed through the research; their belief in the theory being purely grounded in the data is what led them to the name 'Grounded Theory'. Grounded Theory, and the constant comparative method therein, requires multiple stages of data collection, subsequent refinement of collected data and the establishment of inter-relationships of potential categories among the data; this cyclical process goes back and forth between existing and newly collected data until all comparative processes have been exhausted to derive themes determined solely from the data itself (346).

Framework Analysis is articulated by Ritchie and Spencer (347), and was specifically developed to facilitate applied policy research. This approach is often called 'thematic analysis' and shares many elements of other qualitative analyses, consisting of five key stages: i) familiarisation, ii) identifying a thematic framework; iii) indexing; iv) charting and; v) mapping and interpretation (348). The nature of Framework Analysis being developed in the context of applied research was useful for the context of this thesis, since the data was to be applied to the development of potential treatment pathways. While no *a priori* thematic concepts were held, the process of analysis was facilitated in considering about how any emerging themes could be applied to potential treatment design and exploring further themes and sub-categories in relation to this.

Grounded Theory and the Constant Comparative Method were felt to be the most appropriate approach to support the aims of the 3D-study since it was an exploratory study, seeking to gain novel understanding in the field of depression and DSD in people with T2DM. As such, approaching the data analysis with preconceived ideas of themes or codes, such as in a deductive approach with predetermined parameters around intervention design, would be contradictory to the intention of the study as a whole. However, due to the overarching aim of the study being to use the data gained in the development of a treatment outline for people with T2DM, depression and/or DSD, Framework Analysis offered a constructive and systematic method with which to chart and interpret the data once themes had emerged.

Process

The process began by initially familiarising with the data and generating free-codes from the transcripts as they were read. The free-codes were then used to build a preliminary coding framework and outline early emergent concepts. This was followed by the refinement of conceptual coding schemes by re-reading the transcripts, constantly comparing any newly identified codes with existing categories and noting recurring trends and themes developing from these to build analytical categories. Where appropriate the framework would be modified as the analysis progressed, such as adding new codes, or amending existing ones by either collapsing and/or separating them into multiple codes. Once confidence was felt in the coding framework developed from the interviews, framework charting was then used, mapping and interpretating to aid exploration and understanding of the data within the themes identified, continually ensuring that ideas and theories were derived from rather than imposed upon the data. The analysis was initially performed separately with HCP and patient interviews analysed independently, however, through the emergence of repeated themes within both sets of data and acknowledging the significance in the juxtaposed views and experiences of HCPs and patients, these were then brought together as the analysis advanced and reported as a whole. An example of the coding framework from NVivo is given in the appendices (Appendix 21).

Researcher position

My own position came from a naïve qualitative background, with this being the first qualitative interview study I had undertaken. As such, I was vigilant to try not to impose the more deductive stance of quantitative research that I had been more accustomed to, using reflection to try to ensure more inductive and interpretative methods. This was initially challenging, with the preliminary coding framework demonstrating themes derived more so from the questions asked, rather than truly from the answers received. However, as the interviews, analyses, and reflective process progressed, my understanding and method developed. I began to interpret themes that emerged truly from the narratives rather than the questions, resulting in the analysis being restructured accordingly. While I held prior views and understanding of DSD and depression in people with T2DM, I actively sought to not let this influence my interviewing process, again using a reflective journal and discussing this with the supervisory team, so as to remain open and explorative in my line of questioning and subsequent analysis. My epistemological position was that while I might understand depression/DSD in a theoretical and empirical sense, I had not experienced this personally or encountered individuals who had. My belief in acquiring knowledge of the complexity of psychological affect is to either experience this personally, or to empathically learn about the experiences of others, and that true understanding cannot be gained through conceptual reading alone. As such I entered the interview study with the view to gain understanding of the experience of depression/DSD in people with T2DM and the experiences of treating individuals with these conditions.

4.4 Preliminary results

4.4.1 Recruitment process

Recruitment was challenging and took longer than anticipated, both at the practice and participant level. Although practices were first approached in November 2011, and practice reply slips were received from the 24th January 2012, the ten-practice target was not reached until the 27th July 2012.

Of those that sent practice replies in the first few months, agreement to hold meetings with practice managers were not obtained until April 2012; a number of practices expressed that they could not commit their time until after annual reporting requirements set by the Quality and Outcomes Framework (QOF). Further to this, one practice that had expressed an interest in the study, was non-responsive when trying to contact them to arrange a meeting with the practice manager, meaning that the final data came from a sample of nine practices.

Participant responses were initially solely from HCPs, which was a major concern; in response to this practices were contacted by telephone or in person to go over their recruitment strategy and progress, and to discuss if there were any ways that they could be facilitated to improve their response rates. For the most part, practices discussed time as the main issue but agreed to do more. They were asked to prioritise and push their patient recruitment going forward, which then yielded responses starting from 12th June 2012.

Due to a disproportionately high number of GPs expressing interest from one particular practice, the purposive sampling framework was used to exclude three GPs from this practice based on their individual demographics so as to avoid any potential bias in the data collected.

A bias in age-range was evidenced in the patient sample, with the majority of responses being from people in retirement age, thus presumably being able to offer the time to commit to participation; however, due to the difficulty in recruiting patients no exclusions were made by this. The purposive sampling framework was, however, used to alter the recruitment by participant history of depression. Following a reflective meeting with one of the supervisory team to discuss the progress of recruitment and evaluate the initial interviews, it was noted that the first eight patient responses had only been from patients with no history of depression. This could have been because participants themselves were less likely to come forward or agree to participate due to their psychological state, or due to the recruiting HCPs ‘gate-keeping’ and approaching those they considered more willing and/or able. Due to this fact, it was decided to alter the eligibility criteria moving forwards to only include

patients with T2DM and a history of depression so as to adequately explore depression and/or DSD from a lived experience perspective.

Further obstacles were encountered in the recruitment of HCP-participants in that following the receipt of initial expressions of interest, poor responses and/or avoidance were found when trying to contact HCPs to arrange an interview. This meant that the study ran for longer than expected and as such sampling for the interviews ceased due to time constraints rather than necessarily reaching pure theoretical saturation. However, there were multiple instances of repetition and thematic recurrence, with a lack of diversity across a number of the latter interviews, suggesting that sufficiency had begun to occur, although this may have ceased slightly prematurely due to the restrictions in time.

4.4.2 Characteristics of sample and outline of data collected

Healthcare professionals

The characteristics of the HCP participants are given in Table 4-1.

Table 4-1: Sample demographics for healthcare professionals in a qualitative study to elicit and explore the understanding, perceptions and experiences of Type 2 diabetes, depression and/or diabetes-specific distress

Healthcare professional participant characteristics		(n=13)
Job Title	General practitioner	6
	Nurse	5
	Mental-health practitioner	2
Gender	Male	5
	Female	8
Age	25-39 years	3
	40-59 years	10
Professional experience	≤5 years	3
	6-10 years	2
	11-15 years	2
	16-19 years	4
	≥20 years	2

Eighteen HCPs responded with an initial expression of interest. Following the purposive exclusion of three GPs from one particular practice, fifteen HCPs were contacted to arrange an interview. Two HCPs were subsequently evasive or non-responsive when contacted, resulting in a final sample of thirteen HCPs. An outline of the HCP-participant demographics can be seen in Table 4-1; there were six GPs, five nurses and two mental-health practitioners. The sample had a gender ratio of five males to eight females.

Ages demonstrated a majority in the 40-59 years category (n=11), with three HCP-participants in the 25-39 years category. Lastly, years of professional experience was divided into five-year groups with a fairly even spread amongst groups ranging from less than less than five years to more than twenty years.

Patients

The characteristics of the patient participants are given in Table 4-2.

Table 4-2: Sample demographics for patients in a qualitative study to elicit and explore the understanding, perceptions and experiences of Type 2 diabetes, depression and/or diabetes-specific distress

Patient-participant characteristics		(n=16)
Gender	Male	9
	Female	7
Age	40-59 years	1
	50-59 year	2
	≥60 years	13
Ethnicity	Caucasian (White British/European)	14
	Chinese-British	1
	Asian-Indian	1
History of depression	Yes	8
	No	8

There were seventeen responses from patients who expressed an initial expression of interest to participate. From these one individual withdrew when telephoned to arrange an interview, resulting in a final sample of sixteen patients. An outline of the patient-participant characteristics can be seen in Table 4-2. There were nine male and seven female patients, of whom the majority were aged sixty and above (n=13), the remaining three were aged between forty and fifty-nine (n=1) or between fifty and fifty-nine (n=2). The majority of the sample were Caucasian (n=14), with the others identifying as Chinese-British and Asian-Indian. The sample was split evenly (50%) between those who had a history of depression and those who did not.

Other professionals

An outline of the meetings with other professionals which formed the supplementary data are given in Table 4-3.

Table 4-3: Overview of the collection of supplementary data used in a qualitative study to elicit and explore the understanding, perceptions and experiences of Type 2 diabetes, depression and/or diabetes-specific distress

Dates	Meeting	Settings and stake-holder-participants (S)	Purpose and outcome
March 2012	M1	One-to-one meeting with a member of a clinical commissioning group (S1).	Discussed the study and provided me with a list of contact they felt would be useful for me to speak to, and conferences to attend etc.
	M2	Attended East Midlands Mental Commissioning Network meeting.	Opportunity to briefly present study to attendees with the hope of gaining contacts and/or feedback.
	M3	Group meeting with S1 and two members of a district council (S2 and S3).	Discussed the study and how physical activity programmes could be a potential for future care pathways.
	M4	Attended the Joint Strategic Needs Assessment Stakeholder even.	Met further contacts from physical activity programmes and discussed study further.
April 2012	M5	Email communication between myself and S1, S2 and S3.	Gaining further information about physical activity programmes and signposting to other relevant people to speak to in other districts.
May 2012	M6	Attended a 'Healthy Living Club' meeting.	To understand how a well-being group worked, particularly outcome tools they used to set goals, and track progress.
June 2012	M7	One to one meeting with a physical activity development officer (S4).	Discussed GP exercise referral schemes, how they work and process by which they work. Signposted to other contacts for different districts and other well-being programmes and clubs.
	M8	One-to-one meeting with a liaison consultant psychiatrist (S5).	Discussed the progress of the study to date, and signposted to another psychiatrist that they felt better suited to offer advice. Contacted by email by no response received.
	M9	One-to-one meeting with a diabetes nurse consultant (S6).	Discussed the study and my aims and objectives, signposted to a clinical psychologist and recommended that I observe an education programme.
July 2012	M10	One-to-one meeting with a charity education and training manager (S7).	Discussed alternative programmes for health and well being such as volunteering and cycling groups.
	M11	One-to-one meeting with nurse consultant with a specialist interest in mental health in chronic conditions (S8).	Discussed study and was provided with information from specialist interest and given reading to follow-up (sent by email).
	M12	Telephone meeting a general practitioner and mental-health lead (S9).	Discussed the availability of exercise referral schemes within their district.
August 2012	M13	Observed a DESMOND education session.	To understand how the programme worked and the methods used to deliver structured education.
	M14	Telephone meeting with clinical psychologist (S10).	Discussed study outline, work to date and ideas for development. Suggested further reading and avenues to explore such as Improved Access to Psychological Therapies (IAPT) program.
September 2012	M15	Attended DESMOND facilitator training.	To understand how the programme worked and the methods used to deliver structured education to patients.
	M16	One-to-one meeting with S10.	More detailed discussed about delivery, structure and content of potential pathways and how this could be applied to educational components within the study.
December 2012	M17	Structured development meeting inviting all prior stake-holder-participants, with additional signposted (S11, S12, S13, S14, S15) to attend, as well as members of my supervisory team.	Presented work to date and encouraged discussion and brainstorming for potential treatment pathway designs.
January 2013	M18	Group meeting with S13 and another member of a clinical commissioning group (S16) and a district council (S17).	Discussed potential plans in further detail in terms of costs and potential locations for piloting studies.

Due to the process with which the inclusion of supplementary data came about, as discussed earlier, demographic data was not collected from these individuals. However, the job roles included members of a clinical commissioning group; members of a district council; consultants in psychiatry; consultants in clinical psychology; general practitioners; charity education and training managers; and researchers. An outline of the meetings for the supplementary data are given in Table 4-3. In total, forty-seven transcripts were analysed, comprising of sixteen patient interviews, thirteen HCP interviews and eighteen sets of field-notes.

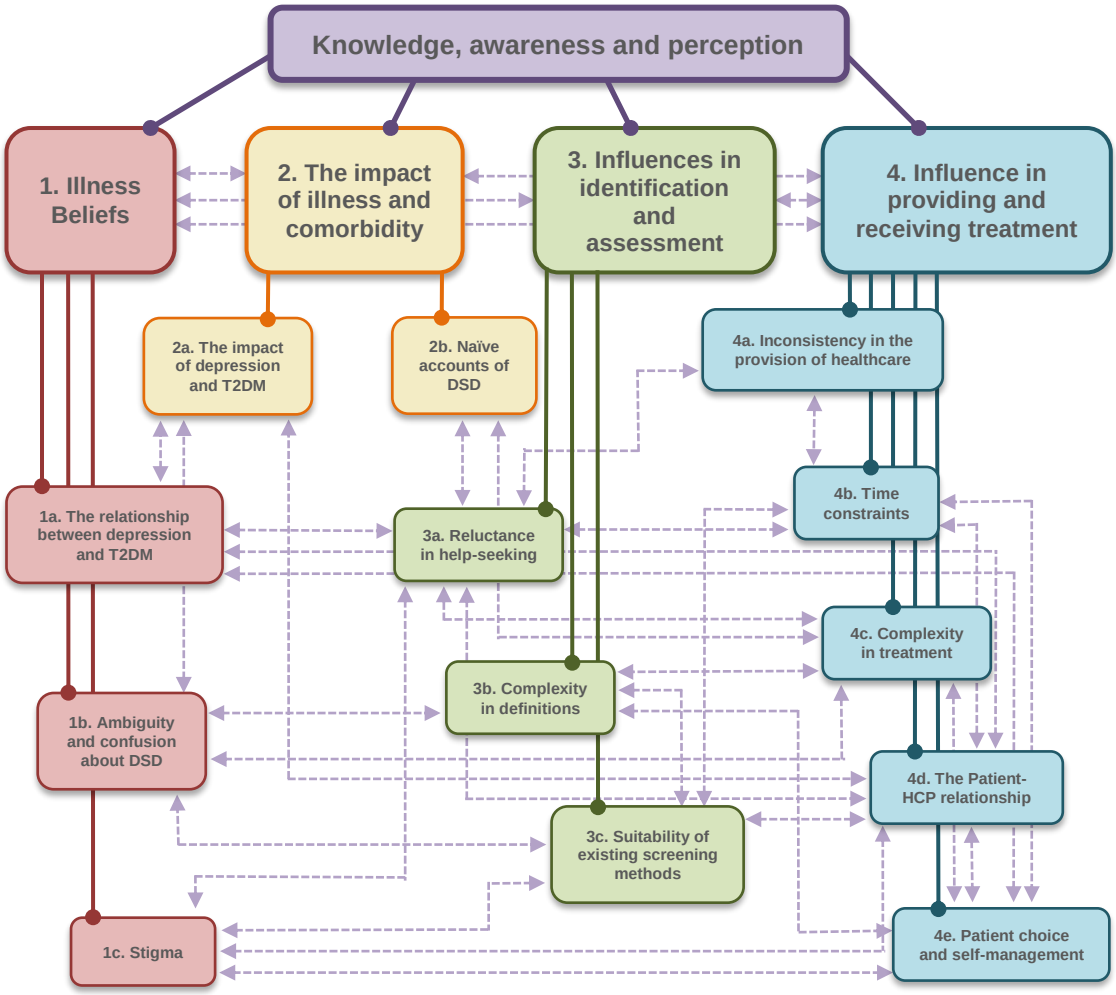
4.4.3 Key themes

The key themes that emerged from the qualitative study can be seen in Figure 4-1.

Through the process of the analyses, an overarching theme emerged from the data about individual's knowledge, awareness and/or perception of psychological comorbidity in people with T2DM. Beneath this overarching from this came four key sub-themes: 1) Illness beliefs, 2) The impact of illness and comorbidity, 3) Influences in identification and assessment, and 4) Influences in providing and receiving treatment.

From these four key sub-themes came thirteen further inter-connected subthemes. The illness beliefs theme consisted of individual's beliefs about the relationship between depression and T2DM, the ambiguity and confusion about DSD and the stigma surrounding both physical and psychological health. The impact of illness and comorbidity theme comprised of how individuals considered the impact of comorbid depression and T2DM, and naïve accounts of DSD. The influences in identification and assessment theme was made up of individuals reluctance in help-seeking, complexity in definitions, and the suitability of existing screening methods, Lastly, the influences in providing and receiving treatment were made up of inconsistencies in the provision of healthcare, time constraints, complexity in treatment, the patient-HCP relationship, and the patient choice and self-management.

Figure 4–1: Themes emerging from a qualitative study to elicit and explore the understanding, perceptions and experiences of Type 2 diabetes, depression and/or diabetes-specific distress



4.5 Chapter summary

A qualitative study was conducted that included data from interviews held with HCP and patients, which was supplemented by data collected during wider consultations with other professionals. The analysis of this data are presented in the subsequent two chapters. In chapter five, the understanding and meanings of co-existing depression and/or DSD with T2DM across the first two key sub-themes: 'Illness beliefs', and 'the impact of illness and comorbidity' are explored. In chapter six, the views and experiences of barriers and facilitators to the management of these comorbid conditions discussing the latter two key sub-themes: 'Influences in identification and assessment', and 'influences in providing and receiving treatment' are explored.

Chapter 5 Qualitative study findings, part one: Understanding and meanings of co-existing depression and/or diabetes-specific distress in Type 2 diabetes

5.1 Chapter overview

In this chapter, I report the findings of a qualitative study exploring the understanding, experiences and perceptions of depression and diabetes-specific distress (DSD) in people with Type 2 diabetes (T2DM). As outlined in chapter four, there were four key sub-themes in the analyses beneath the overarching theme of 'Knowledge, awareness and perception'. In this chapter, the findings are discussed across the first two key sub-themes, 'Illness beliefs' and 'the impact of illness and comorbidity' (Figure 5-1).

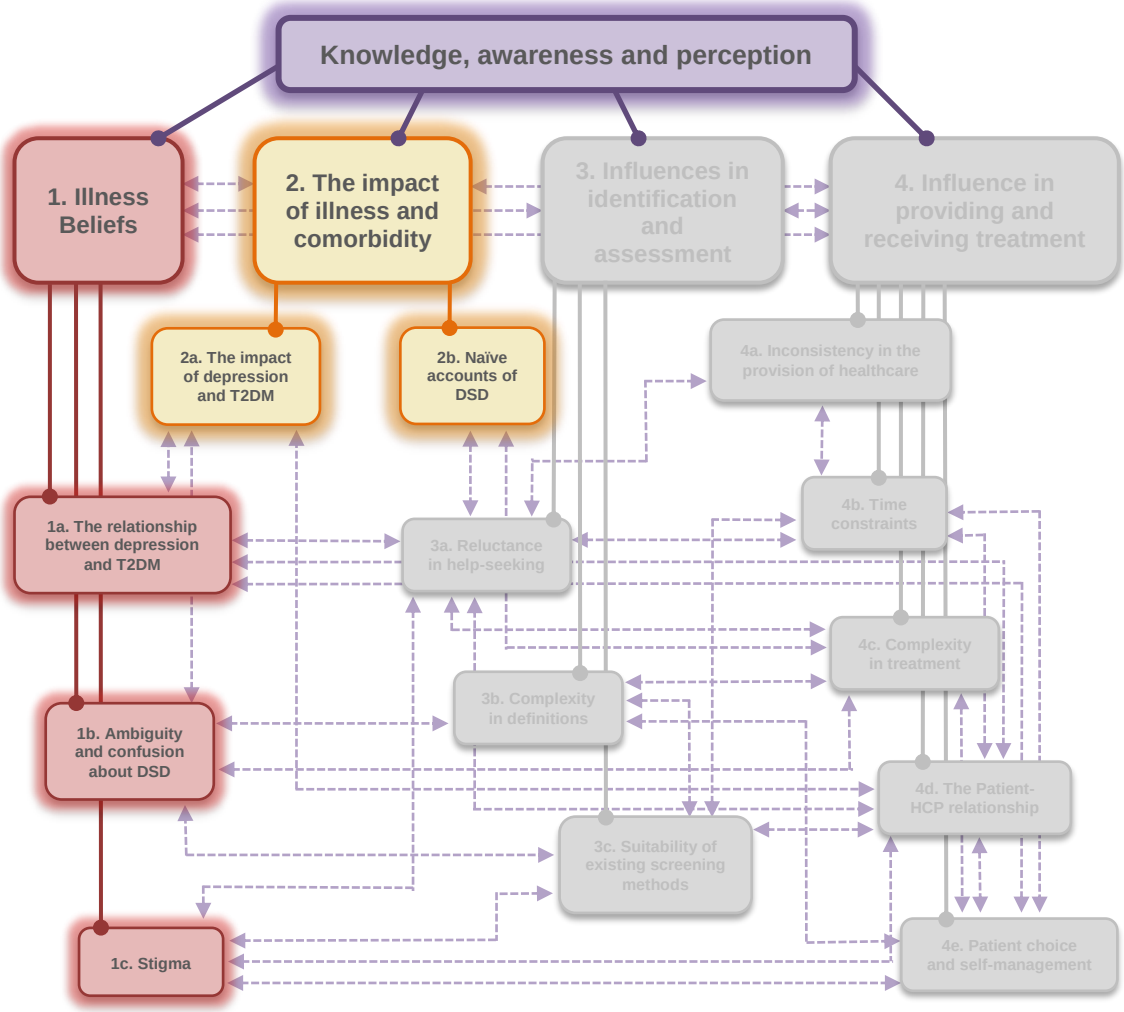
Within the 'illness beliefs' theme, the relationship between T2DM and depression, the ambiguity and misunderstanding of DSD, and the stigma of both physiological and psychological health in people with T2DM are explored. Within the 'impact of illness and comorbidity' theme, the impact of co-existing depression and T2DM and naïve accounts of DSD given by both HCP and patient participants are discussed.

Due to the analyses of this qualitative study being reported across two separate chapters, the decision was made to reflect upon and discuss the findings within the reporting itself; such that critical perspectives, theories and models are interwoven within the results themselves. This was intended to avoid disjointedness in the narrative, since having a conventional results and discussion section, due to the scale of the results, would have required a separate discussion chapter.

In order to facilitate ease of reading and provide context within this chapter, I refer to patient participants as simply 'patients' and HCP-participants and 'HCPs'. I also provide participant demographics in the parenthesis of each quote provided to support the analyses. For all participants I give their gender, given as 'M' for males and 'F' for females, followed by their age group. For patients I also provide their status in relation to having had a history of

depression or not, and for HCPs I give their job roles, broadly defined as GPs, nurses or mental-health practitioners.

Figure 5–1: Themes emerging from a qualitative study to elicit and explore the understanding, perceptions and experiences of Type 2 diabetes, depression and/or diabetes-specific distress: Exploring the first two key sub-themes



5.2 Findings

5.2.1 Theme 1: Illness beliefs

A key theme that emerged during the analysis of the data collected was that of 'Illness beliefs', which herein, is the way in which both patients and HCPs conceptualised, understood and viewed T2DM, depression and DSD. Within the theme of 'illness beliefs', three sub-themes emerged: i) the relationship between T2DM and depression, ii) the ambiguity of DSD, and iii)

the stigma of both physiological and psychological health in people with T2DM.

Theme 1a: The relationship between Type 2 diabetes and depression

As the analyses and exploration of the data progressed, it became reflexively apparent that there were broad and varied views regarding comorbid depression and T2DM. The way in which patients conceptualised the connection between the two conditions emerged into three sub-thematic groups: Firstly, those who did not feel that their T2DM and depression were linked in anyway; secondly, those who felt they were directly related; and lastly those who, regardless of interpretations of temporal associations, shared the view that they were separate entities but reciprocal to one another through the lived experience of comorbidity.

Within the study sample, seven patients held long-standing histories of diagnosed clinical depression, of whom six had received their diagnosis of T2DM much later, completely unrelated, in their opinion, to their psychological state. It appeared that due to the chronology and significant period of time with which their depression pre-existed their diabetes, these patients considered the conditions as entirely distinct from one another and did not consider a causal link between them.

> *"No erm … I mean I do suffer from depression but's been longer than erm … I've had diabetes … erm so I … I can't link the two really"*
>
> *[Patient-13: F, >60, History of depression]*

While some of these participants felt that they could not link the two conditions, they were still ambiguous about the causal attribution of their depression. Some participants, alternatively, were very clear in their illness beliefs, feeling that they understood, without question, the aetiology in the development of their depressive affect. Multiple accounts identified the result of wider-life circumstances and life events, such as work-related stress. One patient account detailed the reasons for the development of their depression as being an adverse reaction to excessive pressures within his employment.

While he could not posit a definitive link between his depression and T2DM, he did acknowledge the potential for a biological underpinning that he may have been unaware of.

> *"I've had two sort of bouts of stress related depression… erm… er … in my view they were caused by work stress, not … not from anything to do with the diabetes … I mean er … you don't know really ' cos obviously in the background you've … you that but er … the stress was brought by external influences impacting upon me… now whether it makes you slightly weaker, I … I wasn't aware of anything … I mean … I mean I really couldn't say that [they were connected]"*
>
> *[Patient-11: M, ≥60, History of depression]*

As discussed in chapter one, prolonged psychosocial stress, such as job strain, has been shown to increase the risk for developing both T2DM (95) and depression (96), which was evidenced in other patients who also attributed the onset of their depression, and in some cases their diabetes, to work-related stress. One participant in particular described a traumatic, and in her opinion, unfair dismissal that resulted in a severe psychological breakdown and resultant on-going depression. Notably, while this individual recognised the cause of her depression to be that of work stress, unlike the Patient-11, she felt that her T2DM was directly related to her affect. She acknowledged a bio-psycho-social impact of her negative life-event, believing that this caused the depression and T2DM to develop as a result of the stress experienced and that the two conditions were interlinked.

> *"So that's when it started. And the diabetes, three weeks later being in such a state of pain and despair and sadness erm … I started noticing that I kept on going to the loo … and I can't eat er .. not only because of the breakdown but … this diabetes was … my GP said it was shock diabetes … that the psychological shock and the ill-treatment of me as a person er … brought the diabetes*

… not only did they give me a breakdown they also gave me diabetes "

[Patient-10: F, ≥60, History of depression]

The language used by this patient was particularly profound in terms of reflecting her illness beliefs as she ascribed blame to others for the development of both her diabetes and depression, using the phrase '*they gave me'*; indicating that the way in which she conceptualised her comorbidity was rooted in blame of others. Her narrative reflects feelings of helplessness and unfairness, believing that her condition was created by her specific negative-life event at the hands of other individuals. This particular narrative could suggest 'learned helplessness', a concept originally developed by Martin Seligman and applied to depression models in the 1970's (349,350). It describes how an individual experiences a sense of powerlessness, as a result of a traumatic event or repeating failures to succeed. In relation to diabetes, this can be understood as a learned behaviour of projecting failure onto decision-making and relinquishing the sense of power and leader-ship over self-management (351). The data could also suggest an external locus of control, first developed by Julian Rotter (352), which refers to an individual's belief in their ability to control the outcomes in their life. Within this theory, an individual's locus is either conceptualized as being internal, meaning that they believe the control comes from within, or external, where they believe that their circumstances are controlled by external influences outside of themselves (352). In the case of Patient-10, her experience was directly reactive to a traumatic experience, which could be more indicative of learned helplessness, but the belief that individuals had no control over their health, either through learned helplessness or having an external locus of control, was evidenced throughout the interviews study both in data relating to T2DM and depression. Learned helplessness and/or holding an external locus of control can have particularly detrimental effects on management and recovery in people with T2DM and depression and/or DSD, which is discussed further in chapter 6.

Other patients, who described the dissolution of relationships or a lack of support as the causes of their depression, further echoed the belief that

depression resulted from wider-life circumstance and stresses. Amidst these disclosures were descriptions of a subsequent lack of self-care and the potential inference of blame back onto the individual, converse to Patient-10, using the phrase 'self-inflicted' when describing poor self-care as resulting from depression.

> *"I have [had depression] but it was … but that was to do with ex-partner leaving …. You know the stress went on and on and on and probably some of it was self-inflicted because I was not self er … you know because I'd … it took a long time to get over it…"*
>
> *[Patient-15: F, ≥60, History of depression]*

While the above patient did not directly associate her T2DM and depression, she described how her poor self-care behaviours, resulting from her depression, negatively influenced her physical health, allowing the potential supposition of a link between depression and T2DM due to reduced motivation and decreased self-care and management. In a review of the importance of health-behaviour in relation to diabetes in 2008, Harvey and Lawson (389) identified the importance of self-blame in diabetes self-care as it has been shown to negatively influence diabetes self-management and outcomes. Further qualitative research by Beverly and colleagues in 2012 (390) demonstrated that self-blame in T2DM can undermine successful relationships between patients and HCPs, impeding effective therapeutic alliance and serving as a barrier to the patient-healthcare relationship, this is discussed in greater detail in chapter six (section 6.2.2).

> *"Well I'm trying to obvio … obviously I've tried to to adjust my diet… I do drink beer and er … I'm not supposed to … I do still have a drink because to honest I just need to, you know, chill out from the stress ... and I do tend to forget the tablets sometimes … quite often actually … So erm … it is having an adverse effect on me, er .. I need to go and see the doctor again…"*
>
> *[Patient-15: F, ≥60, History of depression]*

There was one account of T2DM predating the diagnosis of depression, this particular patient described not only her existing experience of comorbid depression and T2DM, but also pre-existing comorbidity with T2DM with multiple other health concerns, which shaped her illness-belief that her depression was as a direct result of her poor physical health. This highlights not only the complex presentations of many people with T2DM and multiple comorbidities, but also the important role attribution plays in the maintenance, or lack there of, of health. The accounts demonstrate the bidirectional interplay between these conditions and how these can accumulate to create poor health, both physically and psychologically, and negatively impact an individuals' quality of life.

> *"It got me down. I think erm … it added to the list of issues I had already. Erm … the main thing that really affected me was the fact that I couldn't do anything … I'm not old, you know I felt like an elderly person, you know having to get up in the morning, not being able to do you normal housework like even … it was taking everything away from me … and I really went to ground zero really, you know zero … level and it was really horrible. You know I was … just negative thoughts and no motivation"*
>
> *[Patient-16: F, 40-49, History of depression]*

Nearly all the patients with a history of depression acknowledged that, regardless of temporal attribution, the two conditions are related in terms of their impact upon one another and their on-going interactions at both a physiological and psychological level. In those whose depression pre-dated their diabetes, but who did not ascertain a causal link between the two, patients acknowledged that the two conditions are inter-woven with one another in terms of aggravating or intensifying the other through the lived experience of comorbidity.

> *"I think it's interlocked.. you know it's it's … really wears me out, you know … if it ain't the diabetes having a go it's the depression and it's … they sort of work hand in glove"*
>
> *[Patient-4: M, ≥60, History of depression]*

The notion that depression and T2DM are interwoven was corroborated by Patient-10, whom, unlike Patient-4, demonstrated a clear belief in a causal link between depression and T2DM. However, she continued to discuss that the two conditions are connected in their on-going presentation, and that the relationship is changeable, with the continuing impact of one onto the other solidifying her belief in a bidirectional physiological connection between the two conditions.

> *"It's … it's linked physically. Absolutely. There must be a connection between what's missing the pancreas and some enzymes that .. and chemicals that affect the brain … and causes depression. I am sure. I am absolutely sure. I mean I'm no professor but er … this is what I feel very strongly… that there's depression in diabetes, diabetes in depression"*
>
> *[Patient-10: F, >60, History of depression]*

While this particular patient held clear and distinct beliefs in the reasons for the onset of both her depression and T2DM and that the two were directly linked through bio-psycho-social interactions, she went on to describe an interplay between the two and how the lived experience of the two conditions can change in terms of their directional impact. Notably, even though her original belief was that the onset of her T2DM was as a result of her depression, in her day-to-day lived experience of the two conditions, she felt that this direction changed, with the physiological burden of living with T2DM impacting more greatly upon her depression, which she felt was secondary to the diabetes.

> *"I think the depression is secondary to the physical … it is a consequence of being physical not well rather than the other way round, you understand"*
>
> *[Patient-10: F, >60yrs, History of depression]*

The accounts given by HCPs mirrored those of the patients, in an equivocal conceptualisation about temporal attribution between T2DM and depression, with some assigning a clear and distinct link, while others considered them co-exiting but not necessarily related. Regardless of believes about causal impact between the conditions, nearly all accounts acknowledged a reciprocal interaction between them.

Some HCPs gave accounts of how an individual's affective state was the determining factor in the development of their diabetes, describing a clear temporal relationship between the two conditions. One particular account detailed the case of an individual whose wider-life context demonstrated on-going work-related stress, and poor coping as a result. The individual fell into negative health-behaviours, including overeating, as a response to their psychological distress and this led to the development of diabetes as a result, demonstrating a causal link between psychological ill health and the development of T2DM.

> *"a very sedentary lifestyle ... erm ... er ... overeating, but he's overeating for ... for a long time because of stress at work, er ... issue of stress at work was an unmet need for this patient and ... and he didn't come to seek help with it, or go to anybody for help with it ... and this gentleman was a former paratrooper ... ... so he was very physically fit and ... one could postulate that he would not have developed the condition had he erm ... had sought appropriate advice earlier"*
>
> *[HCP-9: M, 25-39, GP]*

A further recognition of the wider-life circumstance of individuals with T2DM and depression, and the impact that this can have on an individual's ability to cope with either condition, was given by another HCP. When asked

about how connected she felt depression and T2DM were in her experience of patients she had worked with, she felt that the two conditions were hugely interconnected and that, in her experience, those with poor psychosocial circumstances were often those presenting with the greater risk of developing either depression or T2DM in conjunction with one another.

> *"Hugely [connected], yes, so I think I … I think hugely. Erm … unfortunately my … my … my biggest observation really is that those who have got huge social issues as well … either money worries, work worries, family worries … all this sort of thing, they're … they're the people with the biggest problems"*
>
> *[HCP-4: F, 40-59, Nurse]*

Other HCPs presented with the opinion that depression and T2DM are associated in the way that they impact upon one other, and that an interplay between the two exists, but that the two conditions are distinct, co-existing with a reciprocal effect upon one another but lacking in any definitive causal link between them.

> *"generally we've had people with depression that er ... the diabetes is obviously erm ... to me secondary. Erm ... so the depression isn't because of the diabetes in a sense … it's ... you know it's ... it's erm ... in conjunction with rather than ... than anything else"*
>
> *[HCP-8: F, 40-59, Mental health practitioner]*

The notion of both patients and HCPs demonstrating varied understanding and interpretations of the temporal relationship between depression and T2DM has been supported by a study conducted in 2013 that investigated the clinical differences of varying presentations of depression and T2DM across alternative temporal relationships, comparing those with T2DM and no depression, those with depression that predated T2DM and vice versa, and those with concomitant conditions (353). Bruce *et al* demonstrated that those whose depression succeeded their T2DM held a higher prevalence of all

chronic complications, apart from stroke, highlighting the considerable impact of associated symptom and treatment burden. They also found that those who experienced depression before they were diagnosed with T2DM displayed various negative self-care and adverse prognostic behaviours, demonstrating the significant risk that depression poses for the development of chronic conditions such as T2DM. A qualitative meta-synthesis study conducted by Gask *et al* in 2011 demonstrated that of 22 papers included, there were mixed and varied perceptions of the relationship between depression, DSD, and diabetes with various studies demonstrating diabetes as a cause of depression and DSD, but also studies identifying depression and DSD as influential to self-care, increasing the risk of developing T2DM or negatively impacting self-management of existing T2DM (354). Gask *et al* acknowledged the considerable emotional impact T2DM can have on an individual, and while depression may be one of these consequences, there are times where the label of DSD would be more appropriate, further reiterating a stark need to determine each individual's presentation when considering how best to approach treatment. How a person with T2DM and comorbid depression experiences and conceptualises their condition is hugely important in terms of their ability to understand their conditions, feel that the support they receive is appropriate, which in turn can improve motivation and willingness to engage in any treatment plans set by their healthcare provider.

Two key theories that appeared to apply to the data and were relevant across varying themes and subthemes emerging from the qualitative study were Leventhal's Common Sense Model (CSM) (355) and the Illness Beliefs Model (IBM), first developed by Wright, Watson and Bell (356). Both models frame how an individual conceptualises their illness and the impact that this can have. In the CSM, there are five core components said to make up a patient's cognitive representation of their condition: the 'identity' of the illness, refers to an individual's beliefs about their illness label and symptoms; 'causes' refers to the perception of casual attribution individuals place on their condition; 'timeline' refers to the timeline individuals ascribe to their illness in terms of it's duration, including symptoms and recovery, such as believing it to be chronic or acute; 'consequences' refers to an individual's beliefs about the seriousness of their condition and the bio-psycho-social consequences

that is can have; and lastly, 'curability and control', added to the model by Lau and Hartman (357), refers to an individuals beliefs in the likelihood of their condition being cured, prevented or adequately managed, particularly in relation to treatment effectiveness.

Further research has added subsequent dimensions including 'illness coherence', referring to the belief of an individual as to whether their illness 'makes sense', added by Moss-Morris *et al* in the development of the revised version of the Illness Perceptions Questionnaire (IPQ-R) (358). The authors in the development of the IPQ also acknowledged the cyclicity in the nature of long-term conditions (LTCs) and that the 'timeline' stage needs to be considered both in terms of an 'acute/chronic' timeline, and a 'cyclical' timeline to fully appreciate the experience of LTCs.

The IBM, a model that champions healing through therapeutic conversation between HCPs and families experiencing illness, acknowledges the impact and importance of considering not only the patient but their family and friends in how illness beliefs are formed and the influence of this on health. Through the use of over 20 years of analysis of paradigm cases, the authors observed that the illness beliefs held by a patient, their family and friends, healthcare providers and even the societal context within which they live, can either 'enhance or diminish suffering' (359).

The CSM, and its core components, could be observed repeatedly throughout the data and demonstrated how varied individual's cognitive representations of their T2DM and/or depression/DSD were, which is particularly salient in terms of how willing individuals may be to seek help, and how they might engage in and/or respond to treatment and self-management regimens. The IBM, particularly the influence of illness beliefs not only of the individual with a condition, but those of wider social groups, could also be seen in the qualitative analysis and is discussed further within the current chapter. Both the CSM and the IBM and their influences in the identification and treatment of people with T2DM, depression and/or DSD are discussed in further detail in chapter six (section 6.2.2).

Theme 1b: The ambiguity of diabetes-specific distress

While both HCPs and patients expressed varied accounts of understanding and experiences of depression in relation to T2DM, when looking at the understanding, experiences and perceptions of DSD, an overwhelming theme that emerged from the data was a distinct lack of awareness of the concept of distress that is specific to diabetes. When asked, nearly all of the twenty-nine participants responded by saying they had 'never heard of it'. Some HCPs attempted to decipher the meaning by breaking down the term but were open in their ambiguity and lack of understanding.

> *"My understanding, I must admit it's fairly new to me that ... that term, erm ... my understanding would be, from ... from the three words, is distress caused by diabetes? Or ... or the ... the side effects of ... the diabetes, you know, all the con ... er ... the complications of diabetes, erm ... anxiety maybe as well in there."*
>
> *[HCP-4: F, 40-59, Nurse]*

While the initial question given was to determine whether or not individuals were aware of the concept of DSD, once participants expressed a lack of understanding of DSD, a brief explanation of this was given, and the question reframed to interpret perceptions and experiences following this. Within the majority of patient responses, DSD continued to be poorly understood, but within the HCP interviews this was then better conceptualised. Some HCPs gave accounts that largely described the construct, acknowledging that the concept of DSD is something that they recognise, once given an explanation, but that the phrase itself and acknowledgement of this was not something they had previously understood.

> *"I think that's something that is definitely erm ... an issue. I mean you can tell that the moment you give somebody a diagnosis of diabetes, they get very, very distressed about it. They don't understand it, erm ... they get worried about it. Some people get ... get very pedantic about it for a very long time ... you often find that their focus on their condition leads them to, sometimes be so*

> *over-cautious erm ... that ... that they are unable to sustain their lifestyle adjustments ...So ... so yeah, I recognise that as a concept ...although I've not heard it couched in those ...particular terms. "*
>
> *[HCP-9: M, GP, 25-39]*

Upon reflection, it may have been more useful to approach the question differently, perhaps encouraging HCPs to reflect on particularly challenging instances within the care of people with T2DM, and then retrospectively determining how DSD may have been evident within the episode they describe. However, determining the understanding of DSD, or lack there of, was important to the study, so perhaps further questioning following this may have been productive in determining experiences of DSD, in spite of poor understanding of the concept or terminology. One HCP gave the opinion that a number of times when patients with T2DM present with depression, that it is often not 'true clinical depression', but rather a reactional affective state, responsive to the impact and realisation of being diagnosed with a chronic and potentially life-threatening condition.

> *"Er ... I think er ... er ... a lot of it [patient's psychological presentation] is not so much depression but the reaction to the initial diagnosis … of diabetes in that diabetes is looked upon as a er ... a sort of life-threatening diagnosis and therefore there's a ... a shock reaction rather than a true clinical depression"*
>
> *[HCP-10: M, 40-59, GP]*

The insights given by HCP-9 and HCP-10, indicates an understanding of a concept without knowing of a definitive term with which to encapsulate it. It highlights that a lack of awareness can hinder treatment since HCPs may inappropriately pathologise patients as depressed and subsequent treatment could be misplaced and leave the true cause of an individual with T2DM and emotional difficulties unaddressed. Further to this, HCPs coming from a more medically focussed background, such as GPs and nurses in primary care practices, have very limited training in psychological formulations, with a stark

focus in care for diagnostic labelling, which can further obscure any understanding or appreciation of DSD due to a perceived need to categorise and label. A factor acknowledged by further accounts from HCPs was the danger of simply prescribing routine depression treatment without appreciating the reasons for which a person may be in distress and accounting for alternative treatment that could be better suited to that individual. The narratives touched upon concerns in current practice that due to a diagnostic focus in care, HCPs may rush to categorise and thus treat patients according to their diagnosis, rather than taking the time to simply observe how individuals adjust to a chronic condition like T2DM and it's management. It is possible, and probable, that through the experience of T2DM, there will be instances that overwhelm patients and create negative affect, but by disallowing the time to observe and determine the causes of this affect, it could lead to incorrect classification and diagnosis, and thus inappropriate or suboptimal treatment.

> *"It's not just a question of treating depression, it's finding out what's making them depressed ... 'cos it may still be misconceptions about diabetes ... the prognosis in diabetes and what the treatment's going to involve, what the implications are for their families as well. So s ... a lot of the treatment of ... of depression in diabetes is patient education rather than saying here's some happy pills, go away and take those and you'll feel that … that much better"*
>
> *[HCP-10: M, 40-59, GP]*

A prominent trend observed in the data was the tendency for DSD to be largely obscured by depression, not only through the lack of understanding or recognition of DSD, but also through a lack of differentiation between the two conditions. A number of HCPs, when asked about depression and T2DM, often recounted scenarios that seemed to describe DSD. In some cases, discussing the impact of a diagnosis of T2DM, or on-going treatment burden, as the main cause of depression, when by its very nature this is a reactive affect related solely to diabetes. This further reiterated and highlighted the

impoverished grasp of many HCPs on the psychological impact of living with a chronic condition, and more importantly that such reactions are both common and valid, not necessarily benefiting from a psychiatric diagnosis, but rather better T2DM focussed education and/or support.

> *"Diabetes itself is ... is life thr ... that's lifelong ... you don't get over from it, you know you ... whether it's diet-dependent or whether it's drugs or what have you, and a lot of … anxiety, I think depression comes on because of insulin and injections and the treatment … rather than anything else anyway."*
>
> *[HCP-1: M, 40-59, GP]*

This was further corroborated by other accounts describing people with T2DM, clearly stating that they are depressed as a result of their T2DM. While it is important not to dismiss the potential for depression in these cases, it is also possible that, should HCPs and patients be more aware of the concept of DSD, the management of their health could be better targeted. For example receiving appropriate diabetes-specific support and education to aid in adjustment would be better suited to an individual whose main cause of concern was their diabetes, rather than standard depression protocols that are not related to diabetes, which could potentially target the wrong areas for patients with T2DM presenting with emotional difficulties.

> "*people come forward and telling you yes, we are depressive because of diabetes"*
>
> [HCP-12: F, 40-59, Nurse]

This was echoed by multiple recollections from patients about their diabetes, and depression (where relevant), which appeared – through closer inspection – to actually described DSD. Of notable interest was that all patients, even those without any history of depression, recounted cognitions and experiences that appeared to encompass DSD. These accounts are discussed further in the 'Impact of illness and comorbidity' section (section 5.2.2).

Theme 1c: Stigma

A theme that permeated throughout the data was the notion of stigma surrounding illness, both in terms of stigma framing an individual's diagnosis of T2DM itself, and a separate stigma related to poor coping and mental illness in people with T2DM.

Data from both patients and HCPs described the impact of stigma surrounding T2DM, describing guilt relating to the culpability in illness and feelings of internalised blame that were reinforced by family, friends, social circles and the media. One patient participant described the impact of her diagnosis and her continued deterioration in poor T2DM management and thus subsequent complications. She recounted the feelings of shame and blameworthiness she held upon herself due to her poor health-related choices. While in many cases it can be true that poor self-care has either led to T2DM or a continuing deterioration into diabetes-related complications, the stigma and guilt associated with this can be particularly detrimental. It can feed into a negative and vicious cycle of poor schemas and resultant health behaviours. As discussed in chapter one, a recent application of the cognitive behavioural cross-sectional formulation, or 'hot-cross bun' formulation, to depression and T2DM by Moulton *et al* (Figure 1-1), describes the complex interplay between situations, altered emotions, physical symptoms and altered cognitions (67,68).

> *"it hit me hard. I ... I expected it in a way but I felt like it was the end of the road … you know I think to myself could I have done more for myself and not have reached this stage."*
>
> *[Patient-13: F, >60, History of depression]*

The notion of shame was seen in further patient accounts, particularly trait-shame, whereby an individual internalises feelings of shame and blame-worthiness, marking a chronic deficiency in their sense of legitimacy, can result in avoidance of interpersonal relationships and/or a negative impact to their self-interest (360). One narrative discussed feelings of shame specific to her illness and avoiding seeing friends, due to shame about being ill, and how

she had actively avoided contact as a result of her multi-morbidity and shame surrounding this.

> *"I used to be ashamed of having people round because I was so ill … and you know I've become a bit of a hermit, you know, staying at home"*
>
> *[Patient-16: F, 40-49, History of depression]*

Various coping strategies can be linked to trait-shame, including avoidance as outlined above, but also negative self-soothing behaviours such as escapism through inactive distractions such as TV or surfing the internet, and over-eating. Of interest is the link between trait-shame and an external locus of control (361), as discussed earlier, and how this can be used to further avoid self-reflection due to chronic feelings of shame. This was further evidenced in the narrative of Patient-16, whom described over-eating to feel psychologically better but then ascribing blame to her T2DM rather than acknowledging the behaviour as a self-soothing mechanism. While polyphagia is well documented symptom of T2DM (2), coupled with the narrative of shame evidenced by Patient-16 and the discussion of both avoidance, and eating to self-soothe, it could be inferred that the ascription of blame for the over-eating to her T2DM, might be evidence of an external locus of control in a bid to appease the feelings of shame through an unconscious coping mechanism.

> *"it was like the more I ate the more bigger my stomach got with food ... I would feel better ... but then ... the pancreas not working properly, so then I was eating more ... anything I was eating it was taking everything .."*
>
> *[Patient-16: F, 40-49, History of depression]*

Her narrative highlights the vicious cycle in shame surrounding illness and how coping mechanisms can further reinforce and internalise negative cognitions, continuing in a vicious cycle of perpetuation. Further to this, Patient-16 also described the experience of how her family reacted to her

diagnosis of T2DM, questioning the reasons for which she was diagnosed and drawing attention to her younger-age and reinforcing the feelings of shame that she felt as a results of her health. Her narrative drew light to the issue of accountability, particularly in how family and friend's opinions can further shape an individual's feelings towards their own illness, either by instigating feelings of shame or guilt, or amplifying already internalised feelings of condemnation surrounding an individual's illness beliefs.

> *"They were like oh you're really young, you know why have you got diabetes?"*
>
> *[Patient-16: F, 40-49, History of depression]*

HCP accounts corroborated the notion that external influences can reinforce the onus of blame onto patients with T2DM, this time through moral judgements made by the media and that this fortifies negative schema. This can serve as a catalyst for the reproaching stigma experienced by people with T2DM, insinuating that they are culpable for their illness and, as such, can bolster feelings of shame and blameworthiness. The way an individual responds to their diagnosis of T2DM was noted as a key theme in the meta-synthesis by Gask *et al*, who noted that whether a person identifies as either 'a person with diabetes' or as 'a diabetic person' can greatly influence their emotional responses through the shaping of a sense of self, and that should the illness define them, this can have grave consequences not only their psychological state but their engagement with health-promoting behaviours (354).

> *"it's hard that there's a lot of guilt attached ... you know they've put on some weight or whatever and they just feel so guilty because ... Er ... erm ... but it's that sort of ... I think er ... there's so much in the ... in the media about, you know, it's being caused by obesity"*
>
> *[HCP-2: F, 40-59, N]*

The theme of stigma was more pronounced in the data concerning mental health and coping in relation to T2DM, particularly in the way that participants legitimised illness, with a profound difference demonstrated in patient perceptions of depression and DSD in relation to T2DM. Among the patients who held no prior history of depression, there was prominent discourse demonstrating a lack of understanding or empathy towards people experiencing depression, often appearing to consider depression as a weakness or a choice, wholly underappreciating the complexity of such an affective disorder and the increased complexity when coupled with T2DM.

> *"I can't understand people that get depressed … I just say well have you got to be depressed about … you know look at the po ... well look at the ... look at the positive things that you've got, you know ... erm ... I ... no I can't understand ... can't understand depression really."*
>
> *[Patient-8: M, 50-59, No history of depression]*

This was corroborated further in accounts from other patients, who when presented with the hypothetical scenario of being screened and identified as having depression, and asked how they might feel in such an instance, expressed distinct anger and annoyance. One narrative relayed that she had a very positive life and family, and implied that being depressed would somehow reflect negatively upon this, suggesting that being depressed would induce shame as a result. Her discourse also highlighted that she would be angry at herself for not coping, suggesting a belief that having depression is both a sign of weakness and an insinuation that an individual does not appreciate the positives they have in their lives. This again demonstrated a stigma and lack of appreciation for both the causes and complexity of depression in people with T2DM, which could negatively influence a person's ability to admit that they might be struggling with their situation and/or reinforce feelings of shame, which can feed into a perpetuating cycle of negative health-related schema.

> *"I'd be angry with myself. [Why?] I don't know. Er ... I find it easier to get angrier with myself for not being able to cope. I think I'd be sad. Yeah, because I would look at things in my life and my family, I mean er ... my family's tremendous ...Yeah. But ... and now I wouldn't like to think anything could be any reflection on them."*
>
> *[Patient-3: F, >60, No history of depression]*

One particular patient was very defensive about the notion of depression; prior to the interview commencing he expressed strong opinions describing psychology as a 'make-believe' concept and that there is 'no such thing' as depression, making very negative assumptions of people who receive a diagnosis of depression. He was asked to wait until the Dictaphone was recording to continue with the discussion. Once the interview was underway, upon being asked if he felt screening for depression could be useful, he seemed to distinguish himself from people with depression, stating that screening would be useful for 'certain people' but not for him. He described people of low intelligence or those who are easily influenced as the 'sort of people' who get depression.

> *"[For] Certain people it will ... in my opinion. It ...Well people that ... what we were talking about earlier who watch soaps, you know, who are not er ... who've got a certain standard of er ... how can I put it, phoo ... certain standard of education and they don't ... they're more or less the followers who they follow people and people will tell them what to do ... "*
>
> *[Patient-5: M, >60, No history of depression]*

The narrative appeared to demonstrate Social Identity Theory, originally developed by Tajfel & Turner (362), whereby individuals base their sense of self on group membership, and in this case demonstrated individuals as identifying as separate to the 'depression group'. Interviews with such patients showed a tendency to view themselves as distinct from those with depression, not only in diagnosis but also in the capacity to be able to even experience depression. Social identity was reiterated in further patient

accounts given when discussing screening and one patient describing a willingness for 'everyone else' to be screened but not herself. In this account she even endorsed screening and highlighted the benefits, but with a distinct 'us and them' discourse that reiterated the theme of stigma surrounding depression in patients with T2DM. This highlighted the engrained stigma of mental health and the distaste for the label of 'depression', even when this particular patient had a history of depression herself, suggesting that stigma to psychological health can also become internalised in those who experience it.

> *"I'd be very happy for everyone else to be screened because I think you know if it picks up anything in anybody that's a good thing. Some people er ... you know don't wanna talk about it or might not wanna mention it but if it's offered to them, you know, in a question they might just say yes... or whatever. I just think, you know, if people are ... if GPs are aware of it and if they've got the time to do it, you know er"*
>
> *[Patient-7: F, 50-59, No history of depression]*

A notable difference in patient perceptions of DSD was observed in the data, particularly in those who previously demonstrated a strong negative schema towards depression. Patient-3, whom earlier described feelings of anger towards the potential of being identified as being 'depressed', saw the term 'distressed' as far more acceptable. She even went on to normalise the notion of not coping, saying that a long-term condition would have an effect on anybody over time. This contrasted greatly to her initial response of feeling 'angry with herself' for not coping should she be identified as depressed. Such disparity in opinion seems to indicate a strong stigma surrounding labels and how being defined as 'depressed' invoked strong opposition whereas 'distressed' was seen as a much more tolerable identifier.

> *"Being er distressed? Yes, see I wouldn't mind that, yes … but I think sometimes yes … it's bound to have some effect because I*

do feel that anything that you know is going to be forever … is bound to have an effect on anybody isn't it"

[Patient-3: F, ≥60, No history of depression]

Among the reactions to being labelled as 'depressed' were adjectives such as 'disappointed', 'angry' and 'annoyed', whereas reactions to being labelled as distressed either evoked no concern, or a much more measured response. For instance, one patient, when considering the potential of being labelled 'depressed', said they would demand a second opinion, however, when considering themselves as being labelled 'distressed' they said that, although they would be surprised, they would not rule it out entirely.

"I would be amazed. Er ... certainly if ... if ... if it happened now I'd be amazed. Erm ... er ... but er ... I ... I don't know about the future. Things change."

[Patient-14: M, ≥60, No history of depression]

The theme of stigma within the patient data appeared to relate to the Modifying Labelling Theory (MLT), developed by Bruce Link, whereby a psychiatric label, such as 'depression' can increase an individual's vulnerability for negative evaluation and social rejection by producing a negative self-view (363). This negative self-view can lead to increasing wider social negative evaluations and rejection, thus triggering further defensive behaviours that can both reinforce the wider negative views and impede recovery. The polarisation in the reactions demonstrated in the patient interviews reiterates a distinct difference in the perception of the labels and since both depression and distress may have very similar presentations, this highlights the stigma associated with depression and the impact that such a diagnosis could have on an individual. Although in some cases appropriate distinctions are both necessary and constructive in being able to support treatment and to facilitate and enhance understanding and collaborative relationships between patients and their families, the data in the present study demonstrated a significant negative impact and marginalisation from being labelled as depressed. This could be even more detrimental should a patient

be inaccurately diagnosed with depression when they are actually presenting with DSD. It appeared that being depressed somehow implied a flaw in a person's character, whereas the notion of DSD appeared to be received as a legitimate response to T2DM. Having a physiological condition like diabetes appeared to somehow permit distress, but depression (a condition defined solely by symptoms rather than through determining a cause) appeared to be interpreted negatively as a defect within the individual rather that a legitimate response to something palpable such as T2DM.

While there was a clear and tangible representation of stigma and negative conceptions around coping and mental health among the patient interviews, a more subtle reflection of stigma was observed in the HCP data. Remarkably, even HCPs who stated that they had a specialist interest in mental health, demonstrated discourse that implied that they viewed depression as a choice, and that patients 'don't bother' with self-care or 'allow themselves' to become depressed.

> *"they don't eat the right things, erm ... don't bother to come for checkups, that ... that ... that sort of thing, so really just not taking control of ... themselves, they allow the ... the depression and those sort of feelings to take over"*
>
> *[HCP-2: F, 40-59, Nurse]*

Such discourse raises concerns for how individuals with T2DM and depression would conceptualise their illness, particularly in individuals prone to or already experiencing internalised shame surrounding their health. Should subtle inferences of blame from an HCP present within a consultation, this could have a stark impact not only on a patient's health status, such as amplifying negative affect, but also in how they might engage in treatment or self-care as a result, potentially feeling misunderstood and under supported, which could result in avoidance behaviours. In spite of HCP-2's seemingly punitive response to the vulnerability of people with T2DM and depression, and what appeared to be a lack of empathy, further comments in her transcript demonstrated that she both understood and incorporated constructive and supportive approaches to assist such patients. She described methods of

behavioral activation and collaborative care, which have been shown to be useful methods in the management of comorbid depression and T2DM, as discussed in chapters one and three (178,179,336,338). This antithesis in HCP-2's dialogue appears to show that while a HCP can have a good understanding of best practice, and what *should* be done to adequately support people with T2DM and depression, their indicated demeanour and attitude can contradict this, showing a deeper-rooted lack of appreciation for the comorbidity.

In the HCP data, a recurring theme that emerged was the notion of 'motivation' and how comorbid depression, with common symptoms of anhedonia and apathy, adversely affects an individual's impetus to engage in self-care, both in general and in how they monitor and manage their T2DM. The dialogue among HCPs described things much more pragmatically, compared to patients, discussing the influence of lowered motivation impacting on self-care and thus affecting physiological measures such as blood pressure and cholesterol.

> *"I think motivation wise really 'cos if they've ... they've got erm ... depression they're less likely to want to manage their diabetes … they don't care as much … they'll probably have a poor diabetic control, erm ... they don't grasp the importance of blood pressure control, cholesterol control, 'cos they just don't care as much ... they just wanna ignore"*
>
> *[HCP-5: F, 25-39, GP]*

HCP-5's language is again indicative of a potential lack of understanding and compassion regarding depression in people with T2DM, with the choice of language such as saying people with T2DM 'don't care' and that they *want* to ignore their diabetes, linking with the subtheme of stigma and insinuating a choice in peoples experience of depression and T2DM. This was further reiterated by multiple healthcare professionals using phrases such as they 'can't be bothered' when describing patients diminished motivation with comorbid depression and T2DM. This again suggests a lack of caring on the patient's part, not accounting for the fact that individuals with depression can

be painfully aware of their situation, and the detrimental effects of their poor self-care, knowing what they *should* be doing, but not feeling able to, which can feeds into negative cycle of thought and behaviour discussed earlier (67). The lack of compassion or empathy shown by some HCPs, believing that individuals simply do not care, can invalidate the patient, leaving them feeling misunderstood and underappreciated. This can feed further into the negative cycle of guilt and shame based cognitions, which only serves to perpetuate the issue and reinforce the experience of depression in people with T2DM.

While the language of a number of HCPs described comorbid depression and T2DM in a way that could be interpreted as showing a lack of compassion or adequate appreciation of the complexity of the patient experience of these two conditions, there were accounts that highlighted the impact of the comorbidity not only on self-care but also upon health-seeking behaviours.

> *".. so I think ... I think er ... one of the challenges that we face as GPs is that of (altering health seeking?) behaviour and helping patients understand what their ... what disease they have and when to seek help."*
>
> *[HCP-6: M, 40-59, GP]*

Health seeking can be negatively impacted further by the stigma discussed in the last section and reiterated throughout the discourse of HCPs demonstrating a potential lack of appreciation of the complexity of depression in people with T2DM. This was evidenced in the account of one patient who discussed the consultation when she was first diagnosed with depression, describing a distinct lack of understanding or appreciation from her GP. She described him as 'a patronising devil' and felt that she was unheard and left with unmet needs. She was prescribed antidepressants despite expressing a strong apprehension and fear of psychotropic medication, saying that it 'scared the hell out of' her. She described how this experience had left her feeling misunderstood and avoidant of seeking help not only from medical services, but also her family and friends, as she felt like no one would understand.

> *"So I left there with a bottle of pills, which I kept in my drawer for probably a year or more and then tipped them down the loo, because I ... no way I could take them, I needed every bloody ounce of everything about me I could get at that time you know. But I did suffer on my own, but I ... I didn't tell anybody erm ... because I didn't think anyone would understand"*
>
> *[Patient-7: F, 40-59, History of depression]*

A recent systematic review and meta-synthesis of both quantitative and qualitative data on the impact of mental health-related stigma and its impact on help-seeking demonstrated that not only was stigma and help-seeking associated, but internalised and treatment stigma were the most associated, with further influences of stigma seen in ethnic minorities, men and health professionals, corroborating the themes within the present data (364). A need for appreciation and understanding from HCPs is a crucial factor in patient care and engagement in treatment, which is discussed further in chapter six (section 6.2.2).

5.2.2 Theme 2: The impact of illness and comorbidity

Theme 2a: The impact of depression and T2DM

Within the theme of 'the impact of illness and comorbidity', there were varied accounts of how depression affected patients with T2DM; while HCP accounts described more functional self-management concerns, patient narratives portrayed a distinctly more interpersonal perspective, discussing how their family systems, work and social lives had been affected by their comorbidity.

Of note in the HCP data was that not one of the thirteen HCPs discussed the impact of depression upon patients' families and wider-life circles, although some discussed how they could influence the development of depression, such as a result of bereavement or financial concerns. HCPs discussed comorbid depression and T2DM at a more physiological level, as evidenced in the latter section. HCPs also only viewed the individual patient presenting with the condition, not allowing for the interplay with, and impact

upon, wider family systems. This starkly juxtaposed to the accounts of patients, who raised concerns with much more psychosocial issues, with the impact of comorbidity noted across three domains: sense of self, interpersonal relationships and employment. While these three reiterated subthemes could be separated, they were often intertwined with one another. One patient described how the two conditions both negatively impacted upon her life, particularly in her ability to cope and how this impacted not only her own sense of capability, but also how her family understood and viewed her. She described her comorbid conditions as 'taking everything away' from her, suggesting the exponential effect of managing multiple conditions and how they how they act cumulatively to engender difficulty.

> *"I couldn't do anything and that put me in a really bad way ... it was ... it was taking everything away from me ... it was really horrible. You know I was ... just negative thoughts and no motivation ... on top of the diabetes that added to it and it just made it worse really … you know it just put a ... a lot of pressure on our ... on our life as a family and a marriage ...you know on our marriage … As a result of my illness my marriage has had a lot of effects erm ... you know it's put it on the rocks kind of thing and my son's become very frustrated and my husband as well … I think my son has lost trust and confidence in my ability to do things"*
>
> *[Patient-16: F, 40-59, History of depression]*

A further narrative on the impact of comorbid depression and T2DM was given by a Patient-10, who earlier described the impact of work-related stress resulting in a psychological breakdown and believing that this led to the development of her T2DM. Similarly to Patient-16, this patient managed not only comorbid depression and T2DM, but also further chronic physical health conditions including colitis. Her account reiterated the cumulative impact of multimoridity, and how the experience of one condition can be contingent on the experience of the other(s). In her narrative, she described how she endeavoured to return to work following the deterioration of her psychological

health and development of T2DM, but due to her multiple conditions accumulating such that she was both physically and psychologically unwell, she was unable to do so and that this severely impacted her sense of identity and self-worth.

> *"they both said the same thing ... that in no way am I fit to go back to work or er … so I left five years earlier. Erm ... I was relieved but then I grieved for my profession. Yeah 'cos I was highly professional, er ... highly responsible, imaginative, creative and suddenly all that was taken away from me. So I grieved for the loss of … of work and for the loss of my integrity and my talents and everything."*
>
> *[Patient-10: F, ≥60, History of depression]*

Further accounts from other patients gave insight into the struggle of managing comorbid depression and T2DM, particularly in relation to the work environment. One participant described how both T2DM and depression require acknowledgement and understanding from employers, and although she felt supported by her current manager, it created a fear of misunderstanding and of potential discrimination should management changes occur.

> *"I do notice at work I do have ... I have to eat regularly else I feel really, really ill, and the lady that's in charge of me she's brill ... she is understanding, she doesn't mind at all but you know if you get ... whether people will start moving round, which is possible, you know, you just have to explain it all again and hope that they understand but… The biggest thing that bothers me with the word depression is your work record. Erm ... I've been where I am for a long while so I feel reasonably okay, although my job is under a bit of a threat at the moment, it's not imminent or anything, but there are lots of changes going on and you kind of think, you know … I think it would definitely go against me"*
>
> *[Patient-7: F, 40-59, History of depression]*

The discrepancies between how HCPs and patients viewed the impact of comorbid depression and T2DM highlights a potential for discordance within therapeutic relationships. HCPs gave much greater focus to the physiological impact of their comorbidity and solely looked at the individual patient, whereas patients gave much greater focus to the psychosocial impact upon their sense of self, relationships and employment. This difference in focus suggests that patient-centred care is not being achieved, and could leave patients feeling misunderstood, or that their needs are undervalued. Although accounts varied between HCP and patient participants, the data demonstrated across all participants how complex and broadly impacting comorbid depression and T2DM can be. Interviews demonstrated comorbidity impacting an individual's life across a number of bio-psycho-social levels and that managing all these areas, as well as trying to treat both conditions, is not only multifaceted but extremely difficult. This is discussed, and the difficulties in patient-centred care explored, further in chapter six (section 6.2.2).

Theme 2a: Naïve accounts of potential diabetes-specific distress

As reported earlier, when asked about DSD, nearly all participants demonstrated a lack of knowledge or understanding of the term or the concept. Yet, upon asking participants about their experiences or understanding of depression in T2DM, both HCPs and participants readily described accounts that appeared to fit more closely to the classification of DSD, demonstrating a lack of differentiation between the constructs of DSD and depression. Additionally, patients who held no history of depression, or articulated strong negative schema towards the concept of depression, described varied accounts that demonstrated potential DSD.

Some HCPs gave detailed accounts that acknowledged patients' descriptions of both physiological and much broader impacts on quality of life across a variety bio-psycho-social levels. They described how an individuals' mental health could be negatively influenced by not only the impact of diagnosis, and subsequent self-management, but also by the risk of complications and the burden of fear instilled as a result of this. Furthermore, they noted adverse impacts on individuals' sense of identify and social interactions, negatively influencing their confidence. This demonstrated the

complex interplay and amalgamation of the multiple facets of patient experience in people with T2DM and how this can lead to DSD, which could potentially be misinterpreted as depression, when it is more closely linked to the experience and inability to adjust and accept the reality of having a LTC like T2DM.

> *"it's a huge life-changing er ... diagnosis to be telling someone, it's not just about popping pills, it's ... you've ... you've got the potential for lots of complications, erm ... a lot of diabetics will eventually end up be ... taking many, many tablets ... but then they also want to have quality of life and ... and ... and for them to want to enjoy this quality of life, go out with friends and try and leave things as unchanged as possible, I think it's the social aspect as well that puts a bit of pressure ...on ... on needing to ... wanting to be norm ... like their normal friends ... and these things actually put on a lot of stress because, you know, insecurities come in … can lead to detrimental sort of erm ... effects on your self-perception, who you think you are, your self-confidence ... and all these things can actually cause mental health illnesses."*
>
> *[HCP-6: M, 40-59, GP]*

As discussed in chapter one, DSD can be understood as either symptom- or emotional-DSD. Symptom-DSD is distress that is related directly to the physical symptoms of T2DM, such as pain, fatigue and impaired vision. Patient narratives evidenced clear and impacting symptom-DSD, relating to numerous T2DM symptoms, notably weakened eyesight, headaches, and peripheral neuropathy. There were three accounts of patients that detailed an inability to walk or severely reduced mobility as a result of their T2DM and comorbidities. This exacerbated their distress directly associated with their health due to an inability to function and negatively impacting and reinforcing other health concerns, such as not being able to exercise and thus better manage their diabetes. This vicious cycle and accumulation of symptoms demonstrated the potential for symptom-DSD and highlighted the

physiological impact of T2DM and how this can negatively impact a person's psychological health and well-being.

> *"Getting up in the mornings are terrible you know, it ... soon as you wake up it's there ... I put everything down to it, and my eyes ... my eyesight's not as good as it used to be and I keep having headaches, and my toes, my feet, you know really hurt, you know, sometimes they'll go dead and numb and next ... and next time it's really painful you know and I have a job to walk"*
>
> *[Patient-12: M, ≥60, History of depression]*

This was further supported by the account of one patient who had very limited mobility as a result of her physical health, and that this impacted not only upon her physical health, but also her psychological affect. Notably, this participant recounted the influence of her family and how they viewed her, and how her physical health, coupled with the psychological impact of this, resulting in her wishing to withdraw, which perpetuated both the physical and psychological concerns. Such accounts seem to demonstrate the interplay and potential coexistence of not only symptom-DSD, but also how this can manifest into, or co-exist with emotional-DSD and/or depression.

> *"I spend hours, and my daughter says this room's like a gaol to me because I ... I spend hours 'cos I can't walk far and ...and ... and erm ... and then you get to the point you don't want to go out and I don't ... I wouldn't answer the phone, I wouldn't answer the door, or ... or nothing, I just wanted everybody to stay out there and leave me in here and I've not er ... you do show signs of it sometimes and my husband er ... he gets frustrated, he doesn't like er ... I'm ... I suppose I'm not such a positive person as I was, you ... you ... you know so ... but he's put up with me for a long time so (laughs) ..."*
>
> *[Patient-6: F, ≥60, History of depression]*

Emotional-DSD is psychological distress specific to living with T2DM, this could be feeling overwhelmed by the demands of self-management; feeling anxious about the possibility of future complications or hypoglycaemia; or harbouring feelings of guilt or shame, such as in relation to obesity or negative self-care behaviours. There were multiple and varied accounts of potential emotional-DSD amongst patients; feeling isolated, inhibited and marginalised at family events because of a need to monitor and manage diet due to needing to follow a healthy diet, but wanting to feel included in the celebrations, and feeling burdened and drained by the relentless need to monitor blood-sugar levels.

> *"I ..... sometimes erm ... you ... you ... you got a bit erm ... only ... only at times like Christmas and Easter when ... when the Easter eggs and ... and all that and they were saying well I haven't bought you one mother, you've got flowers, and I'm thinking oh well I can't eat flowers (amused tone) you know (laughs) ... but that ... only ... only in that sort of way because generally er ... but I get fed up of finger-pricking ... that's the bit that gets me down"*
>
> *[Patient-6: F, ≥60, History of depression]*

Further accounts highlighted the challenge of managing multiple medication and diet plans, and how this can present a cumulative impact and lead to potential emotional-DSD as a result of frustration and difficulty in a managing comorbid conditions harmoniously. One patient recounted particular concerns in adhering to her self-management regimen due to working as a paramedic, resulting in irregular and long working hours. She described feeling overwhelmed and burdened by the prospect of successfully controlling her diabetes without neglecting her work position. Her narrative draws focus to an issue often faced by people with LTCs, and the challenge of successfully managing their health whilst still maintaining their professional and/or social identities. Often, and demonstrated in this example, individuals can place their diabetes lower in their priorities, which perpetuates the cycle of poor physical and psychological health due to an inability to balance all bio-psycho-social needs.

> *"it's very difficult ... to lose a lot of weight isn't it. And I found it difficult because I'm at work and work isn't conducive to losing weight … There's no such thing as taking a meal to work because you don't come back for nine or ten hours so you can't, it's either take snack food and sandwiches or starve all day and er ... you know I've tried to explain this to my doctor and the chemist ... they just don't seem to understand that you can't have a break every four hours, it doesn't happen … So you can't run a regulated meal and diet while you're at work, it's just impossible.... and the other thing is because I work dayshifts and nightshifts, minimum twelve hours, I do tend to forget the tablets sometimes ... quite often actually … So erm ... it is having an adverse effect on me"*
>
> *[Patient-15: F, ≥60, History of depression]*

A fear of future complications was regularly communicated within the data from patients, with the more immediate fear of hypoglycaemia often recounted. Further to Patient-15's potential emotional-DSD outlined above, she expressed concern about experiencing a hypoglycaemic attack. This was coupled with social factors such as living alone, which was the case for six patients, heightening the fear of having an attack due to an increased risk and vulnerability for premature death as a result of experiencing an attack without the potential for assistance.

> *"But I'd ... I mean obviously I live on my own and I know that you can die from a diabetes hypo... if er ... if you're on your own, not ... not that obviously that's hope ... hopefully likely, it wouldn't happen to me at least for a long time, but (draws in breath sharply) you never know"*
>
> *[Patient-15: F, ≥60, History of depression]*

Of note in the patient data, were descriptions from patients who had no prior history of depression, who held negative views towards depression and had described themselves as 'happy' or with 'nothing to worry about'. Their accounts gave more telling descriptions of situations and emotions that

appeared to demonstrate the potential occurrence of emotional-DSD. One account in particular, gave details of quite intense distress and anxiety as a result of experiencing hypoglycaemia, and on-going fear and avoidance behaviours as a result of this. The individual had experienced numerous hypoglycaemic attacks, which rendered him unconscious, notably when travelling on a bus, which left him feeling so anxious that he avoided further bus travel, constraining previously enjoyed trips with his spouse, and magnifying his isolation.

> *"we also used to go on coach trips, erm ... all over the country, and we used to enjoy them very much … Coming back from town one day erm ... just come on me just that quick, as hypos do ... and as we got off the bus I passed out, so they stuck me in hospital, as I have on previous occasions, and do you know what ever since then I couldn't face going on another bus trip ... right, which was ... and I was disappointed in it as well really and ... and erm ... after maybe six months, nine months, I was talking to the wife about it and er ... I said I'm gonna go and see the doc see if he can give me something or, you know, erm ... help me get over this"*
>
> *[Patient-2: M, ≥60, No history of depression]*

The account from Patient-2 demonstrates a 'butterfly effect' such that one event can affect other areas of an individual's life and gain momentum to the point that it has hugely negative effects. This particular account seems indicative of emotional-DSD and demonstrated how negative affect can easily occur as a result of T2DM, even in those who consider themselves to be psychologically well.

5.3 Conclusion and chapter summary

Patients with T2DM, and the HCPs involved in their care, have a wide and varied view of comorbid depression, considering it either directly related to, or entirely distinct, from diabetes. Regardless of participant's views on the

temporal relationship between depression and T2DM, nearly all narratives acknowledged the significant interplay between the two conditions and the reciprocal effect they have upon one another.

Participant understanding of DSD was limited, with the majority of patients and HCPs saying that they had ‘never heard of it’. Of note, was that DSD appeared to be obscured by depression with a palpable lack of distinction between the two. There was notable stigma surrounding both physical and psychological health, evidenced in both patient and HCP narratives. An interesting observation was that DSD appeared to be considered less stigmatising than depression, and was considered a more tolerable label to bear.

When exploring considerations about the impact of comorbid depression and/or DSD with T2DM, the narratives of HCPs and patients demonstrated stark contrast. HCPs revealed a distinct focus on physiological outcome measures, whereas patients highlighted a pronounced focus on psychosocial aspects as the impact upon self-view, family, and work.

In this chapter, the findings from the qualitative interview study have been discussed looking at the understanding and meaning of co-existing depression and/or DSD with T2DM, exploring this across the first two key themes that emerged from the data: ‘illness beliefs’, and ‘the impact of illness and comorbidity’. There were points within this chapter that fitted into the provisions of care for people with T2DM, depression and/or DSD, and these are discussed in greater detail in the subsequent chapter.

In chapter six, the perceptions and experiences of barriers and facilitators to managing co-existing depression and/or DSD in people with T2DM are discussed across the latter two key themes that emerged from the data: ‘influences in identification and assessment’, and ‘influences in providing and receiving care’.

Chapter 6 Qualitative study findings, part two: Perceptions and experiences of barriers and facilitators in managing co-existing Type 2 diabetes, depression and/or diabetes-specific distress

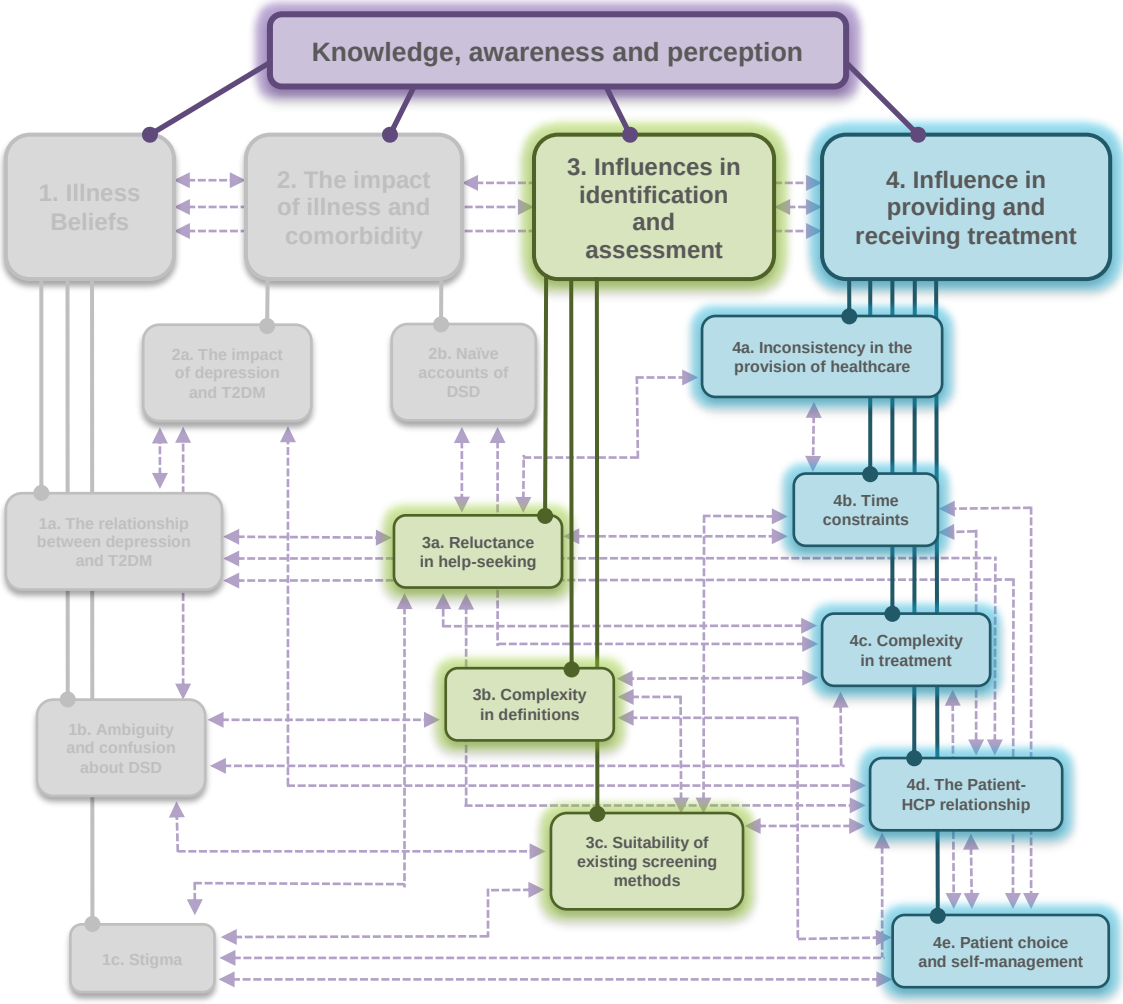
6.1 Chapter overview

In this chapter I outline the findings from the qualitative interview study in relation to both current and potential care for patients presenting with Type 2 diabetes (T2DM) and comorbid depression and/or diabetes-specific distress (DSD) across the latter two key sub-themes that emerged: 'Influences in identification and assessment', and 'influences in providing and receiving treatment' (Figure 6-1). Within the 'Influences in identification and assessment' theme, patient reluctance in help seeking, the knowledge, awareness and complexity in definitions of depression and DSD in T2DM, and the suitability of screening methods available are discussed. Within the 'Influences in providing and receiving treatment' theme, inconsistencies in the provision of healthcare for people with T2DM, depression and/or DSD, how time-constraints impact care, knowledge, awareness and complexity of depression and/or DSD in treatment for people with T2DM, the patient-healthcare relationship, and the importance of patient choice and self-management are explored.

As discussed in chapter five, due to the scale of the analyses of this qualitative study and the need to report across two separate chapters, the decision was made to reflect upon and discuss the findings within the reporting itself; such that critical perspectives, theories and models are interwoven within the results themselves. In this chapter, data from the field-notes are also included, as discussed in chapter four, and once again, contextual information in the parenthesis of each quote is provided. The additional participants from the supplementary data will be referred to as 'stakeholders'. Further to the abbreviations outlined in chapter five, to

facilitate ease of reading and understanding, the parentheses in this chapter may detail meeting numbers (M-1, M-2 etc.), stakeholder numbers (S-1, S-2 etc.), and, where possible, stakeholder job titles.

Figure 6–1: Themes emerging from a qualitative study to elicit and explore the understanding, perceptions and experiences of Type 2 diabetes, depression and/or diabetes-specific distress: Exploring the latter two key sub-themes



6.2 Findings

6.2.1 Theme 3. Influences in identification and assessment

When exploring the data, a key theme emerged around the influences in the identification of people with T2DM and psychological difficulties. While the importance of screening and identification of people with T2DM and psychological difficulties was acknowledged and reiterated by HCPs, concerns were raised across a number of subthemes; including the

reluctance of patients to seek support, confusion in the awareness, knowledge and complexity of definitions of depression and DSD, and lastly the suitability of existing screening methods.

Theme 3a. Patient reluctance in help-seeking

As discussed in chapter five, a stigma surrounding mental health exists which can influence a person's willingness to either admit that they are struggling, and/or negatively affect their inclination to seek advice or support. This was supported in multiple HCP accounts outlining their experience of individual's reluctance or refusal to come forward for help due to the fear of being labelled as 'depressed' and experiencing the social stigma attached to such a diagnosis, linking once again to the Modifying Label Theory (MLT) as discussed in chapter five (363).

> *"some people don't want to admit … erm ... that they are feeling depressed because it's ... it's a big word … Erm ... and it has kind of social stigma attached … I think for some people it's the stigma ... so they don't want to kind of er ... admit that they have any problems"*
>
> *[HCP-11: F, 25-39, Mental health practitioner]*

It was acknowledged that there remains a significant problem with unrecognised illness due to an engrained reluctance for people to not only come forward for help, but in cases where HCPs encourage patients to talk about their concerns, and offer them a space to do so, patients often continue to remain unwilling or avoidant in admitting they need may support.

Of note was the account of one HCP, who drew upon the cycle of change, highlighting that by even attempting to address the topic of mental health with some patients who are not willing to identify with the potential for needing support, this can in turn push them further away from a therapeutic relationship. This can result in an active avoidance of services for not only psychological health, but also routine care, which could negatively influence their T2DM and other potential health concerns.

> *"if you think about the cycle of change, if you think about influencing change, if the person is not ready to accept that diagnosis, or not ready to be screened, or if you don't explain the reasons why properly, that might add ... that might be another obstacle to the ... the clinician/patient relationship … They might feel threatened, they might not want to come back, they might say why are you asking about me ... about this. They might perceive it negatively, erm ... you know are ... are you ... am I not coping, why aren't you being forthright?"*
>
> *[HCP-6: M, 40-59, GP]*

As mentioned in chapter three, the 'transtheoretical model of change' (TMC) is a model developed by DiClemente and Prochaska (365) that is commonly used in health promotion. The model embraces five stages: i) pre-contemplation, where individuals are not intending to make any changes to their behaviour; ii) contemplation, where a behaviour change is being considered; iii) preparation, where small behaviour changes are initiated; iv) where individuals are actively engaging in behaviour change; and v) where individuals sustain the behaviour change over time. What HCP-6, above, indicated is that patients need to be in a willing stage in the cycle to be able to engage and admit the need for support. Should they be in the pre-contemplative stage, for example, raising the issue of psychological health can in turn be more detrimental and cause them to avoid help-seeking, not only for psychological concerns but also for their physical health for fear of being confronted again, highlighting a difficulty in identifying depression and/or DSD in people with T2DM.

A potential approach to try and address such concerns could be to adopt a preventative approach to try and normalise the concept of emotional associations and sequelae at the point of diagnosis of a long term condition (LTC) like T2DM. Doing so as a matter of course could encourage patients to be aware of the potential for psychological comorbidity before it may occur and thus make future disclosures more acceptable and HCPs more approachable.

> *"Erm ... no, I wonder whether erm ... er ... I ... I sometimes wonder whether people at the point of diagnosis should automatically be entered into some sort of er ... therapy. […prevention rather than cure?] Yeah. Erm ... and er ... and ... and to sort of ex ... by merely sort of engaging in a process of exploring their thoughts and ideas ..."*
>
> *[HCP-9: M, 25-39, GP]*

While the TMC is a commonly used and well known model in health promotion, and thus well understood by HCPs, it tends to have a greater focus on physiological conditions, not fully capturing the reality of affective responses with LTCs like T2DM. A potentially more appropriate model for the experience of psychological ill-health in the experience of T2DM could be compassion and acceptance based models. This is particularly salient when considering the shame and stigma associated with both T2DM and psychological health, as well as the potential for learned helplessness and/or external loci of control, as discussed in the previous chapter.

Compassion Focussed Therapy (CFT) is an integrated and multimodal approach developed to address shame and self-criticism, drawing upon evolutionary, social, developmental and Buddhist psychology, and neuroscience (366). The model of care in CFT hypothesises that individuals who possess strong feelings of internalised shame and self-criticism, demonstrate poorly regulated emotions due to a dominance of their 'threat' affect regulation system in their interpretation of both their inner and outer worlds (367). In a recent review on self-compassion in people with diabetes, Friis *et al* suggested that the process of reducing self-criticism improves motivations for self-management and has beneficial effects on both physiological and psychological health, giving merit to self-compassion in the treatment of comorbid depression/DSD and in people with T2DM (368). The review established the authors research agenda for further studies, demonstrating that self compassion moderated the relationship between DSD and HbA1c (368), and that a mindful self-compassion intervention significantly reduced both depression, DSD and HbA1c in the initial findings of a RCT (369).

Acceptance and Commitment Therapy (ACT) is an approach that encourages the mindful focus of individuals to disengage from the content of their thoughts by experiencing their thoughts rather than trying to change or halt them (370,371). When applied to the experience of diabetes and potential depression and/or DSD, previous research on coping styles in people with insulin dependent diabetes demonstrated that glycaemic control was significantly reduced when individuals accepted their diabetes and their diabetes related cognitions (372). In a study testing the effects of ACT on diabetes self-management, analyses indicated that ACT positively influenced coping strategies and improved self-care and glycaemic control (373). There is a paucity of evidence on the effects of ACT on psychological affect in adults with T2DM, with two small studies demonstrating positive effects on depression scores in Iran (374) and India (375), although a larger scale study is currently underway in the Netherlands (376). Although ACT is relatively new in terms of its application to people with T2DM, the research on depression in the general population has demonstrated positive effects since the 1980s (377,378) and continues to demonstrate positive effects, particularly when incorporated within other cognitive therapies (379).

The stigma surrounding mental health and its influence upon people's resistance to engage in health-seeking was acknowledged to be of greater concern in people of BME origin, who, as discussed in chapters one and two, are also at greater risk of having T2DM and DSD (380). Three HCPs from practices within the Leicester City Primary Care Trust (PCT), one of the most culturally diverse cities in the UK (381), touched upon this issue, noting that within BME populations there is an even greater stigma associated with mental health and a fear of being labelled as depressed.

> *"say the word, okay depression … others think oh my God, people will talk about if I say to them I'm depressed ... it's big issue .. in city practices because we're dealing with lots of erm ... Asian and erm ... Afro-Caribbean er ... population here"*
>
> *[HCP 12: F, 40-59, Nurse]*

> *" And then there's obviously some cultural barriers, erm ... some societies don't like to admit depression other societies it's ... it ... it's just seen as a normal part of ... of life and perhaps they don't sort of see it as a ... as a big problem ..."*
>
> *[HCP 7: F, 40-59, Nurse]*

As discussed earlier, a recent meta-synthesis of literature exploring mental health stigma and help seeking demonstrated strong associations with ethnicity and avoidance (364). This issue has been recognised in a recent initiative within the 'Time to Change' movement, an anti-stigma and mental health campaign run by the Department of Health and various UK charities, who acknowledge a need to change attitudes and behaviour within BME populations by encouraging culturally relevant context when discussing mental health (382). Within their initiative, they conducted a survey of 740 BME individuals experiencing mental health difficulties, finding that a third of respondents reported being treated less favourably, either moderately or significantly, by their own communities compared to the general population, calling for an urgent need for work to address and reduce stigma and discrimination within BME communities (383). Further initiatives and qualitative studies held across the UK have explored the reasons for such strong stigma within BME communities, finding repeated trends in beliefs that mental health added to already existing inequalities, was seen as a sign of aggression and violence, was seen as an incurable and uncontrollable 'madness' rather than a manageable psychological stress, and was considered to negatively reflect upon marriage and contribution to communities (384,385).

This was corroborated by the account of a BME patient who described a reluctance to disclose her depression to her husband, although seeking help from healthcare services, feeling shame and embarrassment in admitting her illness to even her closest relative. She further described indignity within her extended family and a heightened stigma towards health in general in Asian communities. Within her narrative she suggested that due to a cultural tendency for arranged marriages, both physical and psychological health are closely scrutinised within communities, with any ill-health considered to reflect

upon the family as a whole due to assumptions made about genetic transmission. Furthermore, she described a lack of discussion and sharing of health information within communities, despite illness being prevalent, and how this further limits people's willingness to seek help and the availability of support in their familial and community circle, reinforcing stigma and isolation further.

> *"I mean I didn't even tell my husband I was going for coun ... I was going to psychotherapy because I ... he didn't believe in it. But then the letter come … [he] weren't happy about it … the reason is because Asian communities, a, they don't talk, b, they don't share and c, they're just so busy demoralising everybody around them that they ... they forget that they're actually going through it themselves … the problem is with the Asian family because of arranged marriages and all that they think oh it's an underlying issue so ... say when my son gets married they'll be like oh well she's had this, what will his kids have ... you know and it's so bad"*
>
> *[Patient-16: F, 40-49, History of depression]*

The language used by Patient-16 was revealing and profound in terms of exposing the various areas that stigma can penetrate within BME communities, and subsequently impact upon the identification and assessment of people with T2DM and potential depression and/or DSD. Although a number of concerns were raised in the influences upon identification and assessment of depression and/or DSD in people with T2DM, some HCPs (below) described a need for normalising screening and discussion of psychological health as a means to improve engagement and help-seeking, making it routine and open so as to remove the stigma associated with poor-coping.

> *"it becomes normal practice and then when it's normal practice it's ... they don't see it er ... you know I think … think it's a sort of a stigmatising thing it's not very helpful to the patient."*
>
> *[HCP 2: F, 40-59, Nurse]*

Theme 3a. Complexity in definitions

As discussed in chapter five, the complexity and overlap between depression and DSD was further evidenced in how HCPs conceptualised mental health in patients with T2DM, with some accounts clearly and openly blurring and interweaving the two conditions. While HCP-2 (below) acknowledged the differences in causality that a patient with T2DM and mental health concerns can be presenting with, they openly admitted that they do not separate the two, raising concerns in HCP understanding. Further difficulties could arise due to a lack of distinction as it could serve to not only confuse the patient and lead to the development of inappropriate illness beliefs, but also lead to potential stigma, such as those outlined previously, should they be diagnosed with depression despite the root of their symptoms being identified as being due to diabetes.

> *"I don't tend to separate it [depression and DSD] when I … when I talk to patients ... some people are more distressed by having that long term condition than others, you know ... other people ... being depressed or anxious may affect the diabetes but it isn't the diabetes that's causing that"*
>
> *[HCP-2: F, 40-59, Nurse]*

The importance of patient understanding in their own health and their conditions was noted by a number of HCPs describing how patients can have difficulty in making sense of their own feelings, due to a lack of understanding of both depression or DSD as concepts, as well as the difficulty in differentiating between the physiological and the psychological in terms of symptom genesis. One HCP recounted how people with T2DM can be prone to confusing potential physical manifestations of depression such as fatigue, sleeping problems, and changes in appetite, for those as physical symptoms

of diabetes. This creates further difficulties in elucidating the true cause of someone's ill-health and appropriately identifying the most appropriate support.

> *"a psychological or mental health problem is often interpreted in the light of physical symptoms and er ... er ... er ... and put down to their diabetes or some other physical problem that they've got because they've got a diagnosis of diabetes they believe that all their symptoms are erm ... physical ... erm ... and the ... the idea of a psychological component is often lacking in their understanding."*
>
> *[HCP-9: M, 25-39, GP]*

The narrative of HCP-9 demonstrates a trend in dichotomy that was evidenced in multiple HCP discussions, whereby the physical and psychological components in T2DM, depression and/or DSD are separated entirely, rather than understood as truly co-existing. Of note in such scenarios is the tendency to focus on one or the other, as also demonstrated in chapter five, rather than appreciating the lived experience of many people with LTCs whom often experience both physical and psychological health problems together. HCP-9 continued to admit that while patients may be 'prone to somatisation' and confuse their physical and psychological symptoms, due to a stark focus upon physiological parameters in T2DM care, psychological factors are often overlooked.

> *"Erm ... the other thing is care for diabetes is demanding, we have so many physical tests that you have to do that the mental side maybe doesn't get enough attention ...you're ... you're too busy sorting out someone's HbA1c or their blood pressure or their kidneys erm ... to ... to focus on that so it can sometimes be erm ... blurred with the ... in the mix of what the patient's prob ... particular problems are. and ... and that I think is actually quite a er ... er ... an issue."*
>
> *[HCP-9: M, 25-39, GP]*

This highlights a further disparity in current practice, and how many practitioners fail to appreciate and satisfy the holistic care needs of patients with multiple conditions. Further to this, qualitative research exploring barriers to managing depression in LTCs (diabetes and coronary heart disease) by Coventry *et al* in 2011 (386), demonstrated that identification can be obscured due to the normalising of depression in people with LTCs, and that this can mitigate its recognition and treatment. Although this was not demonstrated in the data of the current study, it is possible that the misinterpretation of physical symptoms could serve as a factor in the normalising of depressive symptoms as those of diabetes. Further to this, there is the potential for DSD in patients with T2DM, which could also be normalised as a regular experience for people with diabetes, and without HCPs improved understanding of DSD as a concept, they may obviate the need to explore issues further and leave patients with unmet needs for care.

Theme 3c. Suitability of screening methods

A prominent subtheme that emerged within the theme of 'influences in identification and assessment' was the attitude of both patients and HCPs towards current screening methods. While both HCPs and patients agreed with the need for screening for depression and DSD in a notional sense, there was a much greater sense of dissonance towards screening operationally. This juxtaposing notion of the 'ideal vs. reality' for screening was captured by one HCP, who, in acknowledging the huge benefit screening could offer patients, immediately followed with a more concerned tone detailing how the additional workload of screening would impact upon his general practice.

> *"the benefits [of screening] are much, much ... would be, I ... I would think, greatly for the patients ... but also a huge workload for the ... for the practice"*
>
> *[HCP-2: M, 40-59, GP]*

Contained within the subtheme of general practice capacity to offer screening routinely, was that notion that, in order to meet time constraints due to resource limitations within the NHS, existing screening methods hinder in-

depth assessment. The crudity of validated measures reduces the potential of understanding a patient's circumstance by obfuscating the wider context and potentially missing the root cause(s) of the presenting negative affect, diminishing a full bio-psycho-social appreciation of the complexity of patient experience. Again, accounts directly contrasted a positive perception of screening, acknowledging its importance, with an immediate negative comment on the reality of screening practice and how this can adversely impact upon understanding and identification.

> *"Okay, I think it's [screening] important, it's nice. I think in the past not er ... the majority of GPs were not screening because of time issues but now with QOF we're using things like PHQ ... GAD or HAD, all these different scores to screen, and I think it's important to consider this aspect as well because with the busyness of general practice it's very difficult to look at the big picture"*
>
> *[HCP-6: M, 40-59, GP]*

The narratives within the qualitative data demonstrate how screening methods within current practice serve to reinforce the dichotomy between physical and psychological health in people with T2DM, serving as a distraction from complete holistic assessment that is so desperately needed to appreciate the experience and context within which patients present in primary care. By not fully appreciating the cause of a patient's symptomatology, such as determining if psychological affect is due to diabetes, or a wider life issue, or deeper rooted clinical depression, could lead to inappropriate treatment, highlighting the importance of more in depth appraisal of patient presentation.

A further perpetuating sub-theme within identification was a distinct lack of belief in existing tools and their efficacy. This was evident across both HCP and patient participants, with patients commonly expressing a disdain for being made to feel 'like a number' or part of a 'box ticking' exercise with no real gain seen from the process and feeling under-supported in spite of being routinely measured. When asked about whether they had been assessed for depression using screening tools, one patient detailed the monotony and

frequency of questions they received from their health service, feeling that this was merely a standard procedure that never seemed to benefit them in terms of their care.

> *"Only by a GP. Yeah. Well they ... they just give ... give me so many questions as such ... which ... which are, you know, a standard er ... but er ... you know I've ...I've seen a few doctors ... about it, you know. Well I always feel at a ... at a loss."*
>
> *[Patient-12: M, >60, History of depression]*

The lack of belief in screening methods was supported further by HCP accounts who spoke of their unease about making patients feel undervalued and under-supported. Accounts detailed how screening can objectify a patient by their score, defining them as the outcome of the screening method, rather than really trying to understand how they are feeling or appreciating the reasons for which they may be presenting with difficulties.

> *" it's [screening] just a ticking boxes system, it's not asking my patient how he's feeling really, it's we're trying to think okay patient is ... yes, no, yes, no and that's it, so that's the only bit er ... which then makes the patient a number ...it's not a patient then, then you're not talking about diabetes and depression, then you're talking about how much score she will get"*
>
> *[HCP-12: F, 40-59, Nurse]*

Reinforcing the lack of belief in the efficacy and utility of screening tools, were accounts that demonstrated how such negative views actually deterred some HCPs from using them entirely, preferring instead to instigate a discussion with the patient and use their professional judgement in order to explore the patient's individual situation. The phraseology of 'box-ticking' was repeated several times throughout the data and emerged as a strong negative force in the opinion of participants towards current methods in the identification of depression or DSD in people with T2DM.

> *"My view of tools is that the more experienced you are the less you use ... the less you need to use the tools because you ... you know it all ... The risk with tools is that er ... patients just end up s ... filling in boxes and questionnaires and you're not actually having conversations"*
>
> *[HCP-2: F, 40-59, Nurse]*

This was further reinforced by accounts of a similar avoidance from HCPs who also advocated taking time to engage in a discussion with a patient rather than using screening tools, resulting in them either avoiding the tools, or in some cases merely screening as a formality but then dismissing the data collected from them. One disclosure from a HCP demonstrated a seeming sense of obligation to perform screening whilst lacking in belief or trust of the process, resulting in them simply ignoring the outcome of the measure. This account demonstrates the potential for a cycle that feeds into patient-experiences, such as that of Patient-12, leaving them feeling under-valued or under-appreciated, that they are merely part of a system that does not use the data collected and resulting in them feeling 'at a loss' at the hands of screening whilst not feeling any benefits from outcomes.

> *" Uh, honestly? I hate it. I don't actually ... I don't get much out of it. I feel that I've got a good ... I can tell if somebody's depressed. Erm ... and we do screening and see it as a formality and I often don't even look at the results"*
>
> *[HCP-5: F, 25-39, GP]*

The accounts above support a recent review published last year by Petrak *et al* (59) on the healthcare delivery for depression in people with diabetes, as discussed in chapter one, concluding that unless screening is embedded within a comprehensive diagnostic and treatment approach, it does not serve either as an effective or ethical tool. The paper argued that only when appropriate healthcare facilities exist is there a strong rationale to offer screening. This builds upon previous qualitative research from 2013 by Margaret Maxwell who sought to explore the views of primary care HCPs

views in case finding for depression in people with T2DM and coronary heart disease (387). She concluded that routine screening for depression is not straightforward and that it can in fact be counterproductive to engagement, due to a lack of psychological training in primary care, highlighting a need for better guidance to increase confidence in HCPs, particularly nurses, in how to manage mental health problems once they may be identified.

Further concerns with the efficacy of screening methods were raised through discussions about patient engagement and transparency, accounting for the notion that screening tools can only be as revealing as the person completing them will allow. For example patients may answer in a way that portrays them as they wish be seen, rather than being entirely open about their symptoms.

> *" Uh ... I think ... I mean all the screening tools we use for depression and anxiety or whatever we're ... we're ... we're screening for is only as good as the per ... the honesty of the person that's giving it erm ... how honest and open the person is when they're actually filling those screening tools out really ... ... I mean you've got people that, that you know literally everything is worst case scenario ... my cup is always half empty ... erm ... so will always say well that they're at their worst"*
>
> *[HCP 8: F, 40-59, Mental health practitioner]*

Although HCP-8's account described the potential for patients to be more negative in their accounts due to a pessimistic outlook, and how this could obscure the results of screening, the accounts of patients were more telling of an avoidance of being too revealing and/or a fear of being too negative in their responses. One patient narrative displayed an apprehension to being screened; implying a fear of tools delving into areas that they would prefer not to disclose and feeling that there is a 'right' or 'wrong' way in which to answer.

> *"if it was just a routine er ... thing and you know lots of people were doing it... but if I'm being looked at ... particularly then I'd feel oh*

crumbs, I'm going to say the wrong thing, erm ... or ... I don't know … I might start looking further and I might not like what I see"

[Patient-3: F, >60, No history of depression]

Further accounts from patients detailed clear examples of such non-engagement with screening tools, where a patient felt the answers they gave were not suitable because they were 'too negative', even though the patient themselves recognised that their responses were true to their feelings. Their anxiety around being perceived as such caused them to want to change their answers and led to them requesting a new questionnaire so as to alter their responses.

" I've ... had a questionnaire and how do you feel, and it's all about your moods and how you feel mentally and everything er ... over the last month or so and the day I was filling this out I was particularly low and I looked at it afterwards and it was so negative … so I phoned them up and I asked them, I said I've ... I've spoilt this ... and I said could I have another one and they said no ... erm ... that I just had to be honest and fill it out as I was feeling at that time which I suppose is what they were after but the first one I just felt that it was so negative and I just didn't feel that I could send it in."

[Patient-13: F, >60, History of depression]

The accounts from both HCPs and patients suggested a number of areas that obstruct appropriate identification of people with T2DM and potential depression and/or DSD. While screening measures can be useful to not only identify symptoms, but to serve as a marker for comparison following initiation of treatment to measure treatment outcomes, in practice there are a various facets that create difficulty in gaining successful use of the measures. The data suggested that discussion alongside screening is vital, to both reassure the patient that they are understood and appreciated, but to also gain a better understanding of their presentation and how best to move forwards in treatment. Routine screening and/or discussion of psychological health could

be useful to remove the stigma and to normalise the experience of having psychological issues discussed in practice, but only if appropriate patient-centred dialogue were to facilitate this, with clear and defined treatment plans to follow, so as to inhibit the process of marginalisation and negatively influencing a patient's experience.

6.2.2 Theme 4. Influences in providing and receiving treatment

Throughout the data from HCPs, patients and from the supplementary field-notes, there was a resonant and recurrent theme of the influences in the both providing and receiving treatment for people with T2DM with comorbid depression and/or DSD. Five sub-themes developed within this, emerging as the inconsistency in the provision of healthcare; time constraints in the delivery of care; knowledge, awareness and complexity in treatment; the patient-healthcare relationship; and lastly, patient choice and self-management.

Theme 4a. Inconsistency in the provision of healthcare

A prominent sub-theme that emerged within the data was the impact of inconsistent care across and between different organisations, both within and across differing PCTs. This was particularly salient when considering the management of patients for whom the use of both primary and secondary care services is required, such as due to multi-morbidity or diabetes-related complications. One HCP account expressed concern regarding the communication between primary and secondary care services and an absence of true collaboration, creating problems in the management of people with T2DM with depression and/or DSD. They highlighted that due to the nature of secondary care being more specialist and needing to focus on one specific condition or concern, the overall well-being of a patient is not accounted for which can leave patients with unmet needs.

> *"Sometimes the er ... interface between primary and secondary care breaks down and that's ... that's where I think collaborative working can be quite er ... frustrating sometimes, erm ... particularly somebody whose ... whose diabetes is so complex*

> *they're under erm ... secondary care ... they have large clinics, erm ... they've gotta get through so many patients, the patients are there for only a limited time, they need to focus on what they want to do and then patch them up and send them away … the culture is far more of let's deal with our specialism rather than the general well ... overall wellbeing of the ... the individual."*
>
> *[HCP-9: M. 25-39, GP]*

Discussions within stakeholder meetings further corroborated this notion detailing how variations in PCTs and their service provision can lead to inconsistent care and challenges in providing true collaborative care, leading to patients from differing areas receiving entirely different management for their co-existing T2DM and psychological difficulties. Further data from the field-notes also highlighted how substantial variations in processes and the availability of services can exist, even between neighbouring practices. Discussions demonstrated that some services were available but not well established or utilised, highlighting the difficultly in designing and delivering an intervention for T2DM and comorbid depression and/or DSD since it cannot be universally distributed due to such variability in provision.

> *"Discussed intervention potential and advised of difficulties with collaborative care due to practices in different PCTs having either more or less available to work with and/or different approaches to handling diabetes and mental health problems"*
>
> *[Field-notes from M16: S-10, F, Clinical Psychologist]*

HCP interviews highlighted how such inconsistencies in services and care provision between organisations, and a failure to engage with systems designed to allow the sharing of information collected from patients, such as data collected from screening tools, can once again enforce the notion of 'box-ticking'. This can negatively impact on patients' experiences causing them to feel that they need to repeat themselves with each HCP they see, which stands as a tangible issue for people with comorbid T2DM with depression and/or DSD due to the potential for multiple care providers. This draws light

to the concern that, should available systems not be appropriately used, it can enforce a lack of continuity of care in a patient's management.

> *"Collaborative care it can be ... everyone's got to talk to each other … some of those people do not have access to the same computer system … I think everyone has to come from an equal base, you know or at least be able to contribute to the equal base. Erm ... I don't mean to sound negative but that I've got concerns ... people can have ... say have a cons ... conversation with somebody erm ... about something and say well I told so and so and they don't want to say it again and again... patients themselves need to know what everybody's about, who is involved, if it's collaborative care that actually that is quite a ... a nice network and people will not keep asking the questions or use the questions which are being asked and. People, patients themselves expect that information to be used 'cos they don't want to be a ticking box experience"*
>
> *[HCP-3: F, 40-59, Nurse]*

The issue of communication between domains of healthcare, such as primary and secondary care systems, supports existing research into the implications of deficits in communication between hospital and primary care based physicians upon patient safety and continuity of care. Kripalani *et al* performed a meta-synthesis and concluded that challenges in communication and information transfer between primary and secondary care physicians are both common and adversely affective to patients (388). Although the authors suggested that interventions using computer based summaries could facilitate better communication, as discussed in HCP-3's account; even with computer systems in place, it is not guaranteed that all HCPs have fully shared access, or that they will use them appropriately.

Further to the work of Kripalani *et al*, a recent meta-summary of qualitative studies by Haggerty *et al* (389) explored the experience of continuity of care in patients under the care of multiple clinicians. They demonstrated that patients often assume that communication and information is shared between

clinicians until proven otherwise, and that this can lead to a sense of deflation and dejection. Although both pieces of research were not specific to T2DM with depression and/or DSD, they highlight how institutional disparity in health care in LTCs in general, and a lack of sufficient collaboration between the varying agencies that patients with presenting comorbidities have to use, can lead to hindrances in appropriate and successful management.

Further systemic concerns were reiterated in most patient accounts that detailed the disparity between areas of the NHS, describing a deep fragmentation of services that has undermined faith in services and any capacity for change. The account from Patient-8 (below), discussed that services 'will never' work together, believing that the issue is irreconcilable due to being so deep-rooted and engrained within the system,

> *"I think yeah things like that, the communication, and when she spoke to them about it they said they weren't aware, so it seems that ... I know what the NHS is like, they're just little silos and they're all doing their own little thing and they will never work together until somebody gets to grips and I don't think you can, the ... the ... the mountain's too big to move."*
>
> *[Patient-8: M, 40-59, No history of depression]*

Evidence of the impact of such fragmentation of services emerged with patients describing a lack of familiarity with their care, contributing to a dehumanising approach to their management. Very few patients described care with a regular point of contact or the capacity to see their HCP of choice. They expressed a lack of containment, which is potentially extremely detrimental for people with T2DM and comorbid depression and/or DSD. Continuity of care is crucial for management of both physical and psychological health concerns where patients are already experiencing poor coping, without continuity of care, health outcomes could be compromised.

> *"I suppose one of the things today is that er ... in my opinion there is no such thing as a family doctor today. When I used to have a family doctor years ago you always used to see your family doctor*

but today I can see my doc ... family doctor but I have to wait twelve days, or two weeks, and then I say well what happens if I'm dying, well there's a doctor here to see you, well, I say, well that's not the point. Erm ... so, you know, really and truly that er ... if I really had a problem ... er ... er ... I would want to see Dr <10> but I know that I couldn't"

[Patient-2: M, ≥60 No history of depression]

This was reiterated by HCP accounts detailing the need for a central point of contact that is available and approachable, particularly in relation to diabetes-specific concerns, so as to minimise the chance of concerns building and developing into more serious DSD and/or depression.

" I think they need a ... a point of contact really, somebody they can get hold of easily. Erm ... just if er ... they want a bit of advice or a bit of support or a rant to say that I don't like my insulin, I don't like injecting, things like that, I think they need a healthcare professional that they can access"

[HCP-5: M, 40-59, GP]

This was corroborated by accounts from patients who described how having the consistency of a regular and available point of contact gave them encouraging experiences of their care.

"I have got good faith in <4> and I know that I can always talk to <4> I can phone her up, I'm not gonna say she'll answer the phone for me but I can speak to the receptionist and could I speak to <4> and they say what it's about, say it's a diabetic problem and <4> will ring me back within the day if ... assuming that she's working. Er ... that is what I call good service you know".

[Patient-2: M, >60, No history of depression]

Further to this, in discussions with stake-holders (M-17), telephone support was often mentioned as a potential facilitator to support patients with T2DM

and potential depression/DSD responding to brief consultations with their HCP and issues that may not warrant a formal appointment.

A consensus emerged across both HCP and patient interviews recognising that differences between organisations and their accessible services was largely contingent on the availability of funding. Patient accounts repeatedly highlighted 'time and money' as the key initiatives to enhance change within the standard of care they received. Patient-9, below, while expressing a wish for funding for treatments and time given within appointments, recognised that within current financial and political climates, these issues are very difficult to address, reiterating the sense of a 'losing battle' felt by patients in their ability to receive the care they feel is needed.

> *"There is, but again we're back into the area of time and money. You know I fully appreciate these in ... in today's society that we're limited in what can be done by and for us and to us by the amount of funds that are available and the amount of time that professionals have to ... to put towards individuals. So if they have an er ... more time erm ... and funds to go with it then yeah ..."*
>
> *[Patient-9: M, >60, No history of depression]*

This was supported during stakeholder meetings when discussing the potential for an exercise component within a management plan for patients with T2DM with depression and/or DSD. Meetings highlighted how difficulty in acquiring funding can result in inconsistency in the obtainability of services. Further to this, even in cases where sufficient resources are available, further funding would often be required. For example, providing adequate training to HCPs on the psychological aspects of a patient's care, and the funding required to do so, could create difficulty in being able to develop and deliver appropriate and achievable care for patients with T2DM and comorbid depression and/or DSD.

> *"It was noted that the scheme is funded by the PCT, receiving 20k at the moment, and that at present the majority of GP's are not aware of the scheme but numbers for this should hopefully*

increase with awareness - additional funding would be needed. Equally additional funding would be required to train health trainers in the relevant skills for working with people with depression/distress and knowledge of type 2 diabetes."

[Field-notes from M-18: S-13, M, Health enforcement officer &S-16: F, Member of clinical commissioning group]

HCPs highlighted further institutional influences upon successful treatment for people with T2DM and comorbid depression and/or DSD, noting the dominant influence of target driven practice within the management of these patients and how this detracts from the potential for tailored care. In particular, one account also corroborated earlier concerns raised in chapter five (section 5.2.1), about how HCPs tend to give greater focus to physical health over mental health, failing to fully appreciate the complexity in the presentation of people with T2DM and depression/DSD. The account from HCP-2 (below) discusses that the targets within practice reinforce this notion, by encouraging more focus on the physiological outcomes of patients rather that allowing for a whole-patient perspective of care.

"so that's the way I look at things. Erm ... it's ... the way erm ... general practice is set up and the targets and that are set up it ... it doesn't ...it's not really conducive to that … unless you've got a particular interest [in mental health]... that's how I ... try and see people that er ... that they're not just a ... a condition ... but that's not always the case and that because, you know, we're in a medical (amused tone) orientated ... erm ... place and ... and ... and the targets are very medically orientated so it's quite difficult for some people who may not have an interest in that area"

[HCP-2: F, 40-59, Nurse]

This notion of a target-driven focus was reiterated by further HCPs in their accounts of how the stringent objectives in diabetes care can have the tendency to force psychological aspects into the background, in spite of a patient's psychological state being crucial to their diabetes management.

HCP-10 (below) not only detailed the difficulty in how focusing on diabetes outcomes can subordinate any focus on depression or DSD, but that should care be focused more holistically on treating individuals as a whole rather than addressing each concern separately, it would likely lead to better patient engagement and improved outcomes across all areas.

> *"I think we are so concerned to meet certain targets in diabetic care that depression can be put on the ... the backburner and quality of life is very much dependent on not how accurately your diabetes is being controlled but whether depression is being dealt ... dealt with, and depression ... is something is ... is going to colour everything they do ... And I think if we were able to treat the dia ... the depression better we would then be treating the diabetes as a whole better ... because we'd get better compliance, better control"*
>
> *[HCP-10: F, 25-39, GP]*

The account from HCP-10 emphasises a stark need for holistic care and an appreciation for the complexity in presentation, as well as variation in how and why patients with T2DM may struggle to cope. This concept is supported by a meta-ethnography of studies exploring experiences of diabetes care by Campbell *et al* revealing a trend of diabetes patients to seek more from their care providers, as well as not be reduced by outcome measures and prescriptions, reiterating the concerns discussed earlier (390). Campbell *et al* argued for a more holistic approach, moving on from the traditional focus on diet, exercise and education, and noted that HCPs should take time to 'get to know' their patients better, determining not only patient concerns, knowledge and skills, but also appreciate any psychosocial influences in their presentation. Multiple accounts in the present data detailed that should the psychological concerns of a patient be treated first, or be given greater priority in care, then the likelihood is that their diabetes management would improve also. The account from HCP-2 detailed that her experience was often that once patients were well managed psychologically, then their T2DM tended to 'sort itself out'. In patients with T2DM and potential depression and/or DSD,

taking time to determine whether their poor coping is due to depression, or DSD, or a combination of the two, can allow for targeted treatment, and with appropriate care and tailoring of management to the individual presentation is likely to improve overall outcomes both at the psychological and physiological level.

Theme 4a. Time constraints in the delivery of healthcare

A further sub-theme that emerged was that time-constraints influence the provision of care for people with T2DM and potential depression and/or DSD. Of note within the HCP data, was a great deal of discussion of 'an ideal world' supposition when trying to suggest facilitating factors to improve care in people with T2DM and psychological concerns. A similarity between the HCP data and the earlier patient accounts, was a sense of hopelessness and resignation, noting copious potential ideas that were ideal but unattainable. Repeatedly mentioned was the issue of time and that this barrier simply couldn't be overcome within the current NHS structure, with accounts acknowledging a strong desire to be able to do more for patients but feeling unable to do so due to structural restrictions within practice procedures

> *"Yes, time constrictions I ... I think. Er ... the appointments we would like to be able to offer to patients and the appointments we actually do offer to patients are two different figures and it is a question of getting enough time to bring them back and see them and ... and deal with them, I ... I think it is er ... stopping us doing those things that we really would like ... like to be able to do ... with a patient and feel ought to be done with patients … Erm ... I suppose at the back of my mind is always wouldn't it be nice just to have a little bit more time, to do this properly, to enquire properly, to treat properly, to follow up properly, er ... because it's always so … pressure on time. …"*
>
> *[HCP-10: M, 40-59, GP]*

The repetition of the word 'properly' by HCP-10 gives emphasis to the inadequacy of appropriate care, despite good understanding and intention on

the part of the HCP to adequately support patients with T2DM and psychological difficulties. Difficulties with time restraints further resonated the notion of unattainable solutions when considering the appropriate training required to offer the necessary holistic care to patients with T2DM and depression/DSD. A sense of futility was reiterated amongst HCPs in being able to properly care for such patients. One account described the desire to gain better psychological training and to have the capacity to offer longer appointments within which they would be able to utilise such training, so as to engage with true holistic management and provide consistency for patients, but that this was simply unattainable in her experience of current provisions in care.

> *"Well I mean in an ideal world I'd love to go and do a counselling course and erm ... but s ... er ... I mean to be totally holistic that would be ... that would be the ideal thing but you're talking at least forty five minutes, an hour for each appointment then ... Which isn't really realistic, but it would be the better way to go so maybe you just need more diabetes nurses who've also got and then you can actually see everybody holistically all in one because a lot of people do ... do form relationships and they find it difficult to build relationships"*
>
> *[HCP-4: F, 40-59, Nurse]*

When regarding a patient's psychological health, HCPs acknowledged that the limited appointment time for GPs can be restrictive, providing insufficient time for patients to 'open up', and tending to focus on the physiological problems, rather than psychological concerns as a result of time-pressures.

> *"a normal GP practice it might be a ten, perhaps a twenty minute appointment if they're lucky, so er ... there is that temptation to whisk through that immediate sort of physical problem. Erm ... and obviously if people are depressed it ... it might take them ten minutes to open up to somebody and that appointment's gone, erm ..."*

[HCP-7: F, 40-59, Mental health practitioner]

In research to assess the quality of general practice care for people with LTCs in the UK, it was suggested that while GPs possess the necessary and appropriate skills to treat conditions such as depression and T2DM appropriately, concerns lie in a 'lack of confidence, support, or time to use' said skills (391). Patient well-being during discussions of mental health concerns was raised again under the theme of time-constraints, with accounts detailing that, should a patient disclose psychological ill-health, due to insufficient time to discuss and provide appropriate exploration of their concerns. This could be detrimental to a patient by 'opening a can of worms' that a HCP would be unable to provide adequate containment for, thus being unable to ensure patient well-being.

> *" the time constraint in the consultation we can't ask somebody who is here for er ... say a diabetes review ... oh are you feeling low because I know it's going open another can of worms and if then depression is there you cannot finish in fifteen minutes"*
>
> *[HCP 12: F, 40-59, Nurse]*

The time-constraint theme further emerged in accounts detailing a lack of continuity, and a removal of patient choice, with HCPs discussing feelings of 'having their hands tied' by the time-constraints in current practice. They noted that they were often unable to support patients themselves, despite a clear desire for this from patients, needing instead to refer to other services. This further perpetuates a lack of continuity, and poses the risk for patients to feel 'passed around' and having to repeat themselves, which can again lead to patients feeling under-valued and negatively influence their engagement in care.

> *"personally I generally find that if I've diagnosed one of my patients with depression they would prefer to come back to me but then we haven't got time to talk so that then it's the time constraints so I ... I do think generally my patients would prefer to*

> *come to me for the continuity rather than see somebody else, but then some of the other healthcare professionals have got more time ... sometimes it's better to go and see somebody from the mental health team, who might have a thirty minute appointment rather than a ten minute appointment."*
>
> *[HCP-5: F, 25-39, GP]*

Further within the theme of time-constraints was the transverse perception of patients believing that they are 'wasting time' in appointments, and how this juxtaposed with the desire for many patients to have more time. There were evidences of patients perceiving a lower sense of entitlement for time within appointments, with narratives among patients with comorbid depression discussing attempts to not waste their HCPs time with their concerns.

> *"occasionally think I need them, like I do prefer the talking therapy, you know, just to chat to somebody really, basically sometimes to just off-load, you know, erm ... but I try not to waste their time obviously, you know, but er ... but I'm ... I am ... always so aware there's always a million people worse"*
>
> *[Patient-7: F, 50-59, History of depression]*

The perceived entitlement to time in appointments has been previously researched in people with depression in the general population and demonstrated similar themes as those within the present study. Pollock and Grime's (429) findings highlighted that people with depression can experience a sense of time pressure within appointments, sometimes self-imposing time restrictions within appointments and considering them to be wasting the HCPs time by discussing too much in terms of their emotional concerns. This could be extremely invalidating for people with T2DM, depression and/or DSD and influence their engagement in treatment and recovery. The subthemes of 'time-constraints' and 'patient choice' were closely connected and thematically inter-connected; the impact of this is discussed further in the 'patient choice and self-management' subtheme section later in the chapter.

Theme 4a. Complexity in treatment

As discussed in chapter five and earlier in the current chapter, the knowledge and awareness of both depression and DSD in people with T2DM was distinctly lacking in both HCPs and patients alike. When considering the influence of this upon the provision of treatment, a strong and emergent trend within the HCP interviews was that there was poor understanding of existing guidelines for depression in people with diabetes, with nearly all HCPs saying that they were not up-to-date with these.

> *" To a degree yes. (laughs) Yes, I must look ... I must look ... I must look at it again, to be honest ... I haven't looked at it for ages."*
>
> *[HCP-1: M, 40-59, GP]*

There appeared to be an undertone of dismissal in regards to the National Institute for Health and Care Excellence (NICE) guidelines, with nearly all HCPs responding with amusement and some even being somewhat facetious in their responses. Of note was one disclosure that demonstrated there were HCPs who actively ignored the guidelines, favouring their own approach, stating that they have their 'own systems for treating depression' and choosing this over remaining up-to-date with treatment protocols.

> *"Mmm. I'm ... I'm not up-to-date ... I have to say. I've got my own ... I've got my own systems for treating depression and I'm not really up-to-date with NICE ... I know you should be, so slap ... (laughs) ... slap on the wrist for that. (laughs)"*
>
> *[HCP-5: F, 25-39, GP]*

The admission from HCP-5 demonstrates a distinct disparity between HCPs and governing bodies recommending best practice for patients with T2DM and depression/DSD, raising concerns about the consistency and unity of care provided to such patients. This is particularly concerning when considering the interplay between depression and DSD in relation to T2DM and the need for careful and considered assessment and appropriate

management thereafter. When exploring the reasons for nearly all HCPs having inadequate knowledge of current guidelines for depression in people with T2DM, HCPs expressed a difficulty with keeping abreast of guidelines, due to the extensive number of guidelines existing and the frequency with which these can change. In particular, for staff with multi-modal roles, this resulted in a vast quantity of documents needing to be read in order to remain up-to-date with most recent policies. One HCP disclosed that due to her multi-modal role as a practice nurse, she found it difficult to keep up with ever changing recommendations. What was notable in her language was that she initially seemed to legitimise her lack of understanding by stating that nobody else does either, feeding into the theme of dismissal towards guidelines and an incongruence between HCPs and the governing bodies that recommend treatment protocols.

> *"I don't know everything so I wouldn't really think any ... everyone else does ... but what we ought to know, how much we ought to know, we think we know it, but if the guidelines are changing, like you asked me and I said the last I had a look at them three years ago and I'm being very honest ... you don't get ... because if you're looking at a practice nurse and one practice nurse does twenty different kind of stuff every day"*
>
> *[HCP-12: F, 40-59, N]*

Similar concerns were raised about the length of guidelines and their cross-referencing, with HCPs feeling that such complexity was simply not feasible for staff to manage, or be motivated, to keep up with. One account discussed the functional difficulties in checking guidelines for comorbid depression and T2DM. They noted that while HCPs whose main professional focus was in diabetes, such as those running diabetes clinics, may read the NICE guidelines specific to diabetes, they are unlikely to pursue the guidelines for depression, even though they are signposted from the diabetes recommendations.

" I mean it's a huge, big, long … document, which we condense down, you know, most people would read the quick view erm ... most people won't even read that ... nurses who are running diabetes clinics will ... will read the dia ... maybe read the diabetes NICE guidelines ... but they're unlikely to read the NICE guidelines for depression ... I mean they link it, so what you ... if you go into the de ... diabetes guidelines they'll say go and ... depression and anxiety, go to guidelines da de da de dah ... and I think it should actually just be in there ... and ... because they're not gonna ... they're not gonna go and look up another big document"

[HCP-2: F, 40-59, Nurse]

The points raised by HCP-2 highlight operational factors that can limit understanding and appreciation of depression and T2DM and feeds into the theme of knowledge, awareness and the complexity in treatment of T2DM with depression and/or DSD. Further functional accounts raised about the lack of education for HCPs attributed particular concern to the process following the potential identification of depression in someone with diabetes. HCP-2 continued to discuss how a lack of education and appropriate understanding of comorbid depression and/or DSD would mean that even with regular screening to identify potential cases of depression or DSD in people with T2DM, without the appropriate education and understanding to support this, HCPs may not know what to do with the information they collect or how best to ascribe treatment to individuals identified as depressed. This further identifies areas of concern in the management of people with T2DM and potential depression and/or DSD highlighting that without appropriate education and training for HCPs, it can leave patients vulnerable and with unmet needs or inappropriate care, reiterating the issues raised in section 6.2.1.

"I think it's almost the system is wrong ... erm ... you have to educate the people who are the ones that are gonna be looking for it, if they're not educated, even ... even if they're ... if they pick

> *... even if they pick it up what ... are they gonna deal with it correctly . you know, you're getting people to ... to look for something and they don't know what to do afterwards and I think that's really, really important that that doesn't happen because that's worse than not looking for it I think"*
>
> *[HCP-2: F, 40-59, Nurse]*

Upon exploring this sub-theme further, reasons for diminished understanding among HCPs was discussed with issues around training resonating among multiple accounts. Some noted that the majority of current staff-training schemes for diabetes fail to touch upon psychological factors, giving focus to the physical aspects of T2DM and failing to connect the two. Once again, this reiterates the subtheme throughout the data that current care fails to appreciate the complex presentation of people with T2DM and poor coping. This again highlights a stark need to appreciate not only the physiological, but also the psychological and potential social aspects specific to each individual case.

> *" Erm ... most educational programmes erm ... courses about diabetes literature and things, focus on the physical aspects of er ... diabetes ... either the diabetes itself, a complication of diabetes, erm ... whereas mental health is not really heavily publicised either through ... erm ... er ... courses and erm ... teaching of diabetes er ... nor ... nor through programmes, er ... or anything else like that so ... so there's a low ... it's er... low on the radar of many practitioners.*
>
> *[HCP-9: M. 25-39, GP]*

A few HCPs recognised their own limitations, discussing how their tendency to focus on patients' diabetes during consultations can contribute to barriers to successful management of patients with T2DM and depression/DSD. They acknowledged a need to look at the NICE guidelines to improve their understanding, since their knowledge is mostly around diabetes or depression as separate constructs without adequate

understanding or appreciation of the two as a comorbidity, which hinders the possibility of true holistic care, a vital necessity in people with T2DM and depression/DSD.

> *" to be honest I think depression is what, I suppose as a GP personally, I sup ... I'm not always in tune, I get diabetic patients ... I'll concentrate on diabetes ... but something like this, and ... and with the NICE guideline, I think I need to look at it, I need to readdress my own thinking and ... and ... and I think another day look at more ... more depression as well as diabetes"*
>
> *[HCP-1: M, 40-59, GP]*

This was juxtaposed with concerning accounts from HCPs who out rightly discussed their care provisions in a way that revealed a clear separation of diabetes and depression, considering them as distinct of each other and to be treated separately, further corroborating the concern for a lack of holistic care and not viewing patients as a whole.

> *"No, not specific to diabetes, I think it's just specific to depression itself. ... 'cos I think you ... you're ... you're ... you ... I think the ... you know er ... er ... if it's depression ... if it's diabetes and if they're a depression patient you've got to treat the depression as depression, as an entity ..... in its own right, ..."*
>
> *[HCP-1: M, 40-59, GP]*

Suggestions were given for ways to improve HCP knowledge of T2DM and depression/DSD, such as the means of delivery of education. HCP discussions placed particular emphasis on learning through interaction and providing those being trained with the capacity to apply their own professional experiences, rather than simply offering dry literature, so that the information could resonate in their memory through its applicability to their own cases.

> *" Erm ... I think everyone has different learning styles erm ... but I think what I feel is erm ... er ... more of kind of interactive*

> *workshops erm ... where, you know, there ... there is some opportunity to kind of learn about it and then apply it in some kind of ... kind of case studies or something, so ... Understanding the concepts and ... I mean how the health professionals can apply to what they are doing ... er ... so I think that makes it more kind of erm ... interesting for them and then they're more motivated to learn about it 'cos then they can apply the knowledge into their clinical practice"*
>
> *[HCP-1: F, 25-39, Mental health practitioner]*

This recommendation was reflected in stakeholder meetings, where recommendations were given to observe the training received by facilitators in order to deliver the curriculum for the DESMOND (Diabetes Education and Self-Management for On-going and Diagnosed) programme (311,392,393). During the process of observation, it was noted that the programme demonstrated interactive training styles, also using case-like examples to assist learning, encouraging facilitators to draw on their own experience, reflecting accounts given in the interviews.

> *" group given examples or encouraged to consider their own experiences with cases and use these to role-play and demonstrate non-didactic approach - positive way to engage with group and make sense of the curriculum in real world terms"*
>
> *[Field-notes from M-15: Observation]*

The interview data acknowledged a need for better understanding and education in HCPs, but also advocated that when training HCPs in the management of T2DM, not only should education include a focus on psychological factors such as depression, but a broader appreciation of other areas of mental health should be explored. Although this particular account did not discuss DSD, this factor could be incredibly important to include in wider psychological understanding within the T2DM context.

> *"Erm ... er ... I think er ... rather than just focus on the depression the whole concept of mental health in diabetes is something that erm ... should be explored further and ... and ... and education given to ... to doctors and nurses and practitioners about it erm ... because I think there is a unique interplay between mental health, physical health, and dia ... diabetes, so erm ... so ... so doctors and practitioners need to pick up ... be able to pick up tips on how to deal with ... er ... with common er ... mental health problems in diabetics."*
>
> *[HCP-9: M. 25-39, GP]*

Further to knowledge, understanding and awareness of HCPs, the patient data demonstrated a lack of understanding across not just depression and DSD but also with their T2DM. A number of patients appeared to have a confused understanding of the permanence of their diabetes, believing that it could, and in some cases believing it had, disappeared. This misunderstanding of their condition has the potential to influence both their physical and psychological health. For example, they may not continue with self-care behaviours, believing that they may no longer need to, which can risk worsening diabetes outcomes. Or, should their health deteriorate this could lead to poor-coping and potential feelings of shame/guilt about it their diabetes 'returning'.

> *"Well I've actually got some good news for you. Right. Erm ... as of a month ago... I was actually diagnosed with it actually levelling off and I haven't got it anymore.*
>
> *[Patient-16: F, 40-59, History of depression]*

This was reiterated in HCP accounts of the detrimental effects poor understanding can have on a patient's management and subsequent physiological and psychological condition. One account discussed how, even when patients have options available to them in terms of improving their diabetes outcomes, their lack of understanding and confusion of their condition can lead to DSD through feeling overwhelmed and unable to

appreciate why or how their diabetes is deteriorating, which can continue in a cyclical nature, perpetuating the experience of DSD. This links into the negative cycle of DSD reported by Frank Snoek (138), as discussed in chapter one (Figure 1-4). In the cycle, 'diabetes dysregulation' can lead to 'negative feedback', leading to 'demoralisation', 'poor coping' and subsequent DSD, which then feeds back into 'dysregulation' and so on. The data highlights a stark need for appropriate and accessible education for people with T2DM to be able to fully appreciate their condition and know how best to improve their health outcomes.

> *"if you're talking in this area, it's our city practices, there will be good forty person who have got poor control, not because of that they haven't got options or they haven't got choices but they haven't taken it right ... they don't understand it and they don't erm ... uh ... how should I say, they don't know how to deal with it ... so that distress will be then there how do I do it"*
>
> *[HCP-12: F, 40-59, Nurse]*

The understanding of patients shown in this qualitative study links back to the Common Sense Model (CSM) (355), as discussed in chapter five. The cognitive representations that individuals hold about their illness, and how they interpret the information they receive, influences and determines their health-seeking behaviours, or engaging with coping strategies and/or self-management regimens (394). Leventhal determined that within the model, illness beliefs are informed by three sources of information, the first being the already assimilated information an individual holds prior to diagnosis from social communication or 'lay' information sources or general cultural awareness. The second source is that received from individuals perceived as significant or authoritative, such as parents or a HCP. Lastly, an individual would complete their illness belief by including their current experience of the illness, which refers to somatic or symptomatic information they gain through the lived experience of their illness.

The account from HCP-12 continued to discuss DESMOND and that although this was an available service and that she commended it for

educating people with T2DM, she acknowledged that it does not cover depression in its curriculum, and that more targeted psychological education is needed. The outcome of the final stake-holder meeting, that was held to bring together all previous stakeholders and present the data thus far, concluded with the suggestion for the potential development of a programme such as that in DESMOND but specific to depression and DSD for people with T2DM.

> *"It was discussed that training for consultation style and shared decision making etc. is already being done elsewhere (Year of Care programme). It was suggested that there is no use in "reinventing the wheel" as good work is already existing using the methods highlighted in the presentation, rather it might be best to build on already existing work such as DESMOND and IAPT to develop something specific to diabetes, depression and distress"*
>
> *[Field-notes from M-17, Multiple stakeholders, comment from S-18, Advance diabetes practitioner]*

The need for better understanding of depression and poor-coping in relation to T2DM was further evidenced within the theme of knowledge, awareness and complexity in treatment, with HCPs describing poor understanding of depression in their experience of patients with T2DM, particularly in terms of their understanding of the biological basis of depression. Two nurses in the interviews highlight the importance of normalising depression by improving understanding of the biological basis of depression, with one HCP discussing how a poor grasp on this can have a negative impact on a patient's recovery. HCP-4 described how, due to poor understanding that depression can occur as a result of biological imbalances; patients can experience guilt or shame due to believing that it is reactive to their life circumstances and not feeling that this warrants their low mood. This links back to the theme of stigma and legitimacy (section 5.2.1) and highlights a potential area to address in education programmess, such as those described in the latter quotation, to improve patient understanding in the

complexity of diabetes, depression and DSD and the importance of deciphering how and why a person feels the way they do.

> *"Perhaps a better understanding of our er ... serotonin levels as well, that would ... that would be .... you know and ... sort of trying to make it more organic rather than you know pull your socks up and you know how they used to ... okay we realise it could be erm ... situational but also it could be, 'cos a lot of people come in and say I don't know why I feel like this, I've got a lovely family, I've got a lovely job, you know and my diabetes is okay actually, you know I'm not worried about it and I've got no problems with that, and ... and yet they ... they ... they feel low"*
>
> *[HCP-4: F, 40-59, Nurse]*

> *"... it ... it is a normal thing, that's why I say to people you know you ... it's ... it's ... it's like ... it's chemical, it's part of the course to some degree ... and you ... you personally don't make that decision … I think it's helpful to erm ... open up that it's a normal thing in many cases ... to feel like this and it's a chem ... it's a chemical thing"*
>
> *[HCP-3: F, 40-59, Nurse]*

When exploring ways to improve and facilitate better understanding in patients around the interplay of depression, DSD and T2DM, the subtheme of learning styles was a evidenced in the patient data, as with the HCP interviews. The methods used to deliver health-information to patients was discussed to have a great impact on how patients learn about their conditions, with both HCPs and patients describing how even with the relevant information provided to patients, the usefulness of this is entirely dependent on the way in which this information is delivered. Patient accounts detailed a need for better delivery, and that dry literature alone does not allow sufficient engagement with the information, alluding to a preference for explanation and better interaction from HCPs when providing education.

> *"I probably don't [know enough]. Well no because to me dry literature just don't do it, I need somebody to talk to me"*
>
> *[Patient-7: F, 40-59, History of depression]*

Both patient and HCPs praised the idea of structured education as a means to improve knowledge in patients, with HCPs again referring the DESMOND programme.

> *"I think that education is a really important thing, you know the more your patients know about ... education, perhaps through a structured programme like DESMOND"*
>
> *[HCP-9: M, 25-39, GP]*

Data from the field-notes supported the theme of learning styles and encouraged the observation of a DESMOND education session being delivered to patients with T2DM so as to understand how existing diabetes education programmes work to improve understanding in newly diagnosed patients. Although the focus on psychological ill-health was very minimal, the sessions provided useful information on structure and format that is accessible to the patient. The information gained supported a lot of the data collected in the interviews regarding education and that there is a need for improved comprehension in patients for them to take control of their conditions and improve outcomes. It demonstrated positive regard towards interactive learning and the practical methods of delivery seen in DESMOND sessions, such as practical demonstrations, activities, creating personalised action plans and identifying risk factors.

> *"Practical demonstrations and interactive activities to show food content (fat, sugar, types of fat, calories). Making action plans – What am I going to do now? – After identifying risk factors – What are the actions I could take to lower this risk factor? What's going to stop me? What will I do about that?"*
>
> *[Field-notes from M-13: Observation only]*

The appreciation of learning styles is paramount to improving understanding in both HCPs and patients, particularly in patients. The NICE guidelines state that diabetes patient education should be a 'planned and graded programme that is comprehensive in scope, flexible in context, responsive to an individual's clinical and psychological needs and adaptable to his or her educational and cultural background' (395). Treatment that includes education for people with T2DM, depression and/or DSD needs to account for patient needs and various learning styles and abilities, potentially providing choice so that patients feel empowered in their ability to learn and self-manage their comorbidity. This is discussed further in the 'patient choice and self-management' section.

Theme 4a. The Patient-HCP relationship

A prominent sub-theme within the theme of influences on providing and receiving treatment was the theme of the patient-healthcare relationship, discussed in nearly all patient interviews. As discussed in chapter five, and reiterated throughout the themes noted in the present chapter, HCPs tended to show a greater focus on diabetes outcomes when presented with comorbid T2DM and potential depression/DSD. They often reiterated the need for patients to understand the impact of poor self-care on physiological outcomes, rather than appreciating the psychosocial context of the situation.

This juxtaposed against multiple patients accounts of the causal attribution of depression/DSD in T2DM, and the influences of such comorbidity, being far more psychosocial such as impacting upon relationships, employment and a sense of self. The contrast between HCP and patient perspectives highlights the potential for misunderstanding and miscommunication within the therapeutic relationship and this could lead to patients feeling misheard by their healthcare providers, with HCPs potentially feeling frustrated in a patients seeming unwillingness to engage with the care they may be suggesting.

As already alluded to, a common theme mentioned by all participants was the influence of poor therapeutic relationships and communication, and how this influences the recognition and management of patients with T2DM and depression/DSD. It was noted that there is a mutual culpability in forging poor

rapport, with both patients and HCPs playing a part in this, which can negatively impact the capacity to address emotional distress in patients with T2DM. One HCP noted that some patients can be obstructive in their demeanour in appointments, often remaining in a state of denial and 'not wanting to hear' what the physician is telling them about their health. They acknowledged a need for HCPs to use good communication skills to work with such patients to be able to communicate health information effectively.

> *"Yeah ... some people just don't wanna hear it, they don't wanna know. Erm ... some people don't wanna change their lifestyle ... and you ... you know there's only ... so much that you could say to them but if they don't wanna change their lifestyle they're not going to do it ... erm ... and then sometimes I think if ... if we ... if we go on too much then it creates a barrier ... because they're like yeah, doctor's gonna say this blah blah ... and they just put a brick wall up, so I think communication skills are very important".*
>
> *[HCP-5: F, 25-39, GP]*

Communication skills and styles were further noted, particularly when considering the impact of diagnosis, considering the amount of information that is given and how it is delivered as crucial. HCP's acknowledged that the way in which they deliver information about T2DM at the time of diagnosis, and throughout the on-going experience of this, can have a negative influence on a patients psychological state. HCP-4 (below) drew upon the notion of not trying to scare patients when delivering important information, which links again to the CSM by Leventhal (434), who suggested that individuals respond to avoid danger, but can also respond to avoid the emotion of fear. In the context of this data, this could mean that a HCP could encourage the initiation of positive health behaviours to avoid the danger of complications. However, should a HCP's communication of health information be too overwhelming for a patient, then they may be scared into avoiding the *feeling* of fear and as such go into a state of denial and/or avoid engagement with services and health-behaviours.

> *" Erm ... trying to think ... I think erm ... definitely ... definitely er ... the ... I think try not to scare patients. You know I think that is really important with diabetes 'cos people can actually be made to be low in mood by us if we're not careful"*
>
> *[HCP-4: F, 40-59, N]*

Further to Leventhal's CSM, this resonates with the Protection Motivation Theory, developed by Rogers in 1975, to explain the effects of fear on health cognition and behaviour (396). From this theory came the Drive Model, by Beck & Frankel in 1981, which theorised that engagement in positive health-behaviours was dependent on the amount of drive (fear) instilled (397). In relation to the data in this study, for patients with T2DM, if their HCP relayed a diagnosis of T2DM, or the risk of complications, with too much emphasis on threat to that patient's health, it can lead to avoidance and denial. However, should they deliver the information in a supportive way whilst instilling low to moderate fear; this could motivate patients to comply with health-protective behaviours. Due to the subjectivity of each patient experience and their personal 'threshold' of what is deemed as low to moderate fear, this creates a challenge in knowing how best to deliver information in a way that encourages patients to engage in self-management, without causing psychological comorbidity through overwhelming them with fear.

This notion was evidenced by patient participants describing a number of negative experiences with consultations regarding their T2DM and/or depression, which affected their adherence to treatment or further help seeking due to a lack of confidence or trust in their care. Patient-9 (below) recounted how he received his diagnosis of T2DM with no consideration or sensitivity, and with no appreciation for the impact of the diagnosis. As such, this patient was left with a huge burden of confusion and feelings of being under-valued. This then shaped his negative view towards his healthcare, likening the doctor to a veterinarian due to their lack of compassion or care in the delivery of health information.

> *"and they came some erm ... don't even know if it was a doctor or consultant, he ... he might have been a vet, I don't know, and he said you've got diabetes, thank you, next patient."*
>
> *[Patient-9: M, >60, No history of depression]*

Further to this, patients also described a lack of rapport building that, as a product of institutional time-restraints, negatively influenced their capacity to fully engage with their HCP. This corroborates discussions earlier in the theme section about both institutional barriers and time-constraints influencing the way in which HCPs conduct their practice. Patient-12, below, described a lack of continuity due to seeing locum doctors, and that this, combined with limited time, left him feeling under pressure and unable to express his feelings. He described embarrassment, particularly with female HCPs, and that the lack of rapport building left him not disclosing what he needed to, as such he would leave appointments with unmet needs for care.

> *"I've always had the impression that they ... that they just give you a set ... a set time and which is ... is not very long at all is it, and … seem to get a ... a lot of locums, locum doctors I've never seen before ... and you sort of don't, like you know, you don't know them, you know sort of er ... you sort of don't tell them too much ... I mean you ... I seem to get embarrassed with telling them ... but you know 'cos I do get dep ... I do get really ... especially where women are concerned, next to women I get ... you know really get shy and all that with er ..."*
>
> *[Patient -12: M, >60, History of depression]*

Further to the issue of rapport building, there was a distinct lack of trust echoed among many patient participants, with a large number expressing concern in regards to HCP attitudes towards to mental health. A lack of compassion was evidenced across multiple accounts, as discussed in chapter five, with a number of patients describing perceptions that their psychological distress was being under appreciated and that their HCP did not empathise well with them. In the narrative of Patient-7, she disclosed

feelings of being patronised and that her doctor had not appreciated her circumstance at all. By telling her to 'put her feet up' and that she 'needed a holiday', he minimised and invalidated her depression, whilst not offering any constructive support or understanding.

> *"When I first was diagnosed at the doctor's ... they were so ... well I think so backward, I went into the office and I just cried ... and he went put your feet up on the desk and I thought you stupid man, you patronising devil, and I just said no 'cos he was sitting there with his feet up on the desk and then he said what's the matter with you … and he went you need a holiday … there isn't the care or the time or the money anymore ... I know they don't understand"*
>
> *[Patient-7: F, 40-59, History of depression]*

While the notion of rapport was often discussed negatively, positive accounts were also offered, reinforcing the vital role the patient-professional relationship plays in successful management for psychological support. Around a third of the patients gave encouraging accounts detailing that they felt that they held good relationships with their HCPs, discussing them taking their time and showing genuine concern, compassion and understanding as the driving forces in their positive appraisal of the relationship.

> *"I get on very well with my doctor, he's great ... and you know at this time … he was really good ... and really supportive, he'd sit and chat to me, you know he arranged for me to see the counsellors and stuff, he ... he was brilliant, he was just worried about me because I was in such a state and er ... I was losing so much weight"*
>
> *[Patient 15: F, >60, History of depression]*

Of interest in these accounts was that the patients with positive relationships with their HCPs appeared to have more positive outcomes in terms of the physical and psychological health, whether or not they had a

history of depression. This emphasises the importance of therapeutic alliance and the influence this has upon patient engagement and self-care.

When considering the concept of rapport between HCPs and patients, appreciation of the wider-life context of patients emerged as a means to improve relationships. The acknowledgement of a patient's surrounding circumstance was often mentioned as crucial to how patients experience their care, highlighting a need for communication skill training to build genuine and/or authentic relationships.

Reiterating areas discussed earlier, HCP-6 described that rather than marginalising patients by outcome measures, viewing them as a whole and taking time to understand and appreciate their wider-life circumstances is more effective at making the patient feel understood and valued, and thus more likely to engage with treatment.

> *" if you build that rapport and if ... if they know that you're looking at them as a whole ... rather than just Joe Bloggs, blood sugars of eight, need to get this down but Joe Bloggs, blood sugars of eight, father of three, carer of his father, who's dying with cancer, financial difficulties, working fourteen hours, getting stressed, you know and then fair enough, I understand these things, and sometimes I find that understanding patients as a person actually builds that rapport and gets them onside because at the end of the day the most effective medicine, I mean and I talked about all the different medicines, different antidepressants, but the most effective one is the one that they will take and getting them on board with you, making that joint decision, is part of encouraging compliance."*
>
> *[HCP-6: M, 40-59, GP]*

This was echoed in patients accounts of positive care experiences, where one account reiterated the notion of HCPs looking at the 'whole picture', providing an integrative approach to diabetes and other aspects of health and quality of life, describing this as not only making them feel valued, but motivated them in their own care and management.

> *" she didn't just look at the diabetes, she looked at the whole picture and I think it's so important to do ... it's not easy but she was efficient, she was organised, she was ... you know she knew her stuff ... you know and if she didn't know she was honest about it, I'll find out for you ... she didn't just diagnose me and leave me to it, it was like constant reviewing ... I felt I wanted to tell her and keep her updated and I think from a patient's point of view it's so important, a lot of patients would withhold information, you know, because they don't trust the person but with <1> I ... I ... I was eager to go and see her"*
>
> *[Patient 16: F, 40-59, History of depression]*

Within the interviews, both HCPs and participants made suggestions of how to improve rapport across a number of domains. One of these facets was the suggestion of allowing consultations to be either led, or largely influenced by, the patient. One HCP described the benefit of allowing the patient to identify what is bothering them or what they would most like to focus on. They emphasised the importance of not rushing or overburdening patients, taking the time to give them an individually tailored consultation and encouraging them to engage in health promoting behaviours. This is particularly salient in the context of T2DM with potential depression and/or DSD, since there could be various and potentially multiple areas of health or wider-life concerns that need addressing. Taking the time to work through a hierarchy, and giving the patient confidence in their ability to work through these, without feeling overwhelmed could offer positive engagement in treatment.

> *"Erm … trying to get to the root of the problem, you know what is it that's causing the most distress … you know what is it that's bothering them the most… and … and working on that in a very individual sense … start looking at that, things ... you know, slowly one ... one thing at a time. so erm ... so I do quite a bit of sort of behavioural activation … so either give them timetables and stuff, get them to ... slowly add stuff in, stuff like that, erm ...but it really*

... it ... it's what they want to focus on. So if ... if they ... if they really want just more focus on the diet then we'll focus ... focus on that"

[HCP 2: F, 40-59, Nurse]

The concept of advocacy and ensuring that patients feel that they are a HCPs sole focus during consultations was evident in patient interviews and reiterated the importance of taking the time to understand a patient whilst demonstrating empathy and understanding. Patient-9, who held no history of depression, still discussed the need to feel understood and as though their physician was interested in them, also that they understood and could be empathic, whilst offering constructive solutions to any concerns raised

"you're the one that matters ... erm ... the ... the better ... but it erm ... I think would go a long towards erm ... patient care ... to take on to people and say I'm interested in you ... . I haven't ... I haven't got any other patients. Erm ... and to ... and to put that, as I say, that arm round your shoulder and say look ... don't need, don't wanna worry because er ... this is not a problem, and if it is these are the solutions or we can help towards them."

[Patient-9: M, >60, No history of depression]

There was a recurring sub-theme of empathy, and while many acknowledged positive experiences, there were also accounts from both HCPs and patients recounting a lack of empathy, particularly when considering the onus of blame in a patient's presentation surrounding their diabetes. Descriptions detailed how stigmatising attitudes, reinforced by the media and society (as discussed in chapter five) can influence care negatively due to a lack of understanding, inducing shame and increasing the likelihood of avoidant behaviours. Blame in the context of T2DM has been recently reported in qualitative research by Brown *et al* exploring the social experiences of people living with T2DM, privileging perception and experience of stigma specific to their diabetes. Not only was there significant blame related stigma evident in people's experience of T2DM, but also that

this altered people's self-perception, adversely affecting psychological health and engagement with services (398).

> *"Firstly I think that erm ... this er ... I think there's a widespread sort of misconception of, for example, diabetes is the fault of the patient … they've made themselves diabetic, well yes they may ... some people may well have made themselves diabetic, you can't generalise a whole population, and you certainly cannot er ... sort of erm ... cast that particular view on any individual before you know the full facts of the ... the... their diagnosis. Erm ... er ... and er ... and so ... so having an open mind is some ... or having a closed mind is the barrier, having an open mind is the ... the ... the thing that you need to have."*
>
> *[HCP-9: M. 25-39, GP]*

Approachability was another facet that was often mentioned as a way to improve the relationship between patients and professionals, not just within the consultation but also giving patients the confidence that they can approach their HCPs between their reviews should any concerns arise, particularly in terms of psychological support. HCP-4 discussed the inadequacy of the Quality Outcomes Framework (QOF), which at the time of this study recommended that HCPs ask depression-screening questions once a year. They reflected upon this being a long period of time, which does not appreciate the complexity of patient experience when managing T2DM and that patients need to feel able to approach their HCP to discuss any concerns, particularly in the context of mental health.

> *" if I'm only asking that question once a year huh, a lot can happen in a year ... and so having an open door policy and saying you know if you do feel that your mood is dropping and that you're losing interest in things that you normally enjoy doing you know please come and talk to someone early rather than leaving it to get to erm ... a worse point"*
>
> *[HCP 4: F, 40-59, Nurse]*

When exploring the theme of the patient-healthcare relationship further, a number of patient accounts evidenced how a poor therapeutic alliance, framed by a distinct lack of trust in both the individual HCP and/or the wider system within which they practice, can have on a negative influence on treatment engagement and health behaviours. One patient reported refusing referrals for treatment outside this relationship due to a lack of belief in their efficacy, while another discussed non-adherence to prescribed medication, but feigning acceptance during a consultation. Patient-7 disclosed that due to a poor relationship with her HCP she did not feel confident in being able to speak openly about her fear and anxiety of anti-depressants. As a result she was prescribed medication that she did not take, but avoided returning to her GP for fear of having to explain or be questioned. This meant that her depression remained untreated for over a year and her needs were unmet as a result of a poor patient-healthcare relationship.

> *"So I left there with a bottle of pills, which I kept in my drawer for probably a year or more and then tipped them down the loo, because I ... no way I could take them"*
>
> *[Patient-7: F, 40-59, History of depression]*

Concerns regarding antidepressant treatment has been shown in wider qualitative research into the experiences of patients with T2DM and depression (399). This research demonstrated themes of fears about addiction and the harmful properties of antidepressants, a fear of taking too many tablets especially when combined with diabetes medications, and the stigma associated with being on psychotropic medication. Although the latter study explored the views and experiences of a Hispanic population, the themes were highly concordant with the findings in this qualitative study. They highlight a need for better knowledge, exploration, and explanation of, the choice in treatments for patients with T2DM and potential depression and/or DSD.

Theme 4a. Patient choice and self-management

The sub-theme of the patient-healthcare relationship merged closely with the sub-theme of patient-choice and self-management, since, as detailed in the account of Patient-7 (above), the relationship impacted on treatment and the patient did not receive the treatment she wanted and was left with untreated depression for a long period of time. The way in which the relationship between patients and their healthcare providers impacted upon choice and self-management was evidenced further with accounts recognising how differences in opinion, about both diagnoses and treatment options, can lead to avoidance or refusal to engage with treatment.

> *" they've got this erm ... diabetic practice nurse ... erm ... and I can't ... I ... her and I didn't see eye to eye ... erm ... and I'm trying to think what it was now ... oh you ... you need, you've gotta do this and do that, and I can't remember what it was, and I thought no, I don't wanna do that, I don't need to do that ... so I didn't."*
>
> *[Patient 13: M, >60, No history of depression]*

In a recent thematic analysis of patient-centred care in chronic conditions management, Hudon *et al* demonstrated a number of themes that corroborate findings within the present analysis. They found that from thirty-two studies (ten of which specified diabetes, one specified depression and six stated unspecified 'chronic conditions'), six major themes emerged including 'acknowledging the patient's expertise' and 'developing an on-going partnership' (400). The patient-centred model by Moira Stewart and colleagues drove their analysis and focus, first developed in the 1980s and fully defined in the 1990s (401,402). This particular model of care has shaped modern medical recommendations, proposing six dimensions: i) exploring both the disease and the illness experience; ii) understanding the person as a whole, iii) finding common ground; iv) incorporating prevention and health promotion; v) enhancing the patient physician relationship; and vi) being realistic. As demonstrated in the data from the present study, a great deal of these six propositions are not being met in the care of people with T2DM and potential depression and/or DSD.

The way in which patient-choice was impacted upon linked thematically to the previous sub-theme of time-constraints, and how limited time often shaped the delivery of treatment, often against the wishes of patients, leaving them feeling unsupported in their needs, especially in relation to depression. It was noted that due to limited time in appointments, or excessive waiting times for psychological therapies, that many practitioners felt a need to prescribe pharmacological therapy to alleviate symptoms, rather that exploring the causes of their poor-coping, or referring onto a therapy that could work through the difficulties patients presented with. One account reiterated that patients do not have the time to 'get everything out', but also that the methods available to GPs are extremely limited, He detailed that this leads to a favouring of pharmacotherapy, over more in depth psychological therapies, and openly admitted that patients are not always adequately supported as a result. This again demonstrated a sense of futility within HCPs who have the desire and intention to do more for patient care, but due to systemic limitations in their roles and the structure of the organisations within which they work, they acknowledge that patient's with T2DM and depression/DSD are often not given the appropriate care they want or need.

> *" erm ... but I think one of the pressures, and I'm sure you've heard this before, is that with ten minutes it's very difficult to get everything out ... which is why most commonly we tend to use pharmacological methods just to try and hitch things along … I've got ten minutes to change thirty, forty, fifty years of ... of mindset, of thinking ... erm ... I've got limited tools … you know, in ten minutes you can't initiate much, you know, cognitive sort of therapy, you can't change the way er ... you can't use these tools to change the way they think and perceive, it's a challenge and ... and I have to be ... hand on my heart I don't always, well er ... most of the time I don't succeed"*
>
> *[HCP-6: M, 40-59, GP]*

The negative impact of the tendency for HCPs to lean towards pharmacotherapy when offering management for people with T2DM and

depression/DSD was reinforced by a large proportion of patients expressing distain towards being put of psychotropic medication should they have any mental health concerns, with a strong preference given to more patient-centred 'talking therapies'. This was evidenced among accounts from both patients with a history of depression and patients without, who were discussing their opinions on treatment from a conjectural stance. A number of patients with a history of depression described negative experiences with psychotropic medication that shaped their negative cognitions and reinforced a fear of needing to take any in the future.

> *"Obviously antidepressants is what my erm ... erm ... the particular one I was put at ... put on I wouldn't recommend to er to a dog because it's an evil ... I've never felt so ill in my life ... I just felt awful."*
>
> *[Patient-11: M, >60, History of depression]*

Other patients held negative perceptions towards psychotropic medication due to the sheer quantity of prescriptions needed to manage their physiological and psychological needs, a factor that needs consideration, as discussed in chapter five (section 5.2.2). In one account a patient gave a detailed account of feeling overwhelmed by the number of medications she needed to take, but also that she felt little to no positive effect from them, believing that through varying side effects and counter-effects, that they 'fight against each other'. Her narrative again reiterated a lack of understanding in terms of psychological needs and a focus from HCPs on diabetes, thus not providing adequate support for depression. She also expressed a desire for talking or group therapy to be able to feel understood and supported through the experience of managing T2DM and depression.

> *"I don't know, I have th ... I have this thing that erm ... all the medication's fighting against each other and somewhere along there's gotta be a winner that's (amused tone) gonna make me feel better, you know ... I think long-term er ... the best treatment is ... is probably the one to one talking and that ... or ... or even in*

a ... a small group er ... I mean that ... as you didn't feel alone, you ... you know because ... you ... you do feel sometimes there's only you that ... you know ... and nobody understands me. (laughs) … but I don't get answers but it's ... it's not only in relation to diabetes, it ... it's erm ... er ... er ... with everything that I ... I just seem to get in a ... I mean at one stage er ... last month I was on twenty nine tablets a day ..... and ... and ... you ... you ... you're ... all that and no results"

[Patient-7: F, >60, History of depression]

Despite a clear preference for 'talking therapies' expressed by the majority of patients, the issue of time-constraints was again etched into the discourse of the interviews through accounts of long-waiting lists for preferred therapies and HCPs active avoidance of exploring these routes due to acknowledgement and assumption of waiting periods. In a HCP account that gave clear merit to the use of counselling or cognitive therapy for people with T2DM and depression, they professed to 'giving up' on the potential of referring patients due to such long waiting lists. The language used reiterates a sense of futility and hopelessness due to the system within with they provide care, and that although they recognise what would be most beneficial to patients, they feel they cannot provide this.

"Erm ... I mean er ... if I've got a diabetic who's depressed I would s ... just start them on a SSRI ... so an anti-depressant basically, I'm not aware of any other therapies. Counselling, erm ... I imagine cognitive behavioural therapy would probably be very good but I often give up on that because there's always a long waiting list"

[HCP-5: F, 25-39, GP]

Further propagating the theme of patient-choice within the data were patient accounts of experiencing favourable therapies, but then discovering that they are again restricted by time in terms of the number of sessions available. Further reinforcing feelings of hopelessness for recovery due to an inability to cover all that needs addressing in the limited time available. One

patient account further substantiated the HCP discussions on rapport, but highlighted that even across multiple sessions, it takes time to feel comfortable and secure to feel ready to open up and share vulnerabilities and fully engage in treatment. This demonstrates that limited sessions only serves to instill an immediate sense of futility, hindering treatment even before it has even begun, and demonstrating a need for authentic patient-HCP relationships built on trust and mutual understanding.

> *"they can say to you at your deepest, darkest moment we can give you six sessions and you just wanna cry for England 'cos you know you aren't gonna get cured in six half an hour sessions or whatever they are. And also to have decent counselling you've gotta get a rapport with a person and if they've only got that one and you don't get that rapport you've ... that's it, huh."*
>
> *[Patient-7: F, 40-59, History of depression]*

Patient-choice is a factor that has been researched in the Pathways study, discussed in previous chapters, by Katon *et al* (159) who developed a collaborative care intervention that offered patients a choice in their treatment for depression and T2DM. They found that offering choice within a collaborative framework improved depression in people with T2DM, although not improving HbA1c, suggesting a need for a greater focus on diabetes self-management within this. In the wider consultations with stakeholders there were a number of suggestions made around tailoring interventions to patients by offering them choice in their care planning, whilst still providing structure to assist in the therapeutic alliance between HCPs and patients. In discussions surrounding education programmes, there were debates about the benefits around group based education such as that of DESMOND versus one-to-one interventions such as those developed specifically for DSD (279), and being able to provide patients with a choice depending on their personal preferences. Often discussed was the need for a triage system that could provide patients with an initial one-to-one consultation to go through a 'funnelling' process to create a tailored treatment plan from the start.

> *"An initial overview was given around the ideas that had already been formulated regarding the intervention, consultation and offering patients a strategic consultation that helps them problem solve and encourages shared decision making. To encourage patients to discuss all problems and work through, in a funnelling fashion, to draw down to most important problem to address and then explore avenues of treatment/solution."*
>
> *[Field-notes from M17: multiple stakeholders]*

Existing examples given of programmes were a GP-referred exercise scheme, where an initial consultation is held with the patient to make decisions about how the patient would like to proceed; and the Year of Care programme (403), where the focus is to engage and empower patients to be proactive with the management of their condition. This was mirrored by the interviews where HCPs suggested that by not only providing patients with relevant information, but encouraging them to connect with the material and take a leading role within the consultation, this can give them a stronger sense of responsibility and culpability over their health choices, resulting in potential improvements in their overall management.

> *"I think you know getting them to engage in looking after their own health outside of this consultation is also very important ... because I think at the end of the day my job is not to tell patients what to do, it is to share information, erm ... it is to consult with them and it's ... well share ... share specialised information that they ... they need to be aware of and just to say look, you're out there for twenty three hours and fifty minutes in the day, you're only in here for ten minutes ...*
>
> *[HCP-6: M, 40-59, GP]*

In wider stakeholder discussions, this was often referred to with suggestions made around the use of tools to assist in self-monitoring and having visual outcome measures to demonstrate progress and drive motivation. There were a number of considerations around the merit of

support between appointments such as through self-help material, telephone support and/or web-based provisions. Suggestions included self-help CBT interventions recommended by NICE, and visual outcome measures such as pedometers and the Warwick-Edinburgh Mental Well-being Scale (404) and the outcomes well-being star (405), to track progress.

As discussed in the previous sub-themes regarding the knowledge, awareness and complexity both in identification and treatment for people with T2DM and depression/DSD, learning styles are paramount to how patients can conceptualise and understand their conditions; without proper understanding they may struggle to know how best to self-manage. Some patients detailed difficulties with dry literature and needing engagement from HCPs to explain and better understand the health information, while some patients found the internet beneficial and actively using modern approaches, such as mobile phone applications, to self-monitor and seek health information.

> *"Okay, well basically erm ... I'm the sort that loves the internet and I just researched everything I could about it [diabetes] erm ... and what the effects can be. So when I see <4> I always say to her I've done this, I've done this and she just goes great. Erm ... done other things like erm ... I'm a gadget freak, so for example I've got an iPhone and on my iPhone I now have a er ... an ap with a plug-in erm ... blood pressure gauge so it records it onto the iPhone, which I can then email to <5> which I do on a regular basis so she can then put them on my notes"*
>
> *[Patient-8: M, 50-59, No history of depression]*

Both the Internet and mobile phone-based interventions have been shown to improve both diabetes and psychological outcomes in people with T2DM (342,406,407). In terms of using the internet for health-seeking and learning, a study of chronic illness and health seeking information on the internet found that the more frequently people with chronic illness used the internet as a source of information, the more likely they were to engage in health promoting behavior (408). Interestingly, Ayers and Kronenfeld also demonstrated that

the a of chronic condition did not determine the use of the internet in health-seeking, but rather that the greater number of chronic conditions was associated with more frequent internet use, which is important when considering the number of comorbidities people with T2DM can have, including potential depression and/or DSD. They also acknowledged some people might not feel confident in using the internet and this needs to be determined when treating people with T2DM and comorbid depression and/or DSD. Similarly, to treatment approaches, patient choice should be offered in learning styles, such as offering education through literature they can take home, through a web-based or mobile phone-based resource, or through interactive education programmes. It is possible that a combination of various learning styles may offer patients the best chance to engage in a learning style that suits them best, but the element of choice and offering patients a chance to choose their best learning approach as well as treatment options could empower patients and offer the most holistic and patient-centred approach in managing such complex conditions.

6.3 Conclusion and chapter summary

Patients with T2DM and comorbid psychological ill health do not currently appear sufficiently supported by existing primary care pathways, with the data from this qualitative study suggesting that this is due to a variety of barriers. Such barriers begin with difficulties in identifying patients requiring support, often as a result of poor distinction between DSD and depression, alongside a number of factors that limit screening success such as time-constraints, limited belief in the efficacy of tools and concerns about patient transparency when responding.

Ne vertheless, should patients in need of psychological support be identified, further barriers can be encountered when providing management. At an institutional level, differences between existing NHS systems can lead to inconsistent care, target driven practice obfuscates the potential for tailored care, and time-constraints prevent robust continuity of care. At the HCP level, there was a lack of understanding regarding guidelines for T2DM and depression, insufficient education and understanding of DSD, poor

relationships and communication with patients, with the humanity of patients obscured by their disease as a result. Lastly, at the patient level, there was a lack of understanding and education about all three conditions, with a lack of engaging in information provided, and cultural and language barriers impeding progress.

Facilitators, with a role to improve potential treatment pathways, were discussed mostly in terms of building education and understanding in both HCPs and patients, and improving the patient-professional relationship. Proposals to improve knowledge were to increase awareness for HCPs through enhanced staff training, publicising the connection between all three conditions, reducing potential stigma through routine screening for both depression and DSD, and improving patient understanding through the inclusion of DSD and depression in diabetes education. The largest proportion of data collected on facilitators regarded the Patient-professional relationship, describing a need for consultations to be largely led and/or influences by the patient, and providing enough time to build relationships and trust, and appreciating patients' wider-life context.

In chapter seven the findings from chapters one to six, are mapped against existing psychoeducational programmes with a view to identify areas that are currently being addressed within existing provision, and identify areas for further exploration. This is then used to inform the design of a potential treatment model for people with T2DM, depression and/or DSD.

Chapter 7 Informing treatment for people with T2DM, depression and/or diabetes-specific distress: A potential model of care

7.1 Chapter overview

In this chapter, I discuss the exploratory findings of the 3D-study in relation to existing primary care and structured education provision for people with Type 2 diabetes (T2DM), depression and/or diabetes-specific distress (DSD). The is done with the view to exploring how current care pathways meet the needs for these individuals and identify any areas for further exploration and addressing within the design of potential future treatment models.

Initially the background and rationale is given for this exercise (section 7.1.2) before going on to provide a detailed overview of the existing education programme (section 7.1.2), giving the theoretical background and content in relation to T2DM, depression and DSD. The mapping process is then discussed, demonstrating how the 3D-study findings relate to the existing programme, how the programme already addresses factors raised in the 3D-study findings, and what areas still need consideration (section 7.3). This process is then used to inform the outline of a potential 3D-model of care for people with depression and/or T2DM and discuss the process and hypotheses for this in the discussion (section 7.4).

7.2 Introduction

7.2.1 Background and rationale

The overall aim of the 3D-study was to inform the design of a potential treatment pathway for people with T2DM and comorbid depression and/or DSD. The study was exploratory, utilising a range of methodological approaches to gain information by which to do so. Firstly, by exploring the literature on T2DM, depression and DSD to form the introduction to the study, and then determining the prevalence of emotional-DSD in a systematic review and meta-analysis building on existing reviews for the prevalence of

depression in T2DM (28). Following this a further systematic review and meta-analysis was performed to understand what existing interventions are successful at reducing emotional-DSD, building upon previous similar reviews conducted for depression in people with T2DM (155,308). This process then led to a qualitative interview study, with supplementary data from field notes collected during development work, to explore the perceptions, understanding and experiences of depression and DSD in people with T2DM, both at the patient and healthcare professional (HCP) level.

Throughout the study, The Diabetes Education and Self-Management for On-going and Newly Diagnosed (DESMOND) programme emerged in the data, in the introduction (chapter one), the systematic review and meta-analysis of existing interventions (chapter three) and the qualitative study findings (chapter five and six). The DESMOND programme is an existing self-management and education programme for people with newly diagnosed or on-going T2DM. It was first piloted in 2006 (392), and then tested in a cluster-randomised trial in 2008 (393) with follow-up data reported in 2012 (311). The programme was shown to be cost-effective when compared with usual care (409), and continues to be delivered across the UK. The programme has evolved into a collaborative name not only for group self-management education, but also toolkits and care pathways for people with, or at risk of developing, T2DM. The collaboration also includes programmes tailored to various groups including young people, people with polycystic ovary syndrome, sleep apnoea, schizophrenia and learning disabilities (Figure 7-1). The programme currently offers six self-management modules, with a 'Newly Diagnosed' and 'Foundation' module at its core. Following on from the core modules is a module entitled 'Going Forwards with Diabetes', which is aimed at individuals who have had T2DM for more than a year and have already attended the original foundation course (410).

The original DESMOND programme content includes a small section on psychological well-being and depression within its curriculum, and discussions within stakeholder meetings (as reported in chapters four to six) highlighted that further to this, the DESMOND 'Going Forwards with Diabetes' programme includes a core module entitled 'Balancing Life and Diabetes', which discusses thoughts and feelings in relation to diabetes. The main

outcome of the final stakeholder meeting suggested the potential of developing a DESMOND module specific to depression and/or DSD for people with T2DM, building upon existing work

Figure 7–1: The Diabetes Education and Self-Management for On-going and Newly Diagnosed (DESMOND) Family overview, taken from the DESMOND collaborative website(411)

While the 3D findings demonstrated that improved education and understanding is certainly needed for people with T2DM and comorbid depression and/or DSD, and that this could be beneficial in a treatment programme, there were further fundamental concerns within therapeutic relationships and HCP understanding and practice that highlighted additional areas to address in future care pathway design. As such, it was decided that, in order to definitively understand which areas are currently being addressed in the existing provision of DESMOND in people with T2DM, it would be useful to map the findings of the 3D-study against the existing DESMOND

programme and to use this process to inform a potential treatment model design.

7.2.2 Detailed overview of an existing programme of care

The DESMOND programme began with the grounding principle of acknowledging that an individual with T2DM is the person who manages the condition, in that they are the ones who live with it each day, experiencing the symptoms and making decisions regarding how to manage these. While they can be assisted and directed in their care, it is the individual person who is responsible for their management, identifying that nearly all barriers to self-management exist within that individual's world. As such, rather than traditional models of care telling someone what they should do, the DESMOND programme was built upon the notion that people should be supported to make whatever they deem to be the best decisions to achieve their optimum quality of life living with T2DM, and to be encouraged to become the expert in their own understanding and management of their condition.

The programme was developed using various theoretical constructs, some of which have been previously discussed within the 3D-study findings. The first theory being Leventhal's Common Sense Model of Illness (CSM), as discussed in the qualitative study findings in chapters five (section 5.2.1) and six (section 6.2.2). The model is a dominating theory within health literature, suggesting that when an individual experiences illness or the possibility of deteriorating health, they construct mental representations, or illness beliefs, about their condition in order to comprehend, and ultimately understand how to manage, their health (355). The model highlights the importance of exploring how a person views their illness, recognising how this can in turn aid understanding of what initiates an individual's willingness to engage in behaviours that can improve or maintain their health (412).

The second theory that supported the development of the DESMOND programme was Bandura's Social Learning Theory (SLT), which was built upon traditional behavioural theories by suggesting that individuals can learn through observation, highlighting that internal cognitive states are essential to this process and stressing that even if something is learned, this does not

necessarily mean that changes in behaviour will occur (413). The concept of self-efficacy is fundamental to the SLT, which refers to how well an individual believes in their own ability to carry out certain behaviours, or to achieve goals that they set out to achieve. When considering T2DM and perceived diabetes-related psychosocial self-efficacy, this could refer to how well an individual believes in their ability to adhere to a healthy diet, or to regularly monitor and maintain their blood-glucose levels(414). SLT and self-efficacy denotes that an individual may learn and understand about what they *should* do in order to improve their health, but if they do not possess the core belief in their ability to carry out such tasks, then the change in behaviour is unlikely to occur. As such, education and treatment should aim to empower individuals to believe in their ability to engage in identified health behaviours rather than simply identifying what needs to be done.

The last theoretical underpinning to the DESMOND programme was established from multiple theories but rooted in the main idea that learning needs to occur within an individual's 'zone of proximal development', as discussed by Vygotsky (415). The zone of proximal development refers to the notion that people come to a learning environment at different stages of understanding. For example, in relation to T2DM, some people may have already acquired a good breadth of knowledge about their condition, while others may have entirely rudimentary understanding of T2DM and need to start from the 'grass roots' of learning about the condition. This means that education needs to be tailored to meet each individual's needs so as to establish the best possible learning and development.

The original DESMOND programme is a six-hour structured education programme that can be delivered to up to 10-12 people (and a member of their family/carer) by two DESMOND trained educators. The programme is for newly diagnosed T2DM (up to twelve months post-diagnosis) but can be adapted for those with established T2DM (more than 12 months post-diagnosis). DESMOND provides participants with a resource pack that conveys the core messages from the programme as well as providing additional worksheets for participants to work through outside of the session. The content of the programme is outlined in Table 7-1, which demonstrates the various stages in the programme and theories underpinning each section.

This was adapted from the paper published by Skinner *et al* (392), which reported the original pilot of the programme, to represent the most recent version of the curriculum.

Table 7-1: Outline of the Diabetes Education and Self-Management for On-going and Newly Diagnosed programme, adapted from Skinner *et al* 2006 (392)

		Theory	Sample activity
	Session 1		
A	Introduction and Housekeeping		
B	The Participant Story	CSM	Participants asked to tell their story of how they discovered they had diabetes and their current knowledge of diabetes
C	Type 2 Diabetes and Glucose	CSM DPT	Use participants' stories to support them learning how the body regulates blood glucose
D	Managing Blood Glucose	SLT DPT	Support participants exploring benefits of monitoring and how to use it for feedback
E	Food Choices: Glycaemia and Insulin Resistance	SLT DPT	Knowledge and skills for food choices to control blood glucose
F	Reflections So Far: Part One	SLT	Participants reflect on what issues have come up from the programme so far
	Session 2		
G	Reflections So Far: Part Two	SLT	Participants reflect on what issues have come up from the programme so far
H	Long-Term Effects of Type 2 Diabetes	CSM DPT	Use participants' stories to support them discovering how other risk factors (BP, Lipids, depression, etc.) affect diabetes and development of complications
I	Physical Activity	SLT DPT	Exploration of benefits and barriers to physical activity
J	Food Choices: Focus on Fat	SLT DPT	Knowledge and skills for food choices to reduce risk factors
K	Diabetes Self-management Plan	SLT	Participants supported in developing their self-management plan
L	Questions and Future Care	CSM	Check that all questions raised by participants through have been answered and understood. Follow-up care outlines
	Abbreviations: CSM: Common-Sense Model; DPT: Dual-Processing Theory; SLT: Social Learning Theory		

The programme facilitates learning by guiding and asking participants to contribute to the content of the sessions, initially exploring participant illness beliefs and their current understanding of their condition. It then moves on to go into greater detail of T2DM and glucose, and the management of blood glucose considering nutritional intake and physical activity in potential self-management plans. Within the session entitled 'Long-Term Effects of Type 2 Diabetes', the curriculum touches upon how both DSD and depression can

impact upon diabetes self-management. The programme guides participants to consider how they may feel about their diabetes and how this impacts on their self-management behaviours, considering the long-term effects this could have and how they may improve their mood, such as through physical activity, seeking social support from family and friends, and/or seeking therapy or medication through the GP.

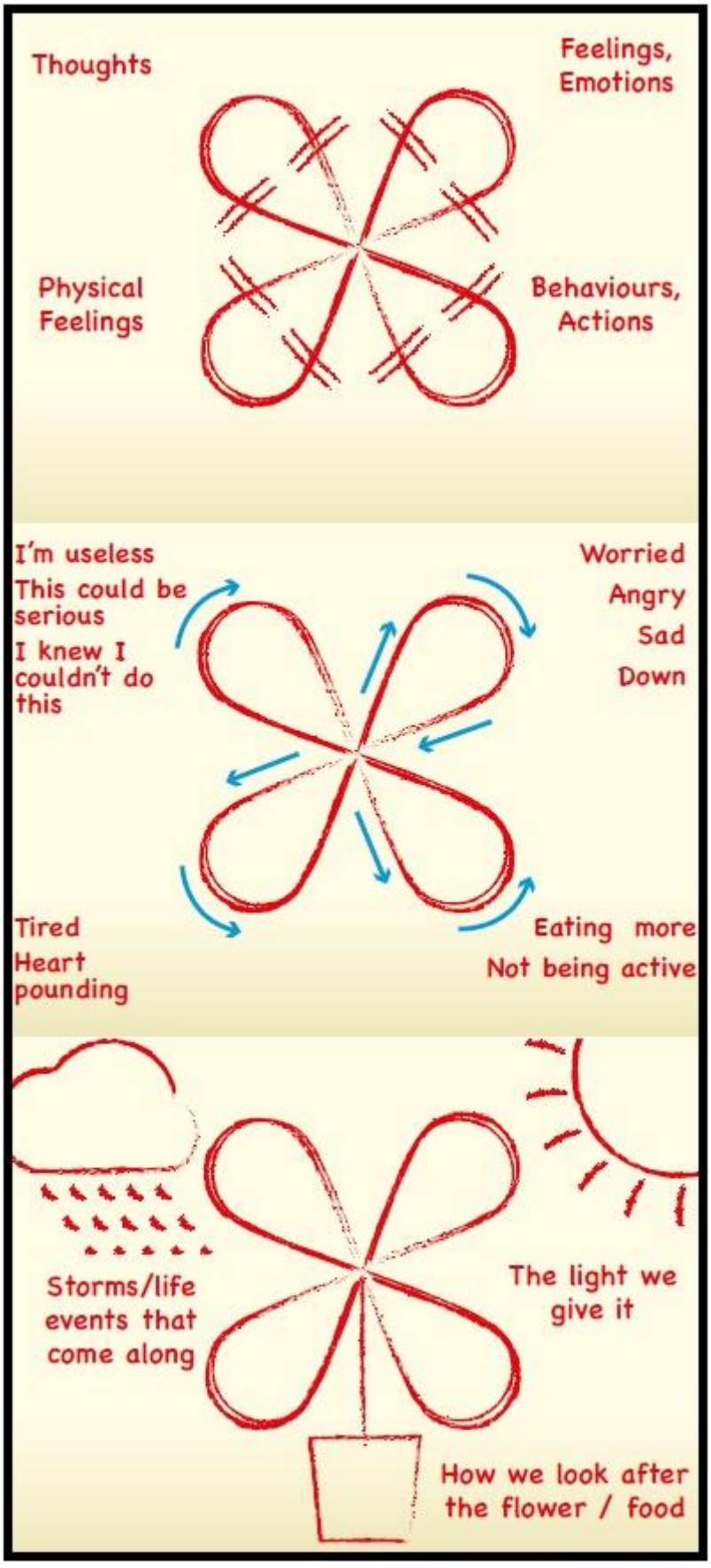
Further to the original DESMOND programme, which very briefly touches upon psychological well-being but has a greater focus on diabetes self-management and physiological outcomes, the DESMOND collaborative developed the DESMOND 'Going Forwards with Diabetes' module. This module was developed to reinforce learning and to reduce the risk of education diminishing over time by providing a continued series of education and self-management sessions to people who have already attended the original programme. Within the 'Going Forwards with Diabetes' curriculum there are five segments entitled 'Balancing Life and Diabetes' that are incorporated within the standard self-management sessions which consider thoughts and emotions in relation to T2DM.

The focus of the 'Balancing Life and Diabetes' sessions is to encourage participants to firstly acknowledge the potentially strong thoughts and feeling they may have in relation to their diabetes, and to recognise that these feelings are both normal and valid. Participants are encouraged to also consider the wider-life pressures and demands that they manage alongside their diabetes, and recognise the impact of avoiding or neglecting their diabetes both on their physical and psychological health. The sessions use interactive and visual material in the form of worksheets that participants can work through to problem-solve and consider constructive strategies to managing both their diabetes amidst their wider-life demands, as well as considering how to maintain these strategies going forwards.

While the 'Going Forwards with Diabetes' programme is still grounded in the theories that form the basis of the original DESMOND program, the content in the 'Balancing Life and Diabetes' sessions draws upon further psychological theories including those from Cognitive Behavioural Therapy (CBT) and literature on resilience. For example, in one session, entitled 'The Diabetes Flower', the curriculum uses cross-sectional formulation, also

known as the ‘hot-cross bun formulation’, that was developed within CBT to assist in the process of identifying a model of how an individual experiences a problem and to consider this when developing a targeted treatment plan (68). The cross-sectional model, as discussed in chapter one, is a 5 stage model with four stages (thoughts, mood, behaviour and biology) that interact bi-directionally to create the fifth overall stage of the environment or situation that an individual is in as a result of the interaction between the previous four stages. In the DESMOND session, this has been translated to the image of a flower (Figure 7-2); with four petals to represent the four stages of the model, which forms a participant’s situation (stage five). The image demonstrates how the bi-directional association between the stages establishes a vicious cycle between an individual’s thoughts and feelings, and their behavior, and subsequent physical symptoms. The curriculum uses the analogy of a flower to consider how the different petals interact with each other and how external influences such as negative life events (storms) can affect the flower, and to consider the ways in which an individual can take care of themselves (the flower) through positive self-care both psychologically and physically (food and sunlight).

Figure 7–2: The Diabetes Flower, from the 'Balancing Life and Diabetes' sessions within the Diabetes Education and Self-Management for On-going and Newly Diagnosed (DESMOND) programme, 'Going Forwards with Diabetes' module, © The DESMOND collaborative 2014



Another session in the curriculum, entitled 'Ways to Manage the Challenges of Life and Diabetes', draws upon the notion of resilience, and the work of Michael Neenan, who considered ways to develop resilience, drawing again upon a cognitive behavioural model (416). Neenan discussed the traditional view of resilience being that people 'bounce back' from a crisis, and that this concept can in fact be a hindrance to well-being as it implies a speedy and seemingly effortless recovery, which can lead to self-criticism as a result of not being able to achieve such an ideal at times of adversity. His work highlights that adversity, and the resilience to coping in the face of adversity is an entirely subjective construct and this needs to be acknowledged and adapted to each individual when considering treatment. Further to the work of Neenan, the programme draws upon subjective well-being from the work of Hefferton and Bonniwell, who consider positive psychological approaches to develop resilience and the need for acknowledging it as a multi-definitional construct. This highlights not only the subjective nature of coping, but also the flexibility required in being able build resilience, highlighting the need for acknowledgement of the negative thoughts and feelings in order to build upon and regain positive experiences (417).

Within the 'Ways to Manage the Challenges in Life and Diabetes' session, the programme encourages participants to consider a more realistic view of resilience and recognise that it is most often neither easy, nor without effect upon the individual. The programme highlights that life events will often leave an effect on a person, and that the notion of 'bouncing back' is both unlikely and unrealistic. The curriculum uses strategy cards (Figure 7-3) to facilitate understanding and highlights that there is no right way of coping, and that what may work for one person, may not for the other, and that multiple attempts at varying strategies may be needed before improvement is seen. Participants are encouraged to consider differing approaches to coping and to allow flexibility within themselves to try different tactics without feeling weak or a failure if they do not experience benefit initially. The programme again normalises and validates emotions, highlighting that experiencing negative thoughts and feelings does not mean that they are not coping, but rather that they are journeying through a process of adjustment. It encourages participants to acknowledge that they need to allow themselves to feel rather

than trying to bury or avoid feelings, reiterating that it is both normal and understandable for negative thoughts and feelings to occur, and that acknowledging and experiencing these is the first step in being able to manage and accept them.

Figure 7–3: Strategy cards using the 'Balancing Life and Diabetes' sessions within the Diabetes Education and Self-Management for On-going and Newly Diagnosed (DESMOND) programme, 'Going Forwards with Diabetes' module, © The DESMOND collaborative 2014

7.3 Mapping Exercise: Process and Findings

To understand how current provision within primary care and referrals to the DESMOND programme addresses factors raised in the 3D-study findings, the outcomes from chapters one to six were mapped against the DESMOND programme curriculum. The mapping process consisted of moving

systematically through the 3D-study findings, summarising the key themes and findings within each stage of the exploratory study.

Following this, the curriculum from the DESMOND 'Newly diagnosed' and 'Going Forwards with Diabetes' were examined, continually referring back to the summaries of the 3D findings to identify areas that are currently being addressed within the DESMOND programme and primary care. Further to this, areas that need further exploration or consideration in the influence to future treatment protocols for people with T2DM and comorbid depression and/or DSD were noted.

An overview of the mapping process can be seen in Figure 7-4, which demonstrates the main findings from the 3D-study work across chapters one to six, and how the DESMOND programme already addresses areas of interest. The diagram also demonstrates areas that are currently unaddressed by current provision that show merit for exploration and consideration in the design of a care pathway for people with T2DM, depression and/or DSD.

In the review of the existing literature (chapter 1) the key points that emerged were that both depression and DSD are prevalent in people with T2DM, with depression shown as having a 30% prevalence (26-34) and DSD estimated at 18-35% (134,139). Depression has also been shown to be more prevalent in those with a longer duration of T2DM compared to those with undiagnosed or newly diagnosed T2DM (66). Whilst both DSD and depression are important concerns in people with T2DM, they are both under-recognised and under-treated (110-112,143,144), despite current guideline recommendations to screen for psychological well-being and provide subsequent treatment for people with T2DM (114,115). DSD is poorly understood in both research and practice, and can be misdiagnosed as depression, with a number of studies demonstrating that patients, who scored as depressed on self-report measures, when assessed in further detail, did not meet the criteria for clinical depression (118,182) and in many cases appear to be diabetes-related rather than actual psychopathology(186). While the relationship between depression and glycaemic control is unclear and varied, DSD and HbA1c are distinctly correlated (157). A number of concerns are faced in the identification of both depression and DSD in people with

T2DM due to poor understanding and a lack of differentiation between depression and DSD, as well as confusion between symptoms of T2DM and those of depression. There is a need for contextual recognition of each individual's case when presenting with T2DM and poor coping, accounting for the wider-life context across a bio-psycho-social model. Promising results have been seen in the collaborative care model (CCM), but this has only been in depression and not in DSD(178) with very few interventions designed specifically to address DSD in people with T2DM (186).

In the systematic review and meta-analyses to determine the prevalence of emotional-DSD in people with T2DM (chapter two), the findings demonstrated that the prevalence of emotional-DSD in people with T2DM is 40%. The findings also demonstrated that prevalence rates are influenced by both glycaemic control and duration of T2DM diagnosis, and the type of scale used to assess and identify emotional-DSD. Prevalence was seen to be higher when the DDS scale was used, which is a more comprehensive and T2DM specific scale (303-305). Prevalence rates increased as HbA1c scores increased (32% to 62% as HbA1c scores increased from 7.0% to 9.9%), and higher prevalence was seen in those with more newly diagnosed T2DM, which steadily reduced as the durations increased. This supports a number of findings in the literature review in chapter one, corroborating the relationship between glycaemic control and DSD, and creating an interesting consideration between the relationship of DSD and depression with T2DM, since depression is more prevalence in people with longer held diagnoses but DSD demonstrated as more prevalent in those with more newly diagnosed diabetes.

In the systematic review and meta-analysis of the existing interventions in the treatment of emotional-DSD in people with T2DM (chapter three), the findings demonstrated that interventions were successful in improving both DSD ($p=0.003$) and HbA1c ($p<0.001$), but not BMI ($p=0.833$). Secondary analyses demonstrated notable results for multiple intervention characteristics when comparing studies that adopted them compared with those that did not. Near-significant reductions in emotional-DSD were seen in studies that utilised coping-skills training ($p=0.054$), with substantial but non-significant reductions seen for studies adopting a collaborative care

approach, demonstrating a more than three times greater reduction compared to those that did not. Significant reductions in HbA1c were seen for interventions that incorporated social and/or peer support (p=0.029) and utilised a mobile-phone based interface (p=0.038). Although non-significant, notable reductions were also seen in interventions including web-based interventions with a more than three times greater reduction compared to studies that did not.

The findings of the qualitative interview study to elicit and explore the understanding, views and experiences of Type 2 diabetes with depression and/or DSD (chapters four to six) demonstrated an overarching theme of 'Knowledge, Awareness and Perception' of psychological comorbidity in people with T2DM. Beneath the overarching theme developed four key sub-themes: 1) 'Illness Beliefs', 2) 'The Impact of Illness and Comorbidity', 3) 'Influences in Identification and Assessment', and 4) 'Influences in Providing and Receiving Treatment'.

Within these themes, sub-themes and key factors to consider in the development of care-pathways for people with T2DM and poor coping were that there was considerably poor understanding of both depression and DSD in relation to T2DM, not only in patients but also in HCPs. The data also demonstrated that DSD is obscured by depression, with not only a stark confusion between the two conditions and often a lack of differentiation between them at all. Further to this a theme of stigma surrounding both T2DM as well as psychological health was seen, and that although naïve, there were multiple accounts of DSD, suggesting a corroboration with the prevalence estimates in chapter one and the high prevalence demonstrated in chapter two. Of note was that DSD was considered far less stigmatising than depression, with the label of being 'distressed' not having the powerful negative connotations and impact as being labelled as 'depressed'. A strong theme within the data was that of the therapeutic relationship between HCPs and patients, demonstrating a distinct lack of patient centred care and a strong discord between how HCPs viewed comorbid depression and T2DM and how patients conceptualised not only the impact of their illness but how they wished their comorbidity to be managed. Further to the concerns within the therapeutic relationship and a lack of holistic care was a lack of

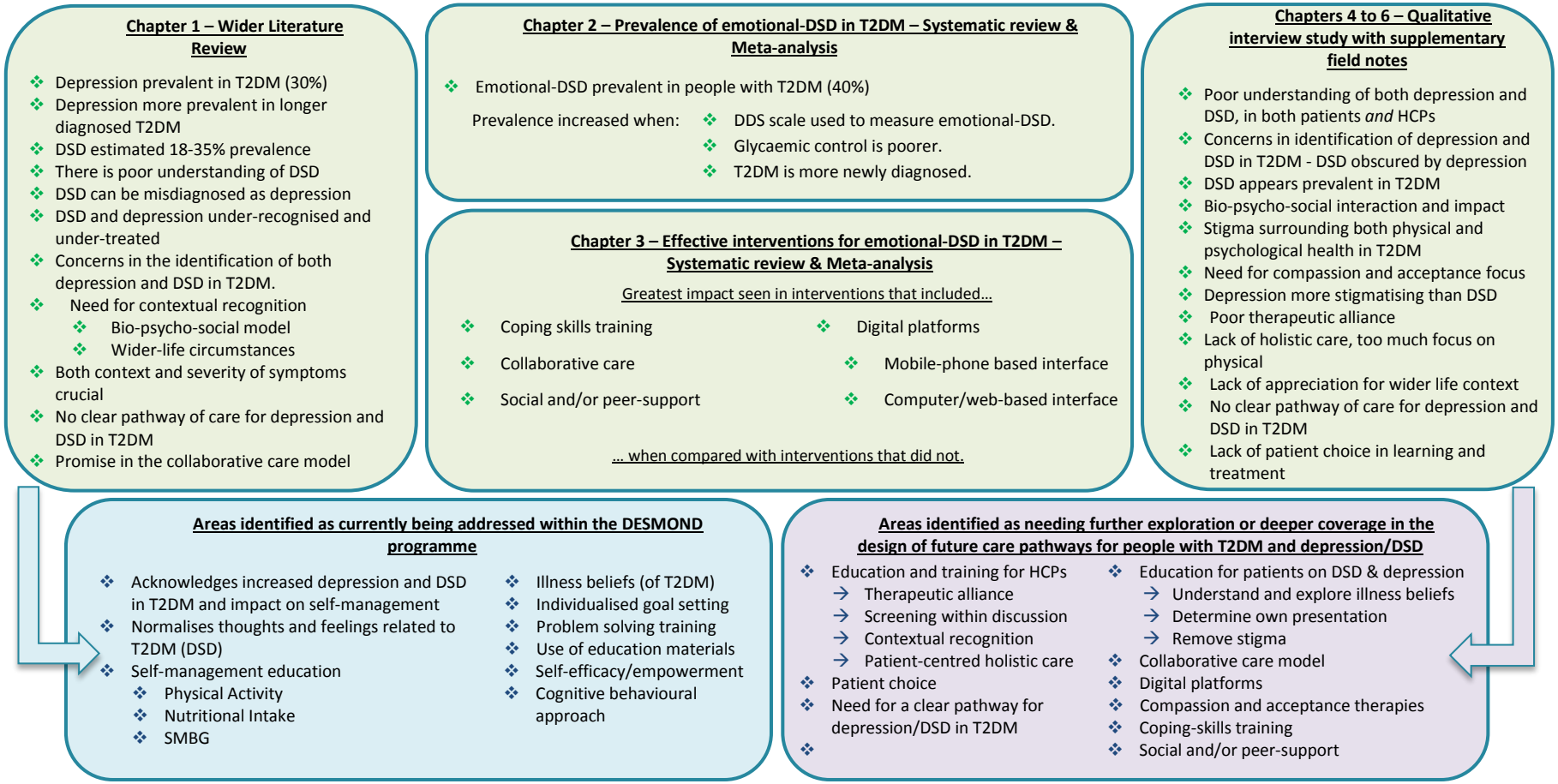
established pathways for depression and/or DSD in people with T2DM. This meant that treatment options varied considerably and were often either inappropriate or not preferred by the patients, highlighting a continuing concern for patients with T2DM and poor coping being left with unmet needs.

When mapping the findings of the current 3D-study to the DESMOND curriculum and the DESMOND 'Going Forwards with Diabetes' module with 'Balancing Life and Diabetes' segments, a number of areas were highlighted as already being addressed in current provision within the DESMOND programme. The main factor being the use of structured self-management education that includes physical activity, nutritional information and self-monitoring of blood glucose levels. The programme is grounded in self-efficacy and empowerment theory and delivered in a way that reinforces this, using cognitive behavioural theory to frame the sections on psychological wellbeing, acknowledging the increased prevalence of depression and DSD in people with T2DM, and considering ways to improve wellbeing with individualised goal-setting, problem solving and coping skills training, and providing educational materials to facilitate this.

Areas of interest for further exploration or consideration were that education is needed not only for patients but also for HCPs, with a distinct lack of understanding surrounding both depression and DSD in T2DM. Concerns in the identification and screening for depression and/or DSD in people with T2DM were highlighted, and a need for discussion, dissemination and contextual appreciation when identifying patients with poor well-being. There is a lack of clear care pathways for depression and/or DSD in people with T2DM, further complicated by a lack both patient-centred and holistic care in current provision, with a lack of therapeutic alliance, suggesting a need to better training and education in HCPs. Intervention factors that emerged of interest were patient choice in both learning styles and treatment options, the use of a collaborative care model, using accountability through self-reported feed-back, telephone support and/or feedback, and social and/or peer support. While there were a number of areas identified as being addressed within the DESMOND programme, and further points for consideration, these should not be viewed as an 'either or' scenario, and further consideration is needed in the contemplation of a potential treatment model for people with

T2DM, depression and DSD, this is reflected in greater detail in the discussion (section 7.4)

Figure 7–4: Overview of a mapping exercise to explore and compare the 3D-study findings against existing Diabetes Education and Self-Management for On-going and Newly Diagnosed (DESMOND) programmes



[Abbreviations: 3Ds – Diabetes, depression & distress; ↓DB: Decreased Body Mass Index; ↓D: Decreased diabetes-specific emotional distress; ↓H – Decreased HcA1c; BME – Black Minority Ethnic; DSD – Diabetes specific distress; Emotional-DSD – Diabetes-specific emotional distress HbA1c – Glycated Haemoglobin; HCP: Healthcare professional; SMBG: Self-monitoring of blood glucose; T2DM – Type 2 diabetes]

7.4 Discussion

7.4.1 Key findings

Through the exploratory nature of the 3D-study, multiple facets were identified as being potentially useful and important for consideration when outlining a model of care for people with T2DM and comorbid depression and/or DSD. This included a need for better understanding and appreciation for not only depression and DSD in T2DM, but the wider-life context within which these may present, to not only improve identification, but also to provide the most appropriate and tailored care. Merit was suggested in interventions that included coping-skills training, adopted a collaborative care approach, incorporated social and/or peer-support, and adopted digital platforms such as mobile-phone or web-based interfaces.

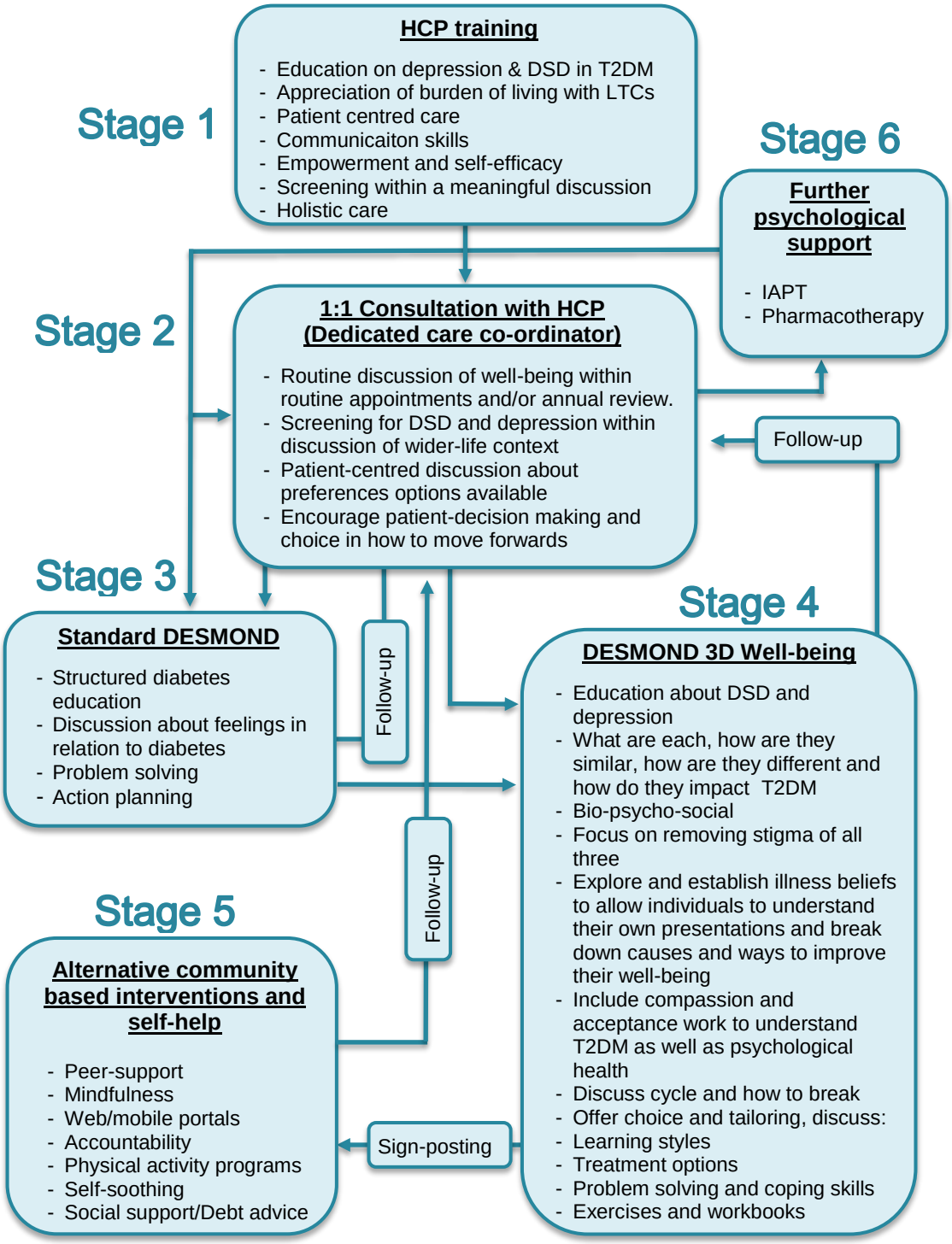
Current provision exists for primary care referrals to a structured self-management education programme for people with T2DM, which includes depression and DSD within its curriculum. While the DESMOND programme addresses a number of the areas identified within the 3D-study findings, no clear care pathway currently exists for depression and/or DSD in people with T2DM, meaning that there is a lack of understanding as to how best to identify and manage people with these prevalent comorbidities. While the existing education programme acknowledges the increased prevalence of depression and DSD in T2DM and includes this within its curriculum, this is only briefly touched upon within a greater physiological T2DM focus. The programme includes ways in which to improve psychological well-being, but does not offer further solutions beyond directing patients back to their general practice for further discussion. This highlights a potential concern since the 3D-study demonstrated concerns within general practice due to a lack of patient-centred and holistic care, with poor therapeutic alliance between patients and their HCPs, meaning that should patients with depression and/or DSD require further support following attending existing DESMOND programmes, then they could be left with unmet needs.

7.4.2 A potential model of care

The main factors identified for consideration were the training and education of HCPs to be able to appropriately identify and differentiate between depression and/or DSD in people with T2DM, and to incorporate discussion and contextual appreciation of bio-psycho-social interactions and individual presentations within a screening process. Further to this, HCP training is required in patient-centred and holistic care, to encourage better therapeutic alliance and empower patients to make choices in their own care and encourage better engagement with services. Further to HCP education, education for patients with T2DM and depression/DSD is vital, and while this is touched upon in the existing DESMOND programmes, more detailed and focussed education may be needed. This should focus on improving understanding of the conditions and remove stigma, but also to allow patients to understand and make sense of their own psychological well-being, use this acquired knowledge explore appropriate strategies and treatment options depending on their presentation.

A potential model of care based on the findings of the 3D-study for people with T2DM and comorbid depression and/or DSD is outlined in Figure 7-5. The 3D-model demonstrates a five-stage process building upon existing provision within current primary care and education programmes to offer a clear and defined process for individuals with comorbid depression and/or DSD and T2DM. The 3D-model recommends a stepped and collaborative care approach, which, as discussed in the previous chapters, is defined as providing treatment of varying intensities through a sequential treatment plan and utilising any of the aforementioned range of treatments depending on the individual case, preference and response (59,184). Adopting such an approach defines and sets targets, offering self-management and support services using a case manager who implements the care plan (114). Stepped and collaborative care models have been shown to improve depression and DSD, but not HbA1c in people with T2DM (159,338) suggesting a need for further consideration into how best to improve physical and psychological health in people with comorbid T2DM, depression and/or DSD.

Figure 7–5: The 3D Model of Care for people with T2DM, depression and/or diabetes-specific distress



[Abbreviations: DSD – Diabetes-specific distress; IAPT – Improved Access to Psychological Therapies]

Stages one and two

The 3D-model highlights that before any intervention can be provided to patients with T2DM, training and education is required at the HCP-level to improve understanding of depression and DSD in the context of T2DM. Further to this, it would aim to also (re)familiarise HCPs with patient-centred and holistic approaches of care to improve therapeutic alliance with patients, encouraging empowerment and self-efficacy for patients to make choices in their own management of T2DM, depression and/or DSD. Current initiatives are already in place to improve therapeutic alliance and to build and maintain a partnership approach between HCPs and patients within the Year of Care (YOC) programme (403). The YOC programme was established as a new approach to standard annual reviews for people with long-term health conditions, using diabetes as a paradigm within the model. Similarly to the DESMOND programme, the approach considers the individual with diabetes as the person responsible for self-management, considering the patient as being 'in the driving seat' of their care. The programme believes that care should be a process of facilitation to support individuals to take charge of their management and empower them to tailor their care through shared decision making within their routine practice through constructive and meaningful discussion with their HCP. The YOC has been shown to be successful and is endorsed by the National Institute for Health and Clinical Excellence (NICE) (418) and The Royal College of General Practitioners (RCGP) (419). Although not yet fully implemented, it suggests that there is no need to 'reinvent the wheel' as discussed within the stake-holder meetings in the qualitative study. While the YOC has been developed for people with multiple long-term conditions and complex needs, and acknowledging this within a treatment model for depression and/or DSD is valuable, this does not discount for a need for greater understanding and training regarding DSD and depression in relation to T2DM. The YOC does not include depression and DSD specifically and this is still a factor that needs addressing to improve identification and exploration, but also to provide a better knowledge base for HCPs to best support patients within a holistic and patient-centred approach to care.

The 3D-study findings demonstrated a trend in primary care for conditions to be treated separately, or for a focus to be given to one condition more so than the other, often against patient preferences. This was evidenced in the qualitative study, where HCPs demonstrated a distinctly greater focus on the physical aspects of T2DM, whilst patients preferred to concentrate on psychological concerns. Although multi-morbidity clinics are gaining popularity in the UK (420), the disparity evidenced in the 3D-study data appears indicative of a need for further training into managing conditions holistically and to consider not only the physical and psychological health of a patient, but also the wider social context within which they experience their conditions.

Screening and identification of psychological well-being emerged as a distinct barrier in the treatment of people with T2DM and comorbid depression and/or DSD throughout the 3D-study. Concerns were raised in the lack of understanding and differentiation between DSD and depression, but also that there was a distinct lack of faith in screening tools and processes held by both HCPs and patients alike. As discussed in chapter one, screening can only serve to be efficacious and ethical when embedded within a comprehensive diagnostic and treatment plan (59), which has been supported by collaborative care interventions for depression and T2DM that demonstrated positive outcomes from identification through screening supported by diagnostic confirmation and subsequent appropriate treatment (178,179). Such concerns could be addressed through training HCPs to screen within meaningful discussion, perhaps initially with regular and routine discussion of well-being during routine appointments and/or annual review, but should an individual demonstrate within this discussion the potential for depression and/or DSD then move on to the use validated tools. Due to the increased risk and nature of depression and DSD in people with T2DM, and the possibility of either developing and/or progressing over time, the 3D-model recommends on-going screening as part of continuing care-plans, such as every three months, but with regular discussion of well-being to remove stigma and normalise the acknowledgement of psychological health in relation to T2DM. The training would encourage HCPs to only use tools within a compassionate and patient-driven discussion and exploration of their wider-

life circumstance, exploring the context within which they may be presenting with emotional concerns so as to establish whether the patient is experiencing depression and/or DSD. Reassuring patients that the tools are being use purposively and with clear and outlined treatment options could reduce feelings of feeling marginalised or as part of a 'box-ticking' exercise, as was reported in the qualitative study. Training and awareness could encourage HCPs to recognise the utility of screening not only as a measure for identification but to use within a management programme to assess progress and allow for potential alterations to care plans in the future.

Stage three

The DESMOND programme is a robust and well-established programme of self-management education for people with T2DM that has demonstrated reductions in HbA1c and depression scores at twelve months, although the effects upon DSD could not be established due to no baseline DSD scores being recorded (393). The aim of the 3D-model was to build upon existing systems for people with T2DM to inform potential treatment that better caters for people with T2DM and poor psychological health. With this in mind, the 3D-model recognises the effectiveness of utilising the original DEMOND programme as a first step in a stepped care programme for people with T2DM and potential depression and/or DSD. Embedding the existing DESMOND programme within a clear and organised follow-up schedule with a care co-ordinator can allow for the discussion of any improvements, changes, or unmet needs following attendance. One could hypothesise that an individual presenting with DSD as a consequence of poor T2DM understanding and management may experience benefit from the original DESMOND programme alone. Patients with more deep-rooted emotional concerns, however, may require further exploration of DSD and depression within a psychological well-being focussed education session. The 3D-model recommends regular and repeated follow-up following each stage within the process to allow for the discussion and reviewing of any changes, in accordance with collaborative and stepped care models. This would aim to encourage and empower the patient to reflect on how they feel about the care

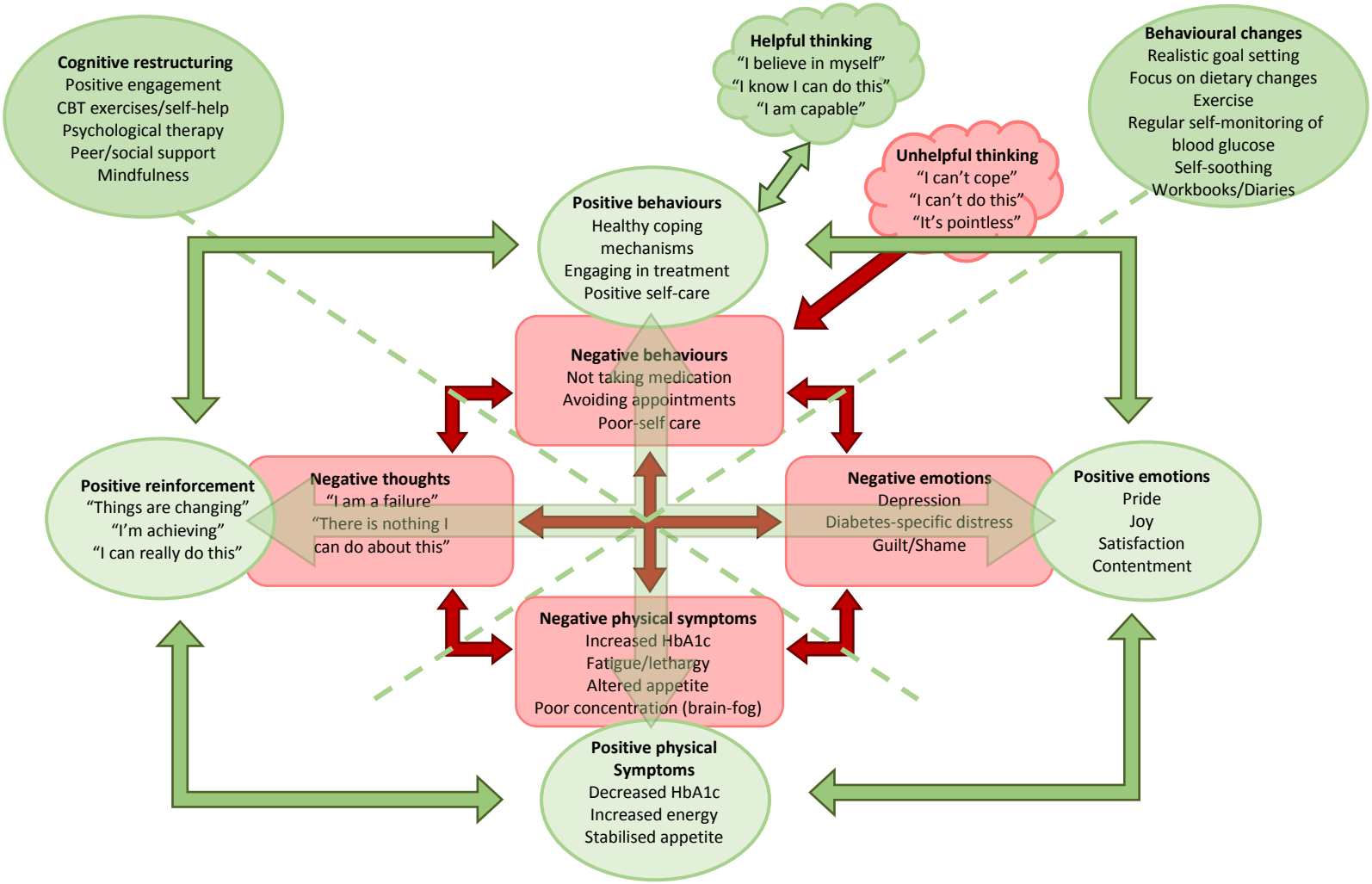
they have received, whether they feel supported thus far and whether they feel further support would be beneficial.

Stage four

The next step in the model is for individuals who have attended the original DESMOND programme, but who demonstrate in follow-up that they are still experiencing depression and/or DSD or wish to continue with more psychologically focussed support. This stage would be an additional DESMOND module focussing solely on well-being in T2DM to offer adequate space for individuals to explore how they are feeling and to reflect on potential strategies for improving their depression and/or DSD. Such a programme within the 3D-model would include education about both depression and DSD, highlighting the similarities in their presentation but the importance of deciphering between the two to be able to explore appropriate treatment options and self-help strategies. The programme would encourage participants to explore their own presentations and encourage consideration of their wider-life context and the factors that influence their psychological status. As part of this, the programme would aim to improve understanding of the biological basis of depression and the interplay between T2DM, depression and DSD, with a focus on removing stigma and negative assumptions about poor coping. Incorporating elements of Compassion Focussed Therapy (CFT) (366,367) and Acceptance and Commitment Therapy (ACT) (370,371) as discussed in chapter 6, could facilitate the removal of stigma and shame associated with physical and psychological ill-health, and encourage the mindful acceptance of thoughts and emotions relating to this. It is likely that specialist training and/or the employment of psychologists would be needed in the development and/or delivery of this programme. The programme would build upon the content in the DESMOND programme, continuing to apply a cognitive behavioural approach to encourage participants to consider their thoughts, feelings, emotions and physical symptoms and the vicious cycle they may be in with their T2DM, depression and/or DSD (Figure 7-6). Building upon the application of the 'hot-cross bun' formulation to depression and T2DM by Moulton *et al* (67), as discussed in chapter one, the model in Figure 7-6 includes both depression

and DSD. It demonstrates how identifying and engaging in more positive behavioural and cognitive exercises within the 3D education programme can break the negative cycle they may be experiencing, instead building a positive cycle of self-management and care. The education session would include workbooks and education materials to facilitate learning and encourage continued engagement following the session, encouraging peer and/or social support both within and without the group as this has been shown, as discussed in chapter three, to improve self-management in T2DM both for the individuals receiving and providing the support (266,330-334,339).

Figure 7–6: The 3D-Model for treating depression and/or diabetes-specific distress in people with Type 2 diabetes, building upon cognitive behavioural cross-sectional formulation (67,68)



Stage five

An education programme for depression and DSD in people with T2DM would provide individuals with a space to explore their own presentations, and consider strategies within which they could improve their emotional well-being. However, the scope of such an intervention would only be to discuss and explore strategies hypothetically, potentially with some small activities such as relaxation and breathing exercises. So as to facilitate the engagement in positive self-care following the education session, the programme would signpost to potential alternative community based interventions or self-help resources, taking time within the session to discuss this with participants and answering any questions they may have. Such examples of existing community-based resources could be physical activity programmes such as GP referred exercise programmes or alternative activity programmes such community walking and/or cycling groups, or volunteering in green space conservation, as explored in the field notes in chapters four.

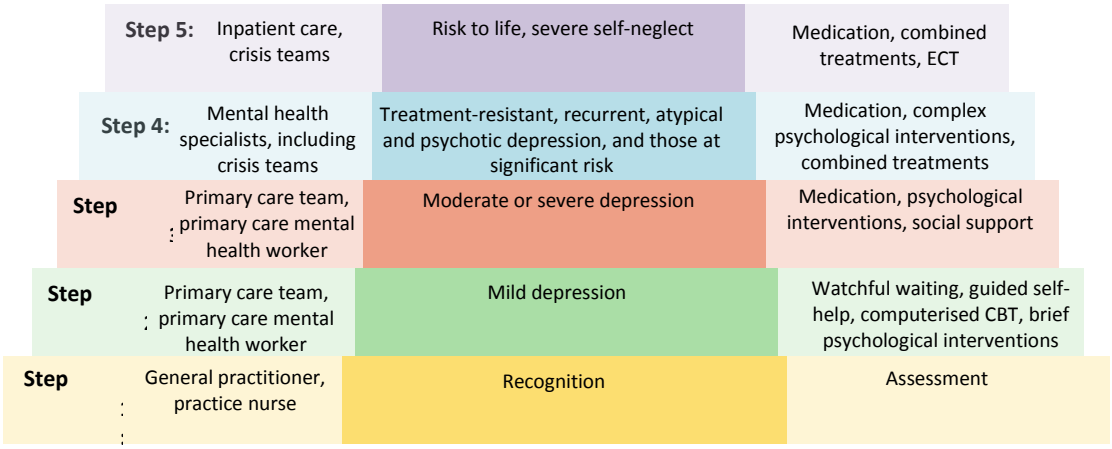
Further to education materials and workbooks given within the session for participants to take home, there could be the potential to signposting to web-based and/or mobile phone based self-help programmes that encourage accountability and offer continued support and guidance. Although chapter three demonstrated non-significant results for web-based and mobile interventions, this was in comparison to face-to-face interventions, not as an additional option to facilitate a face-to-face intervention. Both mobile and web-based interventions have previouslty been shown to be effective in reducing both depression and DSD in people with diabetes (342,343,421). While these are empirical examples of interventions utilising web/mobile-based self-help CBT that may not be readily available within the mainstream, there are various web-based or mobile phone applications for psychological and/or diabetes self-management support (407,422). Some participants may feel they would benefit from support groups to increase peer-support and engagement, and these could similarly be utilised in sign posting with national mental health charities and initiatives such as Time to Change offering directories of potential support local support groups (422).

Participants would be provided with a resource pack with varying strategies for alternative therapies, self-help and support initiatives, and encouraged to consider whether they could benefit from engaging with such strategies, and which may be best suited to them. Further to discussing the programmes within the session, participants would be encouraged to discuss this with family, peers and their care-coordinator, to reduce the risk of feeling overwhelmed by the information and to explore their options. The session will reiterate the importance of choice and that what may work for one individual may not for another, highlighting the usefulness of trying out different approaches whilst remembering not to feel discouraged or defeated if one particular approach does not work for them.

Stage six

The final stage in the 3D-model would be for participants with depression that need more dedicated psychological therapy, either through talking therapies or pharmacotherapy, or a combination of both. An already established model of care for psychological support within the NHS is the Improved Access to Psychological Therapies (IAPT) framework, which would continue to serve participants needing further support through the implementation of stepped care model for depression and anxiety recommended by NICE (Figure 7-7).

Figure 7–7: The National Institute for Care and Excellence Stepped Care model for the treatment of depression within the Improved Access to Psychological Therapies Framework (422)



The 3D-model would fit within steps one and two, but provide a T2DM specific context to not only determine if depression is present but if this could

in fact be DSD or a combination of both. It would offer support across all three conditions to encourage holistic management of people with T2DM and psychological difficulties. However, should individuals still experience psychological problems following the first five stages of the 3D-model, or if their symptoms were so severe in the initial assessment, they would be referred into the standard IAPT stepped care model for moderate to severe depression. HCPs would, however, be encouraged to continue with regular follow-ups with patient-centred and holistic care so that patients are still given choice in their treatments and empowered to make these decisions within their self-management of both their T2DM and psychological health.

7.5 Conclusion

The 3D-model of care is a potential pathway, using research conducted as part of the development work for the Medical Research Council (MRC) framework for the development of complex interventions (191,193), and building upon existing care and education programmes for people with T2DM and potential depression and/or DSD. While one could argue that the DESMOND programme already includes a lot of factors raised in the 3D-study findings within its curriculum, due to the small amount of time given within the session to psychological aspects of T2DM, it is likely that people with depression and/or DSD may not be fully supported by the programme alone. This was evidenced in the qualitative study highlighting that although depression and DSD are included in the curriculum, they may not always be delivered as the sessions are patient driven and the main focus is given to the management of T2DM rather than psychological well-being.

More in depth care is needed for people with T2DM and comorbid depression and/or DSD, with no clear pathway existing for people with these comorbidities. The 3D-model offers a potential outline to inform future research and treatment design, recognising that before interventions can be delivered to patients, there are fundamental concerns within the understanding and practice of HCPs. The model identifies that this needs to be addressed with adequate training in depression and DSD in relation to DSD, and improving therapeutic alliance through patient-centred holistic care.

The model of care following the initial training for HCPs hypothesises that patients with depression and/or DSD can work with their care co-ordinator to identify and explore their own presentation and move thorough the stages of the model depending on the severity of their symptoms to achieve the best outcomes for their depression and/or DSD. The model can do this by offering appropriate education in not only T2DM and management, but detailed and tailored education for both depression and DSD if needed. The model offers choice and empowerment for patients to make shared-decisions with their care-coordinator to specify their preferences in both treatment and learning, whilst providing regular follow-up and re-evaluation so as to allow patient appropriate and tailored care within a stepped and collaborative care programme.

7.6 Chapter summary

In this chapter I have given an overview of the 3D-study findings and how these fit against current provisions of care for people with T2DM, depression and/or DSD by mapping the findings against the curriculum of existing structured education programmes. This process was used to inform a potential treatment model outline that builds upon existing provision with the view to inform future research and treatment for people with these prevalent comorbidities. In the following and final chapter, the 3D-study is evaluated, discussing the strengths and limitations of the work, as well as the clinical and research implications of the potential model in relation to the MRC framework for the development of complex interventions, and provides recommendations for work going forwards.

Chapter 8 Overall discussion: Summary, implications and recommendations

8.1 Chapter overview

In this chapter I conclude my thesis by summarising the findings of the 3D-study (section 8.2) and consider the strengths and limitations of the work (section 8.3). Following this, the implications of the research are discussed in relation to both research and clinical practice, whilst offering recommendations for further exploration (section 8.4). I also discuss how I have personally developed through the completion of this PhD (section 8.5) before concluding the body of work (section 8.6).

8.2 Summary of the 3D-study

The 3D-study was an explorative research project that sought to better understand and investigate the comorbidity between Type 2 diabetes (T2DM), depression and/or diabetes-specific distress (DSD), with the aim of informing the development of an intervention to support individuals experiencing these conditions.

The study began by reviewing the existing literature (chapter one) so as to establish the background and rationale, and identify the aims and overview, of the work intended. The review highlighted that both depression and DSD are highly impacting and detrimental conditions, which both negatively influence T2DM; demonstrating a bidirectional and inconsistent relationship between depression and glycated haemoglobin (HbA1c), but a clear and distinct association between DSD and HbA1c (156,157,171-174). While they are interrelated and highly correlated, they stand as distinct constructs that need disentangling in order to tailor care appropriately (134). The review of the literature also demonstrated that current understanding, recognition and treatment of both depression and DSD in people with T2DM is inadequate, with no clear pathway for people in need of care and further work is urgently needed to address these concerns.

Following the introductory literature review, a systematic review and meta-analysis was performed (chapter two), collating and analysing existing research to determine the prevalence of diabetes-specific emotional distress (emotional-DSD) in people with T2DM. This review demonstrated a 40% prevalence of emotional-DSD in people with T2DM, with secondary analyses demonstrating higher emotional-DSD in studies using the DDS scale to measure emotional-DSD, in people with higher HbA1c and with more recently diagnosed T2DM. The findings of this review supported existing estimates in the wider literature (134,139), building upon reviews of the prevalence of depression in T2DM (28), and establishing that both emotional-DSD and depression are prevalent and in need of appropriate identification and management in people with T2DM.

A further systematic review and meta-analysis was then performed (chapter three) to establish whether existing interventions are successful in reducing emotional-DSD, as well as HbA1c and body mass index (BMI). The results demonstrated that interventions significantly reduced emotional-DSD and HbA1c, but not BMI. Further targeted analyses demonstrated that interventions were better at reducing emotional-DSD when they included coping-skills training, with merit also seen in the interventions utilising a collaborative care approach. HbA1c was significantly reduced by interventions utilising social and/or peer support, as well as mobile-phone based interfaces, with further merit seen in computer/web-based interventions. While the findings of this review should be taken tentatively, since only one study in the analyses specifically targeted emotional-DSD, the results build upon existing reviews looking at interventions for depression in people with T2DM (155,423), and identified potential areas for consideration and exploration in the design of an intervention for people with T2DM, depression and/or DSD, giving particular merit to the collaborative care approach.

The wider literature review and the two systematic reviews and meta-analyses led into the main body of research (chapters four to six), which was a qualitative interview study, including both patients and healthcare professionals (HCPs), to explore the understanding, perceptions and experiences of depression and/or DSD in people with T2DM. The interview

data was supplemented with additional data acquired from field-notes, taken from observations and meetings held with varied stakeholders during targeted development work, to explore development options in intervention design. The analyses demonstrated four key themes: illness beliefs; the impact of illness and comorbidity; influences in the identification of depression and DSD in people with T2DM; and influences in providing and receiving care in people with T2DM, depression and/or DSD. Within these themes, prominent subthemes emerged including poor understanding of depression and DSD in not only patients, but HCPs as well, with DSD being largely obscured by depression. There were multiple naïve accounts of DSD with a sub-theme of stigma demonstrating that DSD was viewed as far less stigmatising than depression, and that stigma was associated with both physical and psychological health for people with T2DM and depression/DSD. One of the most prominent sub-themes that permeated across the key-themes from the qualitative data was the HCP-patient relationship and a lack of therapeutic alliance in the management of both T2DM and psychological concerns. This was evident not only with issues in identification and a lack of faith in screening from both patients and HCPs, but also in a lack of patient-choice or shared decision making in illness management. The data corroborated that there is no clear care pathway for people with T2DM and depression and/or DSD, with varied approaches and outcomes reported and a lack of continuity in both recognition and treatment for people with these comorbid and prevalent conditions.

Within the 3D-study exploration, a repeated emergence was that of a structured self-management education programme entitled The Diabetes Education and Self-Management for On-going and Newly Diagnosed (DESMOND) programme. This emerged both in the initial literature review, the systematic review and meta-analysis of existing interventions, and the qualitative data in both the interview transcripts and the supplementary field-notes. As the DESMOND programme is an already established and robust self-management education programme including content on depression and DSD, this led to the decision of mapping the 3D-study findings against the programme curriculum. This was conducted with the view to establish which areas are already being addressed within existing provision, and to identify

areas for consideration within a treatment model for people with T2DM and comorbid depression and/or DSD.

The mapping process identified that before any intervention can be designed and implemented for patients, training and education is needed at the HCP level and a six-stage model of care was outlined, which included HCP training as the first stage. It was proposed that the HCP training would need to include education in both depression and DSD in relation to T2DM, but also in how to screen for both within a meaningful and constructive discussion so as to not only be able to discern how an individual is presenting, but to avoid potential marginalisation or feelings of being part of a 'box-ticking' exercise. Further to this training was suggested to (re)familiarise HCPs with patient-centred and holistic care, emphasising the importance of therapeutic alliance through a self-efficacy and empowerment driven approach to management for people with T2DM, depression and/or DSD. The patient-level stages of the model outlined a stepped and collaborative care approach, with a sole care co-ordinator and repeated follow-up and appraisal to allow patients to explore and reflect upon the care they receive and how they wish to move forwards should they feel further support is required. The model recognised the efficacy of utilising existing provisions in care and that the original DEMSOND programme may be sufficient as a first step in treatment for people with poor-coping that is specifically linked to poor diabetes understanding or management. Should this however not be sufficient, then a DESMOND psychological well-being module specific to DSD and depression could be beneficial. This would provide education about both depression and DSD, exploring the similarities and differences between the two conditions, and provide a space for individuals with T2DM to explore and understand their own presentations. The session would encourage consideration and reflection of symptoms and the context within which these present, and explore appropriate tailored treatment options and self-help strategies. Further to the DESMOND well-being module, individuals would be sign-posted to various alternative community-based interventions, self-help options, and social-support agencies; such as physical activity programmes, support-groups, web/mobile-based self-help programmes and/or social support/debt-advice charities. These would be discussed within the session

and be included in a resource pack that would not only reiterate the session content, but provide additional exercises and further information to encourage well-being outside of the session. Should individuals still be experiencing continued depression and/or distress upon follow-up, then they would be referred further into the Improved Access to Psychological Service (IAPT) model, an already established stepped care approach for people with depression and anxiety recommended by the National Institute for Care and Excellence (NICE).

The initial aim of the 3D-study was to develop and test an intervention for people with T2DM, depression and DSD, but through the exploratory nature of the study it became evident that a succinct patient-level intervention would be insufficient due to deeper rooted systemic concerns that would need addressing prior to patient-level intervention being delivered. The 3D-study data demonstrated that institutional and HCP-level training and education is needed to facilitate patient-centred and holistic identification and treatment of depression and DSD in people with T2DM, meaning that the development of such an intervention fell outside of the scope of the thesis. The study does, however, lay the foundations for future research and potential clinical practice, which is discussed in the implications and recommendations section later in this chapter (section 8.4).

8.3 Strengths and limitations of the 3D-study

The process by which the 3D-study was conducted was robust and research driven, examining existing research and practice in people with T2DM, depression and/or DSD, and building upon this in an explorative approach to provide novel data in understanding of how best to cater for people with these prevalent and comorbid conditions. Both qualitative and quantitative research methods were used, building upon a systematic review of the literature, before assimilating the findings to inform the outline of a model of care for people with T2DM, depression and/or DSD.

The initial aims of the 3D-study were to design and develop an intervention for people with T2DM, depression and/or DSD. While one could argue that this aim was not met and that this could stand as a limitation, one could also

consider it a strength as it demonstrates the explorative and research grounded nature of the study. The study recognised the depth and detail required to truly cater for the complexity of morbidity in people with depression and/or DSD in T2DM. Furthermore, the 3D-study identifed much deeper-rooted concerns within clinical practice that would need addressing before being able to deliver a patient-centred and holistic model of identification and management to the individual with T2DM and psychological concerns. To be able to fulfil these needs properly would require time and resources that simply fell outside of the scope of this PhD. While the 3D-study did not test an intervention, it gave a detailed outline for a model of care, based on robust research, and lays the foundation for more complex and rigorous work to be conducted that would be more capable of benefiting individuals in need.

A further strength to the 3D-study is that the programme provides novel data to areas that are under-researched. Both the systematic review and meta-analysis to determine the prevalence of emotional-DSD in people with T2DM, and the qualitative interview study to explore the understanding, perceptions and experiences of depression and DSD in relation to T2DM, were the first known studies of their kind, addressing a gap in the literature. While at the time of undertaking the systematic review and meta-analysis of existing interventions for improving emotional-DSD in people with T2DM, it was the first-known review of its kind, during the process of completion, a similar study was published, suggesting that it was no longer providing novel data to a gap in the literature. However, when critiquing the other paper and comparing it to the 3D-study findings, it demonstrated that the reviews varied considerably, suggesting that both offer novel data to the research literature. By providing novel data to the field of depression and DSD, the 3D-study also offers the potential to address the gap in care provision for these conditions and provide a definitive care pathway, which is distinctly lacking in current care models.

While the methods of the 3D study were robust and complex, limitations were evident in both the systematic reviews and meta-analyses and the qualitative study, as discussed within the respective chapters. The systematic review and meta-analysis to determine the prevalence of emotional-DSD in people with T2DM was hindered by a distinct lack of reporting of the data

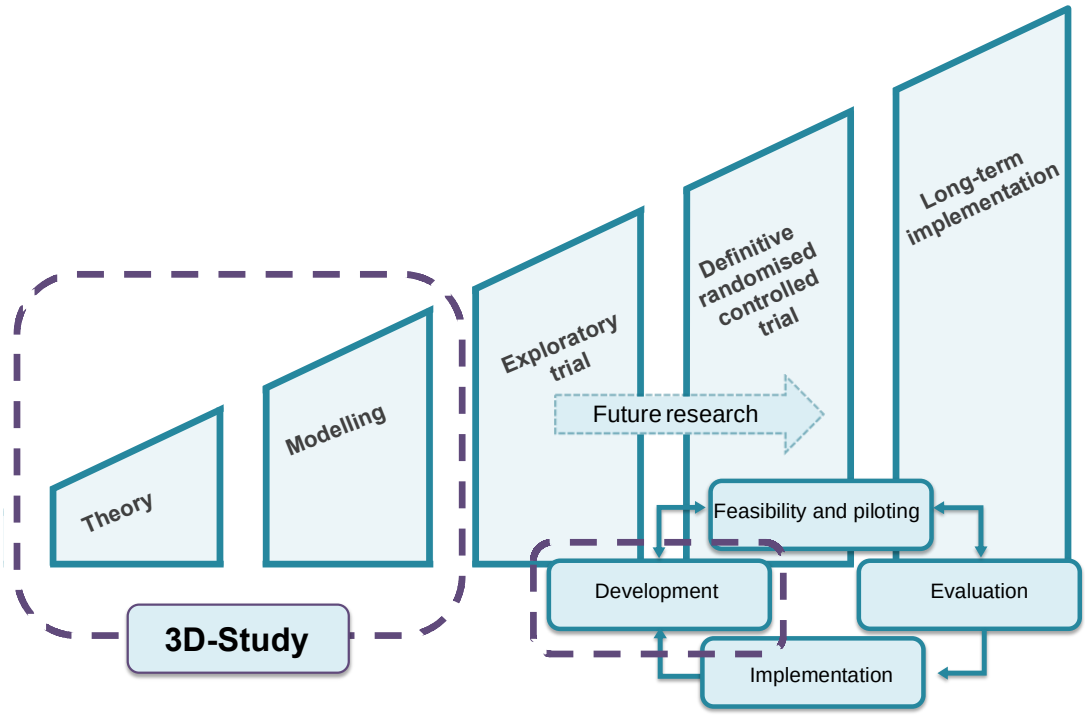
required for analyses, meaning that only just over a third of eligible studies could be included in the analyses. The qualitative interview study presented with limitations within recruitment due to a bias within the patient-participant sample, with the vast majority of participants being within retirement age, which could limit the generalisability of results; although one could argue that the higher prevalence of T2DM in older generations may counteract this. Further limitations were evident in the length of time it took to recruit at all three levels of the qualitative study, at the practice, HCP and patient levels. This meant that the study continued for longer than anticipated, impacting other areas within the study and limiting the ability to reach pure theoretical saturation.

8.4 Implications of the 3D-study and recommendations

The 3D-study set out to explore existing research and understanding of depression and DSD in the context of T2DM, and to gain novel data to build on this with the aim of developing an intervention to provide care for people with these comorbidities. The fundamental outcome of the 3D-study was the recognition that an intervention designed solely at the patient level would be insufficient, due to the acknowledgement of far deeper-rooted concerns within professional understanding and practice that need addressing before any intervention can be delivered to patients. As such the development of an intervention that can address both the HCP and patient level concerns fell outside of the scope of the study, requiring much greater time and resource than initially anticipated.

Recommendations for future research would be to continue the development and implementation of the 3D-model in accordance with the Medical Research Council (MRC) framework, as discussed in chapters one and seven (Figure 8-1). The 3D-study findings make up the ‘Theory’ and ‘Modelling’ stages of the original linear MRC framework (191). In order to appropriately develop and test the 3D-model within an exploratory trial, each stage of the model would need to be developed, piloted to assess feasibility, evaluated and then implemented as per the updated MRC framework, which acknowledges the cyclical nature of research and development (193).

Figure 8–1: The 3D-study findings within the Medical Research Council frameworks for the development of complex interventions (191,193)



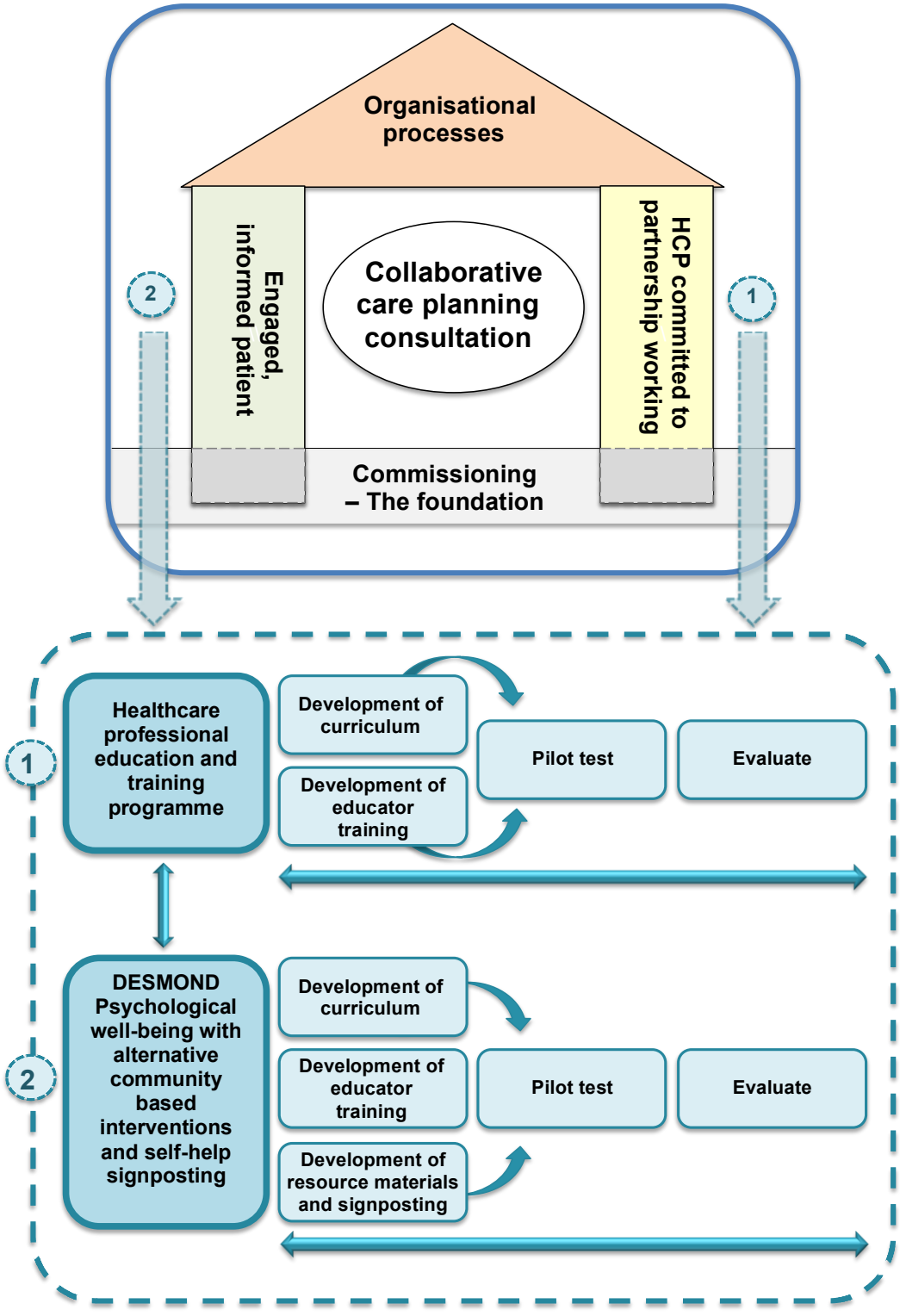
The current provision of care for people with T2DM and psychological comorbidities does not allow for a holistic care approach, with the treatment of any multimorbidity done so in a segregated fashion, with separate specialists for each condition and often a distinct lack of communication between agencies. Concerns with such an approach have been highlighted not only in the lack of clear benefit of treating conditions separately, but also more in the risk for potential harm through the treatment of one condition that could lead to the deterioration or disregard of another. Further to this, lies the potential for treatment burden through the process of treating too many conditions separately with multiple agencies, overwhelming patients and leaving them with unmet needs and potentially leading to further psychological comorbidity (424).

The 3D-model recognised that training in care planning and patient-centred care within a collaborative model is vital to addressing such concerns and improving the therapeutic alliance between patients and their HCP. While existing provision for this exists in proposed models such as the Year of Care (YOC) programme, this does not account for the lack of understanding and appreciation of depression and DSD in the context of T2DM, or how to

improve screening efficacy through assessment and meaningful discussion. As such further targeted training would be needed to facilitate appropriate tailored and holistic care delivery. The YOC demonstrated both patient and professional level improvements following a three-year pilot study across three diverse primary care trusts (PCTs) (425), using the analogy of building a house to depict their model. The Care Planning House Model is made up of HCPs, patients, organisations and commissioning as the various blocks to form the structure, demonstrating the equal importance of all aspects to ensure true integrative care across multiple agencies, as is often the case in people with long-term conditions. The model highlights that, much like the structure of a house, should one of the inter-dependent elements be weaker or missing, the whole structure would no longer be viable. When considering the YOC house model in relation to the 3D-model of care (Figure 8-2), recommendations for future research would be the development of the programme at two levels so as to create the 'HCPs committed to partnership working' and the 'engaged and informed patients' as outlined in the house model. Firstly, the 3D-model would require the development and testing of training and education programmes for HCPs, to better understand depression and DSD in the context of T2DM, and how to screen within a meaningful and patient-centred discussion, so as to identify and determine patient presentations.

Secondly, the 3D-model would require the development and testing of a structured education programme specific to psychological well-being in T2DM, which would include education on depression and DSD, as well as sign-posting to alternative community based interventions, self-help and social support options. Once both of these areas have been developed, piloted and evaluated seperately, then the 3D-model could be piloted as a whole, as per the MRC framework for complex interventions as an exploratory trial, and, depending on the outcomes of this, go on to be tested within a randomised controlled trial (RCT).

Figure 8–2: The Year of Care (YOC) Care Planning House Model (425) and how the 3D-model of care would need to build upon this to include depression and DSD in order to tailor care for people with Type 2 diabetes



The development of the HCP training and consideration of how this could fit within existing structures of professional practice would be the greatest challenge for future research to develop and implement the 3D-model. It has

been demonstrated that many HCPs believe that they are already delivering patient-centred care, when patient-surveys suggest otherwise (426,427) which was supported by the findings of the qualitative study (chapters four to six). As such, trying to train HCPs in how to identify and manage patients with depression and/or DSD in a patient-centred and holistic manner, when they already believe that they do so, may be met with resistance or simply 'fall on deaf ears'.

Further to such challenges is a culture of resistance to change within the National Health Service (NHS) as a whole, with copious reports and recommendations made by NICE and clinical commissioning groups about what constitutes best-practice and adequate care, but the reality of implementing such provision often falling short, as demonstrated once again within the findings of the 3D-study.

Interprofessional education (IPE), defined as a programme of learning where "members of more than one health or social care profession learn interactively together, for the explicit purpose of improving interprofessional collaboration or the health/well-being of patients/clients, or both", has been shown to improve outcomes in diabetes care and collaborative team behaviour (428). When considering the 3D-model, it would be optimal to provide education and training to all potential HCPs involved in the collaborative care of people with T2DM, depression and/or DSD. However, the feasibility of such a programme is unlikely, with challenges to be faced both in the time and planning needed to be able to deliver education to all professionals, but is also likely to be exacerbated by concerns in funding to deliver such a programme at such a large scale. It would be probable that the 3D-model's HCP education would be best targeted to the care co-ordinators, since they would be the main contact for the patient. As such, they would be the most important role from which patients need to experience therapeutic alliance since they will be responsible to directing and tailoring care for the patient, standing as an advocate for the patients' needs when communicating with other agencies. Existing courses focussing on communication skills are available, such as the 'Knuston Hall Diabetes Counselling Course', which is an established programme for HCPs to gain skills in communication and empowerment (429). While this course has been running for twenty-five

years, it is not widely publicised or recognised, suggesting that funding may impeded its accessibility. The potential of utilising such courses may be limited due to the cost but it may be advantageous to explore such courses in the development of the 3D-model's HCP training programme.

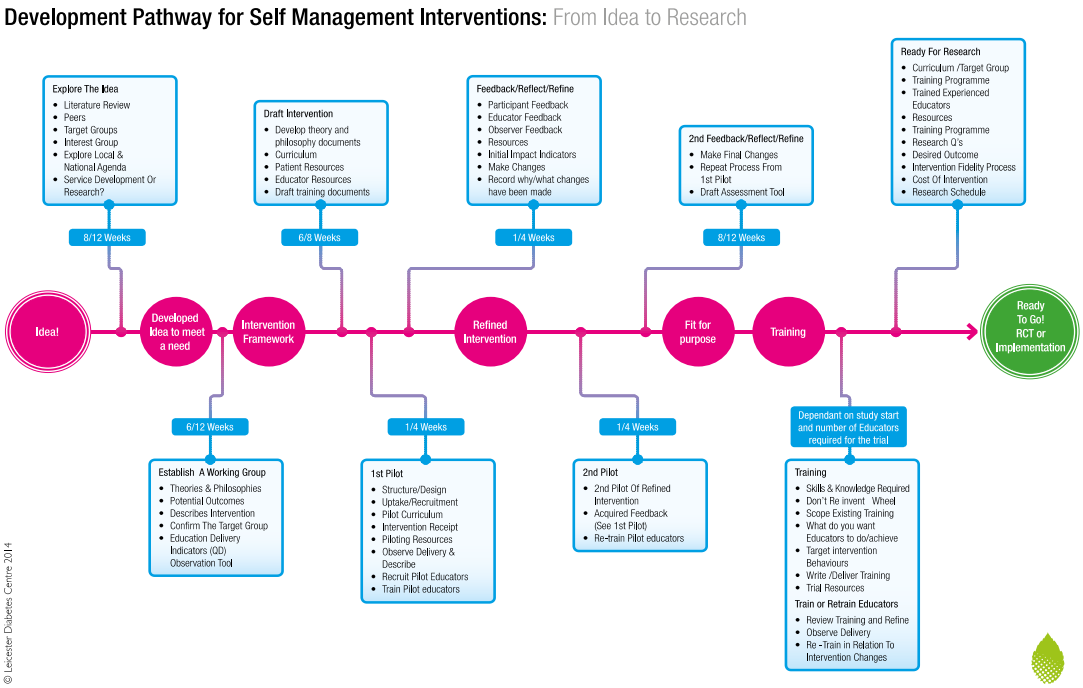
Future recommendations for the design and implementation of education and training for HCPs within the 3D-model of care would be to conduct focus groups to include both HCPs and patients to gain further refined understanding of the issues raised in the qualitative study, and to specifically target research questions before creating a detailed design of the curriculum. The curriculum would then need to be piloted and evaluated, with further focus groups to discuss areas for improvement and/or adaptation following initial pilots so as to refine the content and delivery of the programme.

The patient education programme within the 3D-model would stand as an additional module to an existing programme of care, the DESMOND programme. The Leicester Diabetes Centre (LDC), who initially developed, and continues to advance and deliver, the DESMOND collaborative programmes, built upon the MRC framework outlining an established pathway for the development of self-management interventions (Figure 8-3).

Recommendations for future research would be to include the findings from the 3D-study within this pathway, and build upon it to follow the process by which the other DESMOND programmes have been tried and tested. This would be initially with focus groups, as suggested with the HCP education and training programme, so as to explore the notion of a self-management programme specific to depression and DSD in people with T2DM, and to develop a detailed draft of the curriculum before conducting the first pilot of the module. Following this, evaluations and feedback should be conducted, again through focus groups and feedback from not only participants, but also educators and observers. Feedback should be obtained about the delivered curriculum, as well the resource packs and signposting to additional intervention choices, such as self-help groups, community-based interventions and/or social support choices. Building on from this a second pilot study of the refined programme should be conducted to fine-tune the curriculum and re-train educators. Since the 3D-model includes both HCP and patient education, once both of these elements have been developed,

piloted and evaluated separately, the model would need to then be brought together and tested as a whole. Similarly to the processes outlined above, the overall 3D-model would need to be pilot tested, and evaluated, before being refined and then tested within a definitive RCT and evaluated for cost-effectiveness, should the pilot study findings deem it efficacious, as per the MRC guidelines for complex interventions.

Figure 8–3; The Leicester Diabetes Centre (2014) Development Pathway for Self-Management Interventions: From Ideas to Research



As discussed in previous chapters, a recent series published in the Lancet by leading authors in the field of depression and DSD in diabetes appraised current research and practice, considering existing provision and providing recommendations for both future investigation and clinical practice (59,67,134). A variety of considerations were given within the series, highlighting that the interventions to treat depression in people with T2DM should be capable of addressing both glycaemic control and psychological affect simultaneously, but recommending that due to the rapid nature of depression improving or declining, that this should take precedence in treatment outline (59). The third paper in the series focussed on treatment and healthcare delivery for people with T2DM and depression. The authors

acknowledged considering DSD in this was beyond the scope of the paper, however, the findings of the 3D-study demonstrate that when considering the provision for people with depression and T2DM, acknowledgment of DSD is vital. This is particularly pertinent when considering the relationship between the three conditions. While depression and DSD are inter-related and may often over-lap, they are not inter-changeable constructs (134). They may need careful dissemination and consideration when tailoring treatment, which is particularly pertinent since recent research has continued to demonstrate the association between T2DM, depression and DSD, and that DSD acts as a profound mediator and exacerbating factor in the interplay between all three conditions. DSD has been shown to increase the risk for both incidence and persistence of depressive symptoms (430), and depression is more greatly associated with hyperglycaemia only when DSD in combined (431). Such research highlights the need to account for DSD in presentations of depression in T2DM, since reducing DSD may help to prevent the development or worsening of depressive symptoms, and since depression has also been shown to amplify DSD (430). It is vital to consider the independent influence of each condition and to appropriately disentangle the way in which each individual patient presents so as to determine the source of their psychological state and to tailor care accordingly (432), which few interventions have done to-date. The proposed 3D-model of care would allow for this and future research into the outcomes of the model would be extremely valuable to research on depression and/or DSD in people with T2DM.

While previous research has demonstrated benefits for improving depression in people with T2DM, through either pharmacological therapy, psychological therapy or combined in more complex collaborative and stepped-care interventions (155,160,161,184,423,433), the results on improving glycaemic control continue to be varied and inconsistent, although merit has been given to diabetes education when incorporated within treatment (155,161,210,434). A factor to consider in the current understanding and evidence for the treatment of depression in people with T2DM, is that the majority of research is conducted within primary care settings and that population samples tend to demonstrate moderate to poor

glycaemic control pre-intervention. Although limited, recent research has demonstrated that both psychological and pharmacological interventions are insufficient when treating patients with severely uncontrolled diabetes (435), emphasising a need to adapt care accordingly and offer facilities that can communicate between primary and secondary care services. The 3D-model, although based within a primary care setting, would adopt a collaborative care design, that not only considers depression and T2DM, but also DSD, a factor often lacking in previous collaborative care interventions. It is possible that the process by which the 3D-model would intend to establish and understand an individual's source of poor-coping, considering both the context and severity not only their psychological symptoms but also their physical health and T2DM presentation, could provide more holistic and tailored care and offer the potential for better outcomes. While communication between primary and secondary care services has been shown to act as a barrier in care for people with multiple conditions, as demonstrated in the qualitative study (chapters four to six), the 3D-models intended use of a sole care-coordinator could improve continuity of care through patients having one point of contact who can communicate between both physical and psychological care services.

When considering how to tailor care for people with depression and/or DSD in T2DM, recent models have been proposed to not only differentiate between depression and DSD as standalone conditions, but to also to deduce specific depression profiles so as to personalise management strategies (134,434). When considering the depression sub-typing model within the future design and implementation of the proposed 3D-model of care, this may fall outside of the scope of the intervention, not only since it is such a novel consideration in the care of people with T2DM and depression, but also as this may overcomplicate the model to the point that it could hinder engagement by HCPs or simply make it too complex to deliver effectively. The authors did however discuss the need for standardised screening measures for depression to be facilitated by a clinical interview so as to determine both depression severity and subtype. The proposed training for the 3D-model would be to train care-coordinators to screen within discussion and to explore the context and severity within with depression and/or DSD occur. While this

would not necessarily be a clinical interview, the process of determination and taking the time to ascertain each patient's individual presentation and consider treatment across bio-psycho-social levels could allow for the appropriate tailoring and holistic care that is so desperately needed within the field.

One of the recommendations made in the series was that future research should 'confront and dismantle the general conclusions of studies that suggest that particular interventions are effective for all people with diabetes and depression' (59). The authors highlighted the need to tailor care depending on the presentation of an individual not only in their psychological presentation, but also their diabetes status, such as being a primary care or secondary care patient. They highlighted that needs vary according to culture, clinical settings and countries and that there can be no universality of intervention design. While the proposed 3D-model of care is likely to present with limitations in applicability, the nature of the model meets these recommendations by being adaptable and progressive according to each patient's presentation, needs and desires could show promise in being more widely beneficial to a variety of patient groups. The use of a stepped care approach that utilises existing programmes of care, building upon this with tailored and targeted education, as well as offering alternative life-style, self-help, community-based and social-support choices, within a collaborative framework using a designated care-coordinator could potentially address the concerns raised by the recent appraisal series (59,67,134). By providing the freedom to tailor and adapt learning and treatment choices as per the individual's needs and preferences this could improve health outcomes in people with T2DM, depression and/or DSD. However, to execute this properly would require highly skilled and creative practitioners that are not constricted by protocols, which is difficult to achieve within the target driven and often restrictive environment of both research and clinical practice.

A further consideration for future research is the consideration of multimorbidity and that this is the prevalent reality for many people in healthcare, with figures demonstrating that three in four individuals over the age of sixty-five, and one in four under the age of sixty-five, experience multiple chronic conditions (436). Such figures mean that multimorbidity itself

is the most common condition experienced by adults and needs appropriate consideration in the development of interventions (424). In future development of the 3D-model of care it should be noted that while T2DM, depression and/or DSD are highly comorbid, the likelihood is that further multimorbidity could present in individuals eligible for the 3D-model intervention, as demonstrated in various patient-participants in the qualitative study, and that this would need consideration when tailoring treatment to such individuals. It has been acknowledged that a collaborative care intervention that only targets two or three conditions could fall short at truly accommodating the complexity of a patient's presentation (59). To develop an intervention that would address all possible combinations of comorbidity would be unrealistic, however recommendations for the 3D-model would be to allow for discussion of all conditions within the 1:1 consultation. Should an individual present with T2DM, depression and/or DSD as well as other chronic conditions; the focus of the HCP should be to determine what is the main priority for the patient. In the case of one of the participants in the qualitative study, one participant had ulcerative colitis that impacted her physical and psychological health far more than her diabetes or other wider-life factors. Should a patient identified within the 3D-model present with other conditions that are more impacting or of greater importance to them, then acknowledging that T2DM, depression and/or DSD are not the main priority for that individual is paramount. The model should remain patient-centred and focus on the health goals of the individual to offer truly tailored and holistic care, even if this means not addressing T2DM, depression and/or DSD immediately. Individuals who present as such should be referred out to relevant agencies for that particular condition of concern, or the primary-care focus should be on treating the main priority condition before reassessing for depression and/or DSD. It is possible that any poor coping may in fact be as a result of said other condition and addressing this first could improve outcomes alone without the need for the 3D-model education programmes, and determining this within the 1:1 consultation will not only save resources but also prevent patients feeling that they unheard or receiving 'pointless' treatment as was often evidenced in the qualitative study.

The 3D-model has the potential to offer patients with T2DM, depression and/or DSD a programme of care that encourages self-efficacy and empowerment, giving each individual choice in both treatment and learning styles, within a stepped and collaborative care framework. It would also serve to improve the understanding and procedures of HCPs by offering training and education at the HCP-level before patient-level interventions began. Future work is needed to adequately and robustly develop and test this model, initially through a process of pilot and preliminary studies, using both qualitative and quantitative methods to determine the most appropriate design. Once the model is fully developed and established, it would need testing within a definitive trial to be able to evaluate its feasibility, validity, and efficacy within primary care systems.

8.5 Personal statement

Through the completion of the 3D-study for this PhD thesis, I have developed immensely as a researcher, gaining new skills and building upon existing proficiency, allowing me to develop a multi-faceted portfolio in academia and research.

General research skills that I have acquired included: preparing for and submitting to NHS ethical and research governance committees to gain approval for research; preparing and presenting relevant study documentation such as study information sheets and consent forms; recruiting general practices; recruiting both HCP and patient participants; training practice staff in recruitment protocols; and gaining informed consent. Further general research skills included: searching for, and critically appraising, evidence; recognising appropriate times to collaborate to achieve best practice; optimal time management and prioritisation; project management; presenting to both small and large audiences; and writing for and submitting to peer reviewed journals.

Specific quantitative research skills that I gained through the completion of the systematic reviews and meta-analyses in chapters two and three included: developing a search strategy and adapting this to be used across multiple electronic databases; identifying appropriate articles; contacting

authors and experts in the field for further information and/or guidance; data extraction; assessing the quality of papers; collating relevant evidence; and using statistical programmes (STATA) to perform multiple and varied analyses.

Specific qualitative research skills that I gained through the completion of the qualitative interview study and development meetings were: developing and adapting an interview topic guide; conducting in-depth semi-structured interviews with both HCPs and patients; discussing sensitive and potentially distressing topics in a contained and sensitive manner; risk assessing when concerning disclosures are made; approaching and networking with relevant professionals and experts; presenting and conducting research development meetings to build upon existing work and utilise the knowledge and experience of multiple individuals and agencies; analysis of qualitative data and using qualitative analysis programmes (NVivo) to assist doing so.

8.6 Conclusion

The 3D-study was an explorative piece of original research as part of a PhD thesis. It explored existing understanding of T2DM, depression and DSD, and gained novel information to fill gaps within the literature. It determined the prevalence of emotional-DSD in people with T2DM, as well as identifying existing interventions that reduced emotional-DSD and HbA1c, building upon similar reviews and analyses for depression in people with T2DM and offering insight into potential factors to consider in intervention design. The study explored the perceptions, understanding, and experiences of HCPs and patients in relationship to T2DM, depression and/or DSD and highlighted crucial areas for addressing within the field, most prominently the understanding of depression and DSD in both patients *and* HCPs, and a lack of therapeutic alliance and patient-centred care. Through a process of mapping the 3D-study data against existing provision, a 6-stage model of care was proposed and the foundations for future research have been laid.

The 3D-study has corroborated existing understanding and provided new data to the field of depression and DSD in people with T2DM, offering a model of care that acknowledges and appeases recommendations from leading

authors in the field. Future development and testing of the 3D-model is both valuable and important in improving understanding and outcomes for people with T2DM and psychological comorbidity.

Appendices

Appendix 1: Example of data extraction form used for a systematic review and meta-analyses to determine the prevalence of diabetes-specific emotional distress in people with Type 2 diabetes (Chapter 2)

Study Information											
First Author											
Year											
Country											
WHO region	Europe		Americas		South-East Asia		Africa		Western-Pacific		Eastern Mediterranean	
Culture	Western		Eastern								
Study design											
Randomised?	Yes		No								
If yes, type?	Individual		Cluster								
Controlled?	Yes		No								
Emotional-DSD information											
DSD measure											
N DSD											
% DSD											
Prop' DSD											
SE DSD											
Mean DSD											
SD DSD score											
Study participant demographics											
Total N											
% T2DM											
Gender	% Female		% Male								
Age	Mean		SD								
Mean HbA1c	Mean		SD								
Mean BMI	Mean		SD								
% Caucasian											
% complications											
Mean											
% Comorbid depression											
Mean Dep'											
SD Dep'											
Dep' measure											

Appendix 2: Equations used in both systematic reviews and meta-analyses to determine the prevalence of diabetes-specific emotional distress, and to determine existing interventions successful in the treatment of diabetes-specific emotional distress, in people with T2DM (Chapters 2 and 3)

Combining means: $\mathrm{M} = \frac{\mathrm{N_1M_1+N_2M_2}}{\mathrm{N_1N_2}}$

Combining standard deviations:

$$SD = \frac{(N_1 - 1)SD_1^2 + (N_2 - 1)SD_2^2 + \frac{N_1 N_2}{N_1 + N_2}(M_1^2 + M_2^2 - 2M_1 M_2)}{N_1 + N_2 - 1}$$

Calculating standard deviations from the standard error:

$$SD = SE\ x \sqrt{N}$$

Calculating standard deviations from confidence intervals:

$$SD = \sqrt{\mathrm{Nx}(\mathrm{upper\ limit} - \mathrm{lower\ limit})}/3.92$$

Calculating the mean change:

$$M = followupM - baselineM$$

Calculating the standard deviation change:

$$SD = \sqrt{(baselineSD\ x\ baselineSD) + (followupSD\ x\ followupSD) - (2\ x\ corr\ x\ baselineSD\ x\ followupSD)}$$

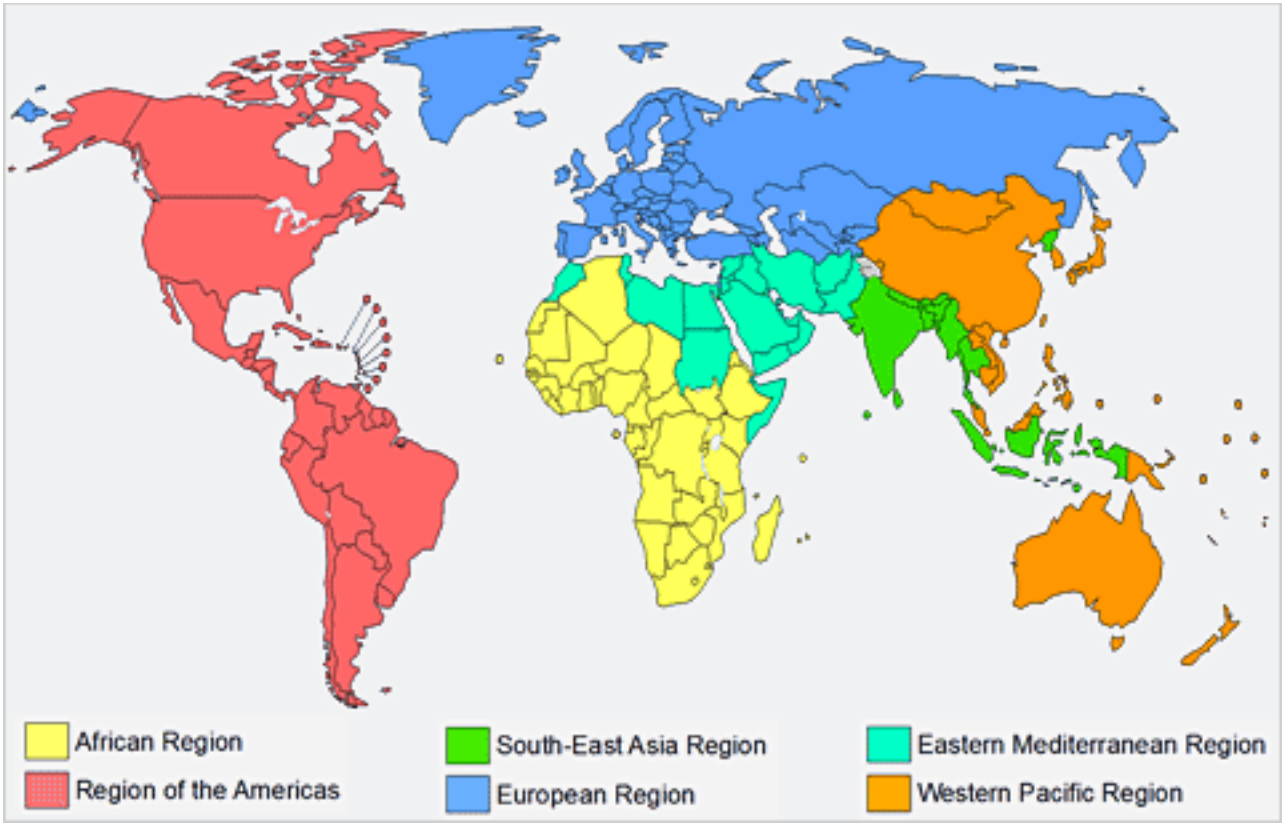
Calculating proportion:

$$prop = \%/100$$

Calculating standard error of proportion

$$SE = \sqrt{(prop\ x\ (1 - prop)/N)}$$

Appendix 3: Map demonstrating the World Health Organisation Member States grouped into six regions, sourced from http://www.who.int/about/regions/en/. Used in a systematic review and meta-analyses to determine the prevalence of diabetes-specific emotional distress in people with Type 2 diabetes (Chapter 2)



Appendix 4: Data extraction form used in a systematic review and meta-analyses to determine effective interventions for the treatment of diabetes-specific emotional distress in people with Type 2 diabetes (Chapter 3)

Study Information												
First Author												
Year												
Country												
WHO region	Europe		Americas		South-East Asia		Africa		Western-Pacific		Eastern Mediterranean	
Culture	Western		Eastern									
Study design												
Randomised?	Yes		No									
If yes, type?	Individual		Cluster									
Controlled?	Yes		No									

Intervention information	**N**	**Type**	**Duration**	**Targets/Key points**	**Theoretical background**
Intervention					
Control					

Study participant demographics					
Total N					
% T2DM					
Gender	% Female		% Male		
Age	Mean		SD		
HbA1c	Mean		SD		
BMI	Mean		SD		
% Caucasian					

Primary outcome: Emotional-DSD												
Measure used												
Intervention	Baseline Mean		Baseline SD		Follow-up Mean		Follow-up SD		Mean Change		SD Change	

Control	Baseline Mean		Baseline SD		Follow-up Mean		Follow-up SD		Mean Change		SD Change	
Secondary Outcome measures												
HbA1c: mmol/mol												
Intervention	Baseline Mean		Baseline SD		Follow-up Mean		Follow-up SD		Mean Change		SD Change	
Control	Baseline Mean		Baseline SD		Follow-up Mean		Follow-up SD		Mean Change		SD Change	
BMI: kg/m^2												
Intervention	Baseline Mean		Baseline SD		Follow-up Mean		Follow-up SD		Mean Change		SD Change	
Control	Baseline Mean		Baseline SD		Follow-up Mean		Follow-up SD		Mean Change		SD Change	
Blood Pressure Systolic: mmHg												
Intervention	Baseline Mean		Baseline SD		Follow-up Mean		Follow-up SD		Mean Change		SD Change	
Control	Baseline Mean		Baseline SD		Follow-up Mean		Follow-up SD		Mean Change		SD Change	
Blood Pressure Diastolic: mmHg												
Intervention	Baseline Mean		Baseline SD		Follow-up Mean		Follow-up SD		Mean Change		SD Change	
Control	Baseline Mean		Baseline SD		Follow-up Mean		Follow-up SD		Mean Change		SD Change	
Cholesterol HDL: mmol/l												
Intervention	Baseline Mean		Baseline SD		Follow-up Mean		Follow-up SD		Mean Change		SD Change	
Control	Baseline Mean		Baseline SD		Follow-up Mean		Follow-up SD		Mean Change		SD Change	
Cholesterol LDL: mmol/l												
Intervention	Baseline Mean		Baseline SD		Follow-up Mean		Follow-up SD		Mean Change		SD Change	
Control	Baseline Mean		Baseline SD		Follow-up Mean		Follow-up SD		Mean Change		SD Change	

Appendix 5: Overall ethical approval for a qualitative interview study to elicit and explore the understanding, perceptions and experiences of Type 2 diabetes with depression and/or diabetes-specific distress (Chapter 4)

NHS

National Research Ethics Service

NRES Committee East Midlands - Leicester
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Telephone: 0115 8839425
Facsimile: 0115 8839294

11 October 2011

Professor Kamlesh Khunti
Professor of Primary Care Diabetes and Vascular Medicine
University of Leicester
Department of Health Sciences
22-28 Princess Road West
Leicester
LE1 6TP

Dear Professor Khunti,

Study title: **Exploring the feasibility, acceptability and efficiency of screening and management for depressive symptoms and diabetes distress for the prevention of poor glycaemic control in people with Type 2 diabetes**

REC reference: **11/EM/0280**

Thank you for your letter, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of

the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Covering Letter		21 July 2011
Evidence of insurance or indemnity		16 August 2011
Investigator CV		15 July 2011
Letter from Sponsor		18 July 2011
Letter from Statistician		
Other: Interview study/Patient reply slip	1	15 July 2011
Other: Interview study/ HCP recruitment information for practice managers	1	15 July 2011
Other: Interview study/ Patient recruitment information for practice staff	1	15 July 2011
Other: Interview study/ HCP invitation letter	1	15 July 2011
Other: Interview study/ Recruitment poster	1	15 July 2011
Other: Letter from funder		01 October 2010
Other: Interview study/General practice invitation letter	1	15 July 2011
Other: Interview study/General practice reply slip	1	15 July 2011
Other: Interview study/ Interviewer guidelines	1	15 July 2011
Other: CV - Student		15 July 2011
Other: CV - Dr Friedman		
Other: CV - Professor Davies		
Other: CV - Dr Robertson		
Other: Interview study/ Interview thank you letter	1	15 July 2011
Other: Interview study/Patient post interview sheet	1	15 July 2011
Other: Interview study/ Draft patient topic guide	1	15 July 2011

Other: Interview study/Draft HCP topic guide	1	15 July 2011
Other: Interview study/Interview monitoring form	1	15 July 2011
Other: Pilot study/Education session/HCP reply slip	1	15 July 2011
Other: Pilot study/General practice invitation letter	1	15 July 2011
Other: Pilot study/Education session/General practice reply slip	1	15 July 2011
Other: Pilot study/Education session/General practice invitation letter	1	15 July 2011
Other: Pilot study/General practice reminder letter	1	15 July 2011
Other: Pilot study/Patient interview reply slip	1	15 July 2011
Other: Pilot study/Patient decline reply slip	1	15 July 2011
Other: Pilot study/Patient invitation letter	1	15 July 2011
Other: Pilot study/Patient contact details sheet	1	15 July 2011
Other: Pilot study/HCP interview invitation letter	1	15 July 2011
Other: Pilot study/Patient interview invitation letter	1	15 July 2011
Other: Pilot study/Screening results letter	1	15 July 2011
Other: Pilot study/Questionnaires reminder letter reply slip	1	15 July 2011
Other: Pilot study/Questionnaires reminder letter	1	15 July 2011
Other: Pilot study/HCP interview consent and reply slip	1	15 July 2011
Other: Pilot study/Interview thank you letter	1	15 July 2011
Other: Interview study/HCP initial expression of interest and reply slip	2	25 August 2011
Other: Interview study/Patient initial expression of interest form	2	25 August 2011
Participant Consent Form: Interview study/ Patient consent form	1	15 July 2011
Participant Consent Form: Interview study/ HCP consent form	1	15 July 2011
Participant Consent Form: Pilot study/Education session/HCP consent form	1	15 July 2011
Participant Consent Form: Pilto study/Patient consent form	1	15 July 2011
Participant Consent Form: Pilot study/Patient interview consent form	1	15 July 2011
Participant Information Sheet: Interview study/ General practice information sheet	1	15 July 2011
Participant Information Sheet: Pilot study/General practuce information sheet	1	15 July 2011
Participant Information Sheet: Pilot study/Education session/General practice information sheet	1	15 July 2011
Participant Information Sheet: Pilot study/HCP interview consent form	1	15 July 2011
Participant Information Sheet: Interview study/ HCP Information sheet	2	25 August 2011
Participant Information Sheet: Interview study/ Patient information sheet	2	25 August 2011
Participant Information Sheet: Pilot study/Education session/HCP information sheet	2	25 August 2011
Participant Information Sheet: Pilot study/HCP interview information sheet	2	25 August 2011
Participant Information Sheet: Pilot study/ Patient information sheet	2	25 August 2011
Participant Information Sheet: Pilot study/ Patient	2	25 August 2011

interview information sheet		
Protocol	1	15 July 2011
Questionnaire: Pilot study/Screening questionnaire pack baseline: PHQ-9	1	15 July 2011
Questionnaire: Pilot study/Screening questionnaire pack baseline: DSC-r	1	15 July 2011
Questionnaire: Pilot study/Screening questionnaire pack baseline: PAID	1	15 July 2011
Questionnaire: Pilot study/Screening questionnaire pack 12 month follow-up: PHQ-9	1	15 July 2011
Questionnaire: Pilot study/Screening questionnaire pack 12 month follow-up: DSC-r	1	15 July 2011
Questionnaire: Pilot study/Screening questionnaire pack 12 month follow-up: PAID	1	15 July 2011
REC application	70466/233860/1/515	20 July 2011
Response to Request for Further Information		

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

11/EM/0280 **Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely

Dr Carl Edwards
Chair

Email: jessica.parfrement@nottspct.nhs.uk

Enclosures: "After ethical review – guidance for researchers"

Copy to: *Student - Miss Nicola Perrin*

R&D Contact - Ms Claire O'Neill

Sponsor – Mr Graham Hewitt

Appendix 6: Overall ethical approval of minor amendment for a qualitative interview study to elicit and explore the understanding, perceptions and experiences of Type 2 diabetes with depression and/or diabetes-specific distress (Chapter 4)

NRES Committee East Midlands - Leicester

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Tel: 0115 8839425
Fax: 0115 8839294

03 November 2011

Miss Nicola Perrin
Department of Health Sciences
22-28 Princess Road West
Leicester
LE1 6TP

Dear Miss Perrin,

Study title: **Exploring the feasibility, acceptability and efficiency of screening and management for depressive symptoms and diabetes distress for the prevention of poor glycaemic control in people with Type 2 diabetes**
REC reference: **11/EM/0280**
Amendment number:
Amendment date: **27 October 2011**

Thank you for your letter of 27 October 2011, notifying the Committee of the above amendment.

The Committee does not consider this to be a "substantial amendment" as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

Documents received

The documents received were as follows:

Document	Version	Date
Letter of invitation to participant	3	27 October 2011
Notification of a Minor Amendment		27 October 2011

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

11/EM/0280:	Please quote this number on all correspondence

Yours sincerely

Miss Jessica Parfrement
Committee Co-ordinator

E-mail: jessica.parfrement@nottspct.nhs.uk

Copy to: *Sponsor - Graham Hewitt*

R&D Contact - Ms Claire O'Neill

Chief Investigator – Professor Khunti

Appendix 7: Site-specific ethical approval from Leicester City PCT for a qualitative interview study to elicit and explore the understanding, perceptions and experiences of Type 2 diabetes with depression and/or diabetes-specific distress (Chapter 4)

NHS
Leicester City

Leicester, Leicestershire & Rutland Primary Care Research Office
C/o Leicestershire, Northamptonshire and Rutland
Comprehensive Local Research Network
Marriott Ward
Second Floor, Victoria Building
Leicester Royal Infirmary
Leicester, LE1 5WW

Miss Nicola Perrin
PhD Student
19 Two Yard Land
Nuneaton
Warwickshire
CV10 9FH

13th January 2012

R&D Ref: 70466
REC Ref: 11/EM/0280

Dear Nicola

Letter of Access to conduct the research study:
Diabetes, Depression and Distress - the 3D Study

This letter confirms your right of access to conduct research through NHS Leicester City for the purpose and on the terms and conditions set out below. This right of access commences on **13th January 2012** and ends on **31st December 2013** unless terminated earlier in accordance with the clauses below.

You have a right of access to conduct such research as confirmed in writing in the letter of permission for research from this NHS organisation. Please note that you cannot start the research until the Principal Investigator for the research project has received a letter from us giving permission to conduct the project.

The information supplied about your role in research at NHS Leicester City has been reviewed and you do not require an honorary research contract with this NHS organisation. We are satisfied that such pre-engagement checks as we consider necessary have been carried out.

You are considered to be a legal visitor to NHS Leicester City premises. You are not entitled to any form of payment or access to other benefits provided by this NHS organisation to employees and this letter does not give rise to any other relationship between you and this NHS organisation, in particular that of an employee.

While undertaking research through NHS Leicester City you will remain accountable to your employer the **University of Leicester** but you are required to follow the reasonable instructions of **Kamlesh Khunti - General Practitioner** in this NHS organisation or those given on his behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by this NHS organisation in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with NHS Leicester City policies and procedures, which are available to you upon request, and the Research Governance Framework.

You are required to co-operate with NHS Leicester City in discharging its duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on NHS Leicester City premises. You must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of any other contract holder and you must act appropriately, responsibly and professionally at all times.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice (http://www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf) and the Data Protection Act 1998. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that this NHS organisation accepts no responsibility for damage to or loss of personal property.

We may terminate your right to attend at any time either by giving seven days written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of this NHS organisation or if you are convicted of any criminal offence. As from 26 July 2010, your HEI employer may initiate your Independent Safeguarding Authority (ISA) registration (where applicable), and thereafter, will continue to monitor your ISA registration status via the on-line ISA service. Should you cease to be ISA-registered, this letter of access is immediately terminated. Your employer will immediately withdraw you from undertaking this or any other regulated activity. You MUST stop undertaking any regulated activity.

Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

NHS Leicester City will not indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

If your current role or involvement in research changes, or any of the information provided in your Research Passport changes, you must inform your employer through their normal procedures. You must also inform your nominated manager in this NHS organisation.

Yours sincerely

Clare O'Neill
RM&G Manager - Primary Care
Leicester, Leicestershire & Rutland Primary Care Research Office

cc: Rod Moore – Deputy Director of Health and Health Improvement, NHS Leicester City
Lisa Surti – HR Projects Officer, NHS Leicester City

Appendix 8: Site-specific ethical approval from the University Hospitals of Leicester NHS Trust for a qualitative interview study to elicit and explore the understanding, perceptions and experiences of Type 2 diabetes with depression and/or diabetes-specific distress (Chapter 4)

University Hospitals of Leicester NHS
NHS Trust

Research & Development Office
Leicester General Hospital
Gwendolen Road
Leicester
LE5 4PW

DIRECTORATE OF RESEARCH & DEVELOPMENT

Director: **Professor D Rowbotham**
Assistant Director: **Dr David Hetmanski**
R&D Manager: **Carolyn Maloney**

Direct Dial: (0116) 258 4109
Fax No: (0116) 258 4226

1st November 2011

Miss Nicola Perrin
PhD Student
Department of Health Sciences
University of Leicester
22-28 Princess Road West
Leicester
LE1 6TP

Dear Miss Perrin,

This letter confirms your right of access to conduct research through **University Hospitals of Leicester NHS Trust** for the purpose and on the terms and conditions set out below. This right of access commences on **1st November 2011** and ends on **1st November 2014** unless terminated earlier in accordance with the clauses below.

You have a right of access to conduct such research as confirmed in writing in the letter of permission for research from this NHS organisation. Please note that you cannot start the research until the Principal Investigator for the research project has received a letter from us giving permission to conduct the project.

The information supplied about your role in research at **University Hospitals of Leicester NHS Trust** has been reviewed and you do not require an honorary research contract with this NHS organisation. We are satisfied that such pre-engagement checks as we consider necessary have been carried out.

You are considered to be a legal visitor to **University Hospitals of Leicester NHS Trust** premises. You are not entitled to any form of payment or access to other benefits provided by this NHS organisation to employees and this letter does not give rise to any other relationship between you and this NHS organisation, in particular that of an employee.

While undertaking research through University Hospitals of Leicester NHS Trust, you will remain accountable to your employer **University of Leicester** but you are required to follow the reasonable instructions of **Jo Howe** in this NHS organisation or those given on her/his behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by this NHS organisation in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with **University Hospitals of Leicester NHS Trust** policies and procedures, which are available to you upon request, and the Research Governance Framework.

You are required to co-operate with **University Hospitals of Leicester NHS Trust** in discharging its duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on **University Hospitals of Leicester NHS Trust** premises. You must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of any other contract holder and you must act appropriately, responsibly and professionally at all times.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice (http://www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf) and the Data Protection Act 1998. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that this NHS organisation accepts no responsibility for damage to or loss of personal property.

We may terminate your right to attend at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of this NHS organisation or if you are convicted of any criminal offence. Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

University Hospitals of Leicester NHS Trust will not indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

If your current role or involvement in research changes, or any of the information provided in your Research Passport changes, you must inform your employer through their normal procedures. You must also inform your nominated manager in this NHS organisation.

Yours sincerely

Carolyn Maloney
R&D Manager

cc: **Copy to University of Leicester HR**
Nicola Junkin – UHL HR
Copy for File
Jo Howe UHL

Appendix 9: Site-specific ethical approval from the Leicester County and Rutland PCT for a qualitative interview study to elicit and explore the understanding, perceptions and experiences of Type 2 diabetes with depression and/or diabetes-specific distress (Chapter 4)

NHS
Leicestershire County and Rutland

Leicester, Leicestershire & Rutland Primary Care Research Office
C/o Leicestershire, Northamptonshire and Rutland
Comprehensive Local Research Network
Marriott Ward
Second Floor, Victoria Building
Leicester Royal Infirmary
Leicester, LE1 5WW

Miss Nicola Perrin
PhD Student
19 Two Yard Lane
Nuneaton
Warwickshire
CV10 9FH

14th February 2012
R&D Ref: 70466
REC Ref: 11/EM/0280

Dear Nicola

Letter of Access to conduct the research study:
Diabetes, Depression and Distress - The 3D Study

This letter confirms your right of access to conduct research through NHS Leicestershire County & Rutland for the purpose and on the terms and conditions set out below. This right of access commences on **14th February 2012** and ends on **31st December 2013** unless terminated earlier in accordance with the clauses below.

You have a right of access to conduct such research as confirmed in writing in the letter of permission for research from this NHS organisation. Please note that you cannot start the research until the Principal Investigator for the research project has received a letter from us giving permission to conduct the project.

The information supplied about your role in research at NHS Leicestershire County & Rutland has been reviewed and you do not require an honorary research contract with this NHS organisation. We are satisfied that such pre-engagement checks as we consider necessary have been carried out.
You are considered to be a legal visitor to NHS Leicestershire County & Rutland premises. You are not entitled to any form of payment or access to other benefits provided by this NHS organisation to employees and this letter does not give rise to any other relationship between you and this NHS organisation, in particular that of an employee.

While undertaking research through NHS Leicestershire County & Rutland you will remain accountable to your employer the **University of Leicester** but you are required to follow the reasonable instructions of **Dr Kamlesh Khunti - General Practitioner** in this NHS organisation or those given on his behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by this NHS organisation in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with NHS Leicestershire County & Rutland policies and procedures, which are available to you upon request, and the Research Governance Framework.

You are required to co-operate with NHS Leicestershire County & Rutland in discharging its duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on NHS Leicestershire County & Rutland premises. You must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of any other contract holder and you must act appropriately, responsibly and professionally at all times.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice (http://www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf) and the Data Protection Act 1998. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that this NHS organisation accepts no responsibility for damage to or loss of personal property.

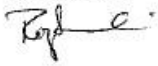
We may terminate your right to attend at any time either by giving seven days written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of this NHS organisation or if you are convicted of any criminal offence. As from 26 July 2010, your HEI employer may initiate your Independent Safeguarding Authority (IISA) registration (where applicable), and thereafter, will continue to monitor your ISA registration status via the on-line ISA service. Should you cease to be ISA-registered, this letter of access is immediately terminated. Your employer will immediately withdraw you from undertaking this or any other regulated activity. You MUST stop undertaking any regulated activity.

Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

NHS Leicestershire County & Rutland will not indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

If your current role or involvement in research changes, or any of the information provided in your Research Passport changes, you must inform your employer through their normal procedures. You must also inform your nominated manager in this NHS organisation.

Yours sincerely



Roz Sorrie
Lead RM&G Manager
Leicester, Leicestershire & Rutland Primary Care Research Office

cc: Julian Mallinson – Consultant in Public Health, NHS Leicestershire County & Rutland

Appendix 10: Site-specific ethical approval from NHS Northamptonshire PCT for a qualitative interview study to elicit and explore the understanding, perceptions and experiences of Type 2 diabetes with depression and/or diabetes-specific distress (Chapter 4)

NHS
Northamptonshire

PUBLIC HEALTH DIRECTORATE

Trust ref: Oxford Vaccine Group Studies
Email: Sue.palmer-hill@northants.nhs.uk
CSP ref: 70466

Northamptonshire Teaching Primary Care Trust
Francis Crick House
Summerhouse Road
Moulton Park
Northampton
NN3 6BF

Tel: 01604 651100
Web: www.northamptonshire.nhs.uk

Business Manager – Jean Smith
Tel: 01604 366304
Fax: 01604 745375

Date: 16th March 2012

Nicola Perrin
University of Leicester
Department of Health Sciences
22 -28 Princess Road West
Leicester
LE1 6TP

Dear Nicola,

Letter of access for research – Exploring the feasibility, acceptability and effectiveness of screening and management for depressive symptoms and diabetes distress for the prevention of deteriorating glycaemic control in people with Type 2 diabetes (Diabetes, depression and distress: The 3D study)

This letter confirms your right of access to conduct research through NHS Northamptonshire for the purpose and on the terms and conditions set out below. This right of access commences on 16th March 2012 and ends on 3rd January 2014 unless terminated earlier in accordance with the clauses below.

You have a right of access to conduct such research as confirmed in writing in the letter of permission for research from this NHS organisation. Please note that you cannot start the research until the Principal Investigator for the research project has received a letter from us giving permission to conduct the project.

The information supplied about your role in research at NHS Northamptonshire has been reviewed and you do not require an honorary research contract with this NHS organisation. We are satisfied that such pre-engagement checks as we consider necessary have been carried out.

You are considered to be a legal visitor to NHS Northamptonshire premises. You are not entitled to any form of payment or access to other benefits provided by this NHS organisation to employees and this letter does not give rise to any other relationship between you and this NHS organisation, in particular that of an employee.

While undertaking research through NHS Northamptonshire, you will remain accountable to your employer University of Leicester but you are required to follow the reasonable instructions of Sue Palmer Hill in this NHS organisation or those given on her behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by this NHS organisation in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

Your healthcare partner

You must act in accordance with NHS Northamptonshire policies and procedures, which are available to you upon request, and the Research Governance Framework.

You are required to co-operate with NHS Northamptonshire in discharging its duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on NHS Northamptonshire premises. You must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of any other contract holder and you must act appropriately, responsibly and professionally at all times.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice (http://www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf) and the Data Protection Act 1998. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that this NHS organisation accepts no responsibility for damage to or loss of personal property.

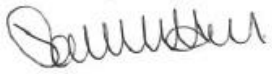
We may terminate your right to attend at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of this NHS organisation or if you are convicted of any criminal offence. As from 26 July 2010, your HEI employer may initiate your Independent Safeguarding Authority (IISA) registration (where applicable), and thereafter, will continue to monitor your ISA registration status via the on-line ISA service. Should you cease to be ISA-registered, this letter of access is immediately terminated. Your employer will immediately withdraw you from undertaking this or any other regulated activity. You MUST stop undertaking any regulated activity.

Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

NHS Northamptonshire will not indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

If your current role or involvement in research changes, or any of the information provided in your Research Passport changes, you must inform your employer through their normal procedures. You must also inform your nominated manager in this NHS organisation.

Yours sincerely



Sue Palmer Hill
Research & Development Manager

Appendix 11: Recruitment documents for the recruitment of general practices in a qualitative interview study to elicit and explore the understanding, perceptions and experiences of Type 2 diabetes with depression and/or diabetes-specific distress (Chapter 4)

Interview study/General practice invitation letter_V1_15/07/2011

NIHR CLAHRC
Leicestershire, Northamptonshire and Rutland (LNR)

University of Leicester
Department of Health Sciences
New Academic Unit
Leicester General Hospital
Gwendolen Road, Leicester, LE5 4PW
Tel: 0116 256 6047

The 3-D Study: Diabetes, Depression and Distress
(Interview Study; Principle Investigator: Prof Kamlesh Khunti)

PRACTICE INVITATION LETTER

Date as postmark

Dear Practice Manager

We are writing to invite your general practice to volunteer to take part in an interview study in which we aim to explore and understand healthcare professionals' and patients' views and experiences of depression and/or distress in the context of type 2 diabetes. This research study will involve recruiting and interviewing healthcare professionals (including mental health practitioners) and patients in primary care. The findings will help us to design a screening and management programme for people with diabetes and depression/distress that can be implemented in general practices.

Enclosed is a study information sheet which explains the purpose of the study and what will be required if you take part. If you decide that your general practice would like to volunteer to take part in this study, please complete the reply slip enclosed with this letter and return it in the reply pre-paid envelope. The reply slip also asks for additional information about your general practice. We may not need to use all of the general practices that volunteer, so this information will help us to make a selection on the basis of list size and location of the practice and the patient population. We would, however, like as many practices as possible to volunteer at this stage. If you volunteer and we do not need to use your practice, we will let you know.

Yours sincerely

Kamlesh Khunti, Prof. of Primary Care Diabetes & Vascular Medicine (Principal Investigator)
Nicola Perrin, PhD Student

Encs.

NIHR CLAHRC Leicestershire, Northamptonshire and Rutland (LNR)

Diabetes Depression Distress

University of Leicester
Department of Health Sciences
New Academic Unit
Leicester General Hospital
Gwendolen Road, Leicester, LE5 4PW
Tel: 0116 258 8047

The 3-D Study: Diabetes, Depression and Distress

(Interview Study; Principle Investigator: Prof Kamlesh Khunti)

PRACTICE INFORMATION SHEET

Background to the study

Many people with type 2 diabetes may at some point experience low mood ('depression') which may or may not be related to living with their diabetes ('diabetes distress'). Research has found that people with diabetes are twice as likely to be depressed, and for some people, some of these feelings are related to their diabetes (such as, distress related to burden of symptoms). People with diabetes and depression are often at greater risk of poor self-management, including reduced adherence to medication, poor diet, and physical inactivity, which may lead to poor diabetes control. Studies have shown this to have damaging effects on people, including an earlier onset of diabetes complications; impairments in physical and mental functioning; poor quality of life; and an overall increase in mortality. There may also be a financial burden on the NHS.

There is currently a shortage of published research evidence that explores both healthcare professionals' and patients' views and experiences about depression and distress in type 2 diabetes. The purpose of this study is to explore and understand, from the perspectives of healthcare professionals (including mental health practitioners) and patients, views on screening people with diabetes for depression and diabetes distress and how best to manage people with both conditions. We would also like to discuss patients' understanding of depression and distress, including their experiences in relation to their diabetes. The findings from the study will be used to inform the development of an intervention to support and guide practices in delivering a feasible and acceptable screening and management programme for their patients with diabetes and depression/distress.

How to take part in the study

1. General practices who are interested in taking part should complete the attached reply form and return it in the pre-paid envelope to indicate their interest.
2. A member of the research team will contact the general practice upon receipt of the reply form with a view to arranging a mutually convenient time for a meeting to explain the research study in more detail.

Interviews with general practice staff will generally be conducted at their place of work or, if they prefer, at the University of Leicester. Interviews with patients will usually take place in their homes, or at the University of Leicester if they prefer. All interviews will be audio-recorded and confidential.

We are aiming to recruit a diverse range of up to 20 patients and 25 healthcare professionals (including mental health practitioners who may be linked to general practices) we would like to include people with varying levels of expertise and experience of depression in the context of diabetes.

Patients and healthcare professionals who are interviewed will receive a £10 store voucher as thanks for their participation.

If you would like to offer for your practice to participate in this research study, please complete the attached reply slip. A reply pre-paid envelope is enclosed.

If you have any queries about the research study, please feel free to contact:

Professor Kamlesh Khunti (Principal Investigator) or Nicola Perrin (PhD Student)
Department of Health Sciences
University of Leicester
22-28 Princess Road West
Leicester
LE1 6TP
Telephone: 0116 252 5445/5401 (nedp1@le.ac.uk).

NIHR CLAHRC
Leicestershire, Northamptonshire and Rutland (LNR)

Diabetes Depression Distress

University of Leicester
Department of Health Sciences
New Academic Unit
Leicester General Hospital
Gwenddolen Road, Leicester, LE5 4PW
Tel: 0116 258 8047

The 3-D Study: Diabetes, Depression and Distress

(Interview Study; Principal Investigator: Prof Kamlesh Khunti)

PRACTICE REPLY SLIP

I would be willing for my practice to volunteer to take part in the above study as described in the study information sheet (Interview study/General practice information sheet_V1_15/07/2011).

Name: (Please PRINT)_____

Signature: _____ **Date:** _____

Role in the practice: _____

Practice name: _____

Practice address: (include postcode)_____

_____

_____

Contact telephone number: _____

It would be helpful if you could provide us with the following information. This information will help us to select a range of different general practices for the research study.

What is the approximate number of patients with diabetes registered at your practice? ☐

Does your practice currently screen people with diabetes for depression?

(Please delete as appropriate) **Yes/No**

If yes, what is the approximate percentage of people with diabetes who also have depression and are registered at your practice? _____

Thank you. A reply-paid envelope is provided for you to return this reply slip. Alternatively, this form can be returned by fax (0116 252 5413) marked for the attention of Nicola Perrin.

Appendix 12: Purposive sampling frameworks for recruiting participants in a qualitative interview study to elicit and explore the understanding, perceptions and experiences of Type 2 diabetes with depression and/or diabetes-specific distress (Chapter 4)

Purposive sampling framework: **Healthcare professionals** (up to 25)

Characteristics		Target number to recruit	Responses (Participant study ID numbers)		Chosen & available for interview (Participant study ID numbers)	
			Responses total:	**18**	**Recruited total:**	**13**
Job title	GP's	7-9	2-3-4-6-7-8-9-22-23-24-26	11	2-3-9-22-23-26	6
	Nurse's	7-9	1-5-10-18-25	5	1-5-10-18-25	5
	MH practitioner	7-9	19-27	2	19-27	2
Gender	Male	10-13	2-4-7-9-22-23-24-26	8	2-9-22-23-26	5
	Female	10-13	1-3-5-6-8-10-18-19-25-27	10	1-3-5-10-18-19-25-27	8
Age	25-39 years	7-9	3-4-23-27	4	3-23-27	2
	40-59 years	7-9	1-2-5-6-7-8-9-10-18-19-22-25-26	13	1-2-5-9-10-18-19-22-25-26	11
	60-79 years	7-9	24	1	-	-
Experience	≤ 5 years	3-5	19-23-27	3	19-23-27	3
	6 – 10 years	3-5	3-9	2	3-9	2
	11 - 15 years	3-5	4-6-7-10-18	5	10-18	2
	16 – 20 years	3-5	1-5-22-25	4	1-5-22-25	4
	> 20 years	3-5	2-8-24-26	4	2-26	2
Practice	Practice 1 (Leicester City)	1-3	Non-responsive	-	-	-
	Practice 2 (Leicester City)	1-3	2	1	2	1
	Practice 3 (Leicester City)	1-3	10	1	10	1
	Practice 4 (Northamptonshire)	1-3	3-4-5-6-7-8-9-18-19	9	3-5-9-18-19	5
	Practice 5 (Northamptonshire)	1-3	1	1	1	1
	Practice 6 (Leicester City)	1-3	23-25-27	3	23-25-27	3
	Practice 7 (Leicestershire County)	1-3	26	1	26	1
	Practice 8 (Leicestershire County)	1-3	Non-responsive	-	-	-
	Practice 9 (Leicestershire County)	1-3	24	1	Non-responsive	-
	Practice 10 (Leicestershire County)	1-3	22	1	22	1

Purposive sampling framework: **Patients** (up to 20)

Characteristics		Target number to recruit	Responses (Participant study ID numbers)		Chosen & available for interview (Participant study ID numbers)	
			Responses total:	**17**	**Recruited total**	**16**
Gender	Male	9-11	11-12-13-16-17-21-28-31-34	9	11-12-13-16-17-21-28-31-34	9
	Female	9-11	14-15-20-29-30-32-33-35	8	14-15-20-29-30-33-35	7
Age	Below 30 years	3-5	-	-	-	-
	30 – 39 years	3-5	-	-	-	-
	40 – 49 years	3-5	35	1	35	1
	50 – 59 years	3-5	20-21	2	20-21	2
	Over 60 years	3-5	11-12-13-14-15-16-17-28-29-30-31-32-33-34	14	11-12-13-14-15-16-17-28-29-30-31-33-34	13
Depression status	Recently diagnosed	6-8	-	-	-	-
	Previously diagnosed	6-8	15-20-28-29-30-31-32-33-35	8	15-20-28-29-30-31-33-35	8
	Never diagnosed	6-8	11-12-13-14-16-17-21-34	8	11-12-13-14-16-17-21-34	8

Appendix 13: Recruitment documents for the recruitment of healthcare professional participants in a qualitative interview study to elicit and explore the understanding, perceptions and experiences of Type 2 diabetes with depression and/or diabetes-specific distress (Chapter 4)

NIHR CLAHRC Leicestershire, Northamptonshire and Rutland (LNR)

Diabetes Depression Distress

University of Leicester
Department of Health Sciences
New Academic Unit
Leicester General Hospital
Gwendolen Road, Leicester, LE5 4PW
Tel: 0116 258 6047

The 3-D Study: Diabetes, Depression and Distress

(Interview Study; Principle Investigator: Prof Kamlesh Khunti)

HEALTHCARE PROFESSIONAL RECRUITMENT INFORMATION FOR PRACTICE MANAGERS

Thank you for agreeing to help with recruitment of healthcare professionals for the above study. The information below will tell you about the study and who we would like to recruit.

The study:

In this interview study, we are conducting some interviews with patients with type 2 diabetes and healthcare professionals (including mental health practitioners) involved in their care. We would like to understand their views on screening people with diabetes for depression and distress and how best to manage people with these conditions. We would also want to discuss with patients' their understanding and experience of depression and distress in relation to their diabetes. We hope that the findings will help to inform patient management. We need only around 20 patient and 25 healthcare professional volunteers in total for this study from all of the practices involved.

Recruitment to the study is in 3 stages. Practice managers will be involved in stage 1 only:

1. Practice managers will identify eligible healthcare professionals who are directly involved in the case of people with diabetes and/or mental health problems who are registered at their practice. Eligible healthcare professionals include:

- General practitioners;
- Practice nurses;
- Diabetes specialist nurses;
- Counsellors;
- Therapists;
- Clinical psychologists;
- Psychiatrists;

- Psychological wellbeing practitioners;
- Primary care mental health workers;
- Community psychiatric nurses.

Practice managers will give an information sheet, reply slip and a pre-paid envelope to healthcare professionals in the practice, or linked to the practice, deemed eligible for participation in the study. Healthcare professionals interested in taking part will send their reply slip to the study researcher.

2. Upon receipt of reply slips from volunteers, the study researcher will select who to interview (based on the information provided by healthcare professionals on their reply slips). They will then contact chosen volunteers and discuss the study, confirm that they wish to take part and then arrange a mutually convenient date and time for the interview. Volunteers not selected to take part in interviews will be notified and thanked.
3. Full consent to being interviewed will be obtained by the researcher at the time of the interview.

Thank you for your help. If you have any questions about the study please feel free contact:

Professor Kamlesh Khunti (Principal Investigator) or Nicola Perrin (PhD Student)
Department of Health Sciences
New Academic Unit
Leicester General Hospital
Gwendolen Road, Leicester, LE1 6TP
Telephone: 0116 252 5445/ 0116 258 8047 (nedp1@le.ac.uk)

NIHR CLAHRC
Leicestershire, Northamptonshire and Rutland (LNR)

Diabetes Depression Distress

University of Leicester
Department of Health Sciences
New Academic Unit
Leicester General Hospital
Gwendolen Road, Leicester, LE5 4PW
Tel: 0116 258 8047

The 3-D Study: Diabetes, Depression and Distress

(Interview Study; Principle Investigator: Prof Kamlesh Khunti)

HEALTHCARE PROFESSIONAL INFORMATION SHEET

The general practice where you work has agreed to be involved in the above study that forms part of a PhD qualification. We would like to invite you to volunteer to take part in some interviews. Before you decide, you need to understand why this research is being done and what it will involve. Please read the following information carefully and ask us if there is anything that is not clear or if you would like more information.

Why is this research being done?
People with type 2 diabetes are likely to experience low mood ('depression'), which may or may not be related to their diabetes ('distress') and can often result in them getting serious complications such as heart disease earlier. Our aim is to explore and understand, from the perspectives of healthcare professionals and patients, views on screening and managing people with these conditions. We would also like to discuss patients' understanding of depression and distress, including their experiences in relation to their diabetes. The findings will be used to inform the development of a programme to help general practices provide enhanced care for their patients with diabetes, depression and distress.

What will be involved if I take part?
The interviews will be audio-recorded and will last about 30 minutes. They will generally be carried out at the general practice where you work, but, if you prefer, we can arrange to hold the interviews at the University of Leicester. We would like as many people as possible to offer to be interviewed so that we can select a good variety of people, for example, practice nurses, general practitioners, and mental health practitioners. It is possible that we may not need to use everyone who volunteers for the interviews, but if you offer to be interviewed and we find that we don't need you, we will let you know this.

Who can volunteer?
We are looking for healthcare professionals who are involved in the care of people with type 2 diabetes, including practice nurses, general practitioners, diabetes specialist nurses, and mental health practitioners who may see people with diabetes for treatment of depression, such as: counsellors, therapists, clinical psychologists, psychological wellbeing practitioners and community psychiatric nurses.

Will the interview be confidential?
The audio-recording will be treated in the strictest confidence and will be stored without your name on it. Anyone who takes part can request a copy of their interview if they wish. The audio-recording will be destroyed at the end of the study and we will not use your name or any other identifying information in the publication or dissemination of results.

What if a disclosure of malpractice is made?
Firstly, you should try to avoid mentioning instances of anything that you consider to be bad practice, except in a way than cannot be linked to any specific individual. Secondly, it is not

part of the role of the research to report information given in the course of this interview except as part of the overall findings of the research, and it is your own responsibility to take action regarding anything that you consider to be bad practice. However if anything should emerge, either about your own or other peoples practice, that could be considered to pose an 'immediate risk' to others it will be considered appropriate to take action. You should also be aware that if the interviewer suspects malpractice, this will be discussed with the study team.

What will happen to the results of the study?
The results of this research may be published in a medical journal or presented at research meetings.

Who is responsible for this research?
This research is being carried out by the University of Leicester. The Principal Investigator, who will take responsibility for the study, is Professor Kamlesh Khunti.

Who has reviewed this study?
To protect your safety, rights, well-being and dignity, all research involving patients is looked at by an independent group of people, called a Research Ethics Committee. This study has been reviewed by the appropriate ethics committee in accordance with local regulations.

What if I am harmed by the study?
As this study just involves interviews, it is highly unlikely that you would be harmed. However, if you wish to complain or have any concerns about the way you have been approached or treated in connection with the study, you can speak to Professor Khunti, the principal investigator in the study team (address and phone number below). However if you prefer to speak to someone other than the researchers please contact the Research and Development (R&D) Team at Leicester City PCT 0116 295 1400 or St. Johns House, 30 East Street, Leicester, Leicestershire, LE1 6NB.

Do I have to take part?
No, we are looking for volunteers. Even if you volunteer and agree to take part, you can change your mind at any time, without giving a reason.

Will I be reimbursed for participating in the study?
People who are interviewed in this study will receive a £10 store voucher as thanks for taking part.

What do I do if I decide to volunteer?
If you have decided to volunteer to take part in the study, please send us the interview reply slip in the envelope provided, which does not need a stamp. A member of the research team will contact you to arrange a mutually convenient time and place to hold the interview.

If you still have any queries about the research study, please feel free to contact:

Professor Kamlesh Khunti (Principal Investigator) or Nicola Perrin (PhD Student)

Department of Health Sciences

New Academic Unit

Leicester General Hospital

Gwendolen Road, Leicester, LE1 6TP

Telephone: 0116 252 5445/ 0116 258 8047 (nedp1@le.ac.uk)

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Diabetes Depression Distress

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Department of Health Sciences
New Academic Unit
Leicester General Hospital
Gwendolen Road, Leicester, LE5 4PW
Tel: 0116 258 8047

The 3-D Study: Diabetes, Depression and Distress

(Interview Study; Principle Investigator: Prof Kamlesh Khunti)

HEALTHCARE PROFESSIONAL REPLY SLIP

I would like to volunteer to take part in this study as described in the study information sheet (Interview study/HCP information sheet_V2_25/08/2011).

Signature: _____ **Date:** _____

Name: (Please PRINT) _____

Practice name: _____

Practice address: (include postcode) _____

_____

_____

Contact telephone number: _____

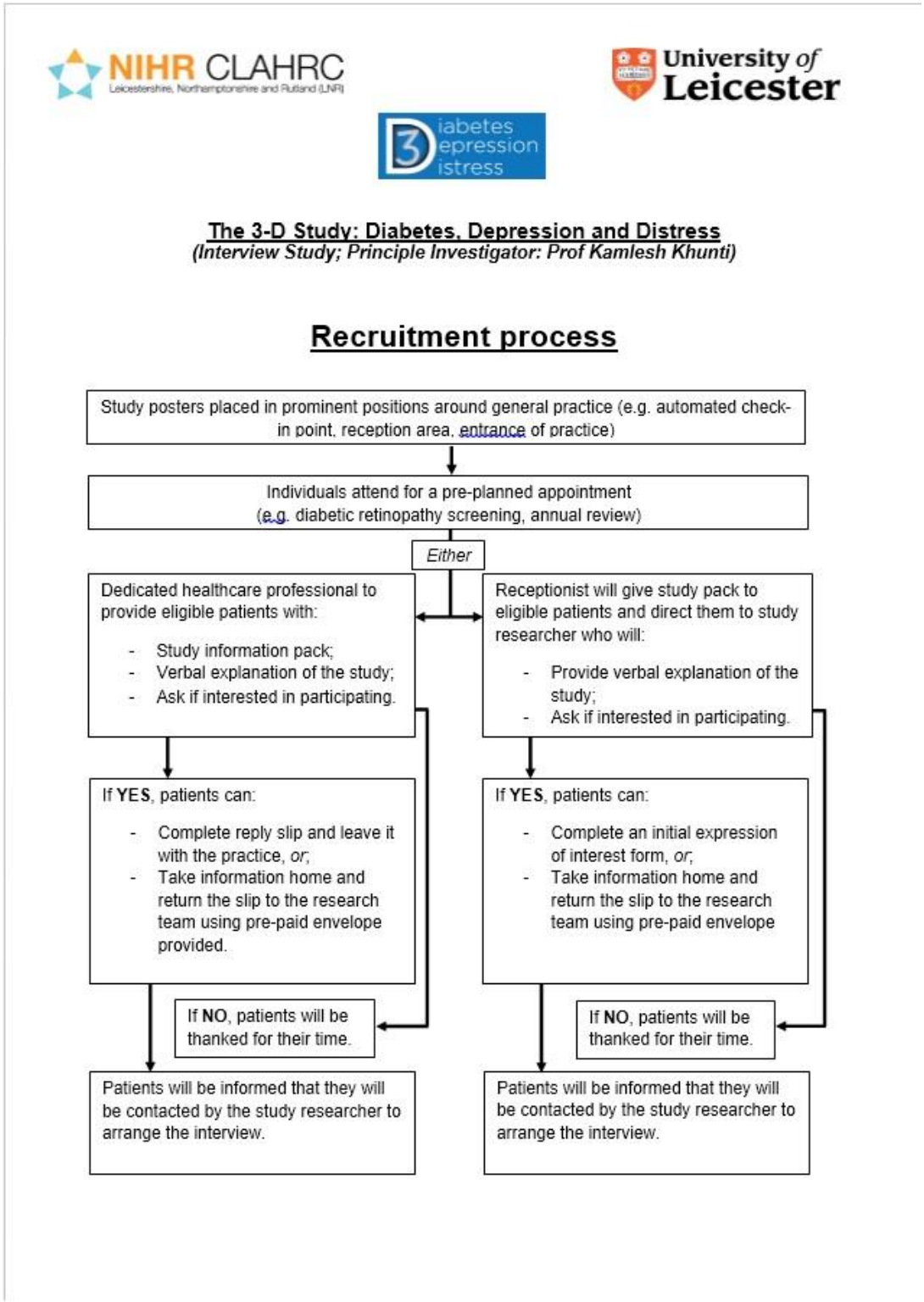
We may not need to interview everyone who volunteers. To help us to choose a range of different types of people, it would be very helpful if you could provide the following information about yourself:

1. Are you? Male/Female (Please delete as appropriate).
2. What is your job title? _____
3. What is your age? (Please tick one box only).

   i) 25-39 ☐ ii) 40-59 ☐ iii) 60-79 ☐
4. Approximately how long have you worked in primary care? ☐
5. How many patients with Type 2 diabetes do you currently manage who also have diagnosed depression and/or distress related to their diabetes? ☐

Thank you. A reply-paid envelope is provided for you to return this reply slip. Alternatively, this form can be returned by fax (0116 258 4982) marked for the attention of Nicola Perrin.

Appendix 14: Recruitment process flow diagram for the recruitment of patients in a qualitative interview study to elicit and explore the understanding, perceptions and experiences of Type 2 diabetes with depression and/or diabetes-specific distress (Chapter 4)



Appendix 15: Information for practice staff for the recruitment of patients in a qualitative interview study to elicit and explore the understanding, perceptions and experiences of Type 2 diabetes with depression and/or diabetes-specific distress (Chapter 4)

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Leicestershire, Northamptonshire and Rutland (LNR)

Diabetes Depression Distress

University of Leicester
Department of Health Sciences
New Academic Unit
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Tel: 0116 258 8047

The 3-D Study: Diabetes, Depression and Distress
(Interview Study; Principle Investigator: Prof Kamlesh Khunti)

PATIENT RECRUITMENT INFORMATION FOR PRACTICE STAFF

Thank you for agreeing to help with recruitment of patients for the above study. The information below will tell you about the study and who we would like to recruit.

The study:

In this interview study, we will be conducting some interviews with patients with type 2 diabetes and healthcare professionals (including mental health practitioners) involved in their care. We would like to understand their views on screening people with diabetes for depression and distress and how best to manage people with these conditions. We would also like to discuss with patients their understanding and experience of depression and distress in relation to their diabetes. We hope that the findings will help to inform patient management. We need around 20 patient volunteers in total for this study from all of the practices involved.

Recruitment to the study is in 3 stages. Care providers will be involved in stage 1 only:

1. A member of general practice staff will identify eligible patients from clinic lists of pre-planned appointments, and will determine whether people have or do not have diagnosed depression. When eligible patients attend for their appointment, practice staff will give them a copy of the patient information sheet and will ask patients to consider whether they would be prepared to take part in the study. They will inform the patient that there is a researcher present at the clinic to discuss the study further and answer any queries and that they should speak to her if they would be willing to consider volunteering. For patients who would prefer to read the study information at home, practice staff will provide a reply slip (PINK form) and pre-paid envelope, and advise patients to return this to the research team if they are interested in volunteering

2. The researcher will discuss the study with the patient, confirm that they wish to take part and obtain consent to make a note of their contact details for arranging an interview. Patients will be aware from the information sheet that the researcher will also ask them to provide some details on their age, gender, ethnicity, and depression status as part of the recruitment and initial consent process. For patients who return a reply slip to the research team to volunteer with the study, the researcher will contact them to discuss the study and confirm that they wish to take part, and will then arrange a mutually convenient time for the interview.
3. Full consent to being interviewed will be obtained by the researcher at the time of the interview.

Thank you for your help. If you have any questions about the study please feel free contact:

Professor Kamlesh Khunti (Principal Investigator) or Nicola Perrin (PhD Student)
Department of Health Sciences
New Academic Unit
Leicester General Hospital
Gwendolen Road, Leicester, LE1 6TP
Telephone: 0116 252 5445/ 0116 258 8047 (nedp1@le.ac.uk)

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University of Leicester

Diabetes Depression Distress

The 3-D Study: Diabetes, Depression and Distress
(Interview Study; Principle Investigator: Prof Kamlesh Khunti)

Patient Eligibility Criteria

Diagnosed with Type 2 diabetes

Diagnosis or history of depression

Aged 18 years or over

Able to speak and understand English

Appendix 16: Recruitment documents for the recruitment of patients in a qualitative interview study to elicit and explore the understanding, perceptions and experiences of Type 2 diabetes with depression and/or diabetes-specific distress (Chapter 4)

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Leicestershire, Northamptonshire and Rutland (LNR)

Diabetes Depression Distress

University of Leicester
Department of Health Sciences
New Academic Unit
Leicester General Hospital
Gwendolen Road, Leicester, LE5 4PW
Tel: 0116 258 6047

The 3-D Study: Diabetes, Depression and Distress
(Interview Study; Principle Investigator: Prof Kamlesh Khunti)

PATIENT INFORMATION SHEET

You are being invited to volunteer to take part in a research study that forms part of a PhD qualification. Before you decide you need to understand why the research is being done and what it will involve. Please read the following information carefully and discuss it with a healthcare professional at your practice, such as your practice nurse or GP, if you wish. Please ask us if there is anything that is not clear or if you would like more information.

Why is this research being done?
We would like to hear what people with type 2 diabetes think about low mood (or 'depression') which may or may not be related to living with their diabetes ('diabetes distress'). By finding out about their views and experiences, we hope to improve our understanding of how people feel about depression and diabetes distress, what they think about being measured for depression and distress at their general practice, and what kind of care they would like to receive. This should help us to know whether there are any things that doctors and nurses can do to give people a better experience of care if they have depression or are finding it hard to manage their diabetes.

What will be involved if I take part?
We are looking for volunteers who will agree to being interviewed about depression and diabetes distress. The interviews will be carried out in people's homes, or if you prefer, at the University of Leicester; they will last about half an hour to one hour at the most, and they will be audio (voice) recorded. If you volunteer for the interviews, we will need your contact details to get in touch with you, but after we have done the interview or let you know that you are not needed, we will destroy these contact details.

Will everyone be interviewed who volunteers?
It is possible that we may not need to use everyone who volunteers for the interviews, but if you offer to be interviewed and we find that we don't need you, we will let you know this. However, we would like as many people as possible to offer to be interviewed so that we can select a good variety of people, for example, men and women and people from different age groups.

Who can volunteer?
People aged 18 or over who have type 2 diabetes and who speak English (this is because the interviews will be conducted in English). Your healthcare professional has approached you and given you this information about the study because of your current or past medical problems, which will include type 2 diabetes and may also include depression.

Will the interview be confidential?
The audio-recording will be treated in the strictest confidence and will be stored without your name on it. Anyone who takes part can request a copy of their interview if they wish. The audio-recording will be destroyed at the end of the study and we will not use your name or

any other identifying information in the results. Your contact telephone number will be deleted from our records once the interview has been completed. Healthcare professionals at your general practice, including your doctor or practice nurse will not know what you have said in the interview.

What will happen to the results of the study?
The results of this research may be published in a medical journal or presented at research meetings.

Who is responsible for this research?
The Principal Investigator, who will take responsibility for the study, is Professor Kamlesh Khunti.

Who has reviewed this study?
To protect your safety, rights, well-being and dignity, all research involving patients is looked at by an independent group of people, called a Research Ethics Committee. This study has been reviewed by the appropriate ethics committee in accordance with local regulations.

What if I am harmed by the study?
In this research we will just be interviewing people, so it is unlikely that it will cause harm to anyone. However, if you wish to complain or have any concerns about the way in which you have been approached or treated in connection with the study, you can speak to Professor Khunti, the principal investigator in the study team (address and phone number below). However if you prefer to speak to someone other than the researchers please contact the Patient Information and Liaison Service (PILS) by telephone at 08081 788337.

Do I have to take part?
No, we are looking for volunteers. Even if you volunteer and agree to take part, you can change your mind at any time, without giving a reason.

Will I be reimbursed for participating in the study?
People who are interviewed in this study will receive a £10 store voucher as thanks for taking part.

What do I do if I decide to volunteer?
If you have decided to volunteer to take part in the study, please discuss this with the researcher who is available at the general practice. If you decided to take the information home with you to read, please send us the reply slip in the envelope provided, which does not need a stamp. A member of the research team will contact you to arrange a mutually convenient time and place to hold the interview.

If you still have any queries about the research study, please feel free to contact:

Professor Kamlesh Khunti (Principal Investigator) or Nicola Perrin (PhD Student)
Department of Health Sciences
New Academic Unit
Leicester General Hospital
Gwendolen Road, Leicester, LE1 6TP
Telephone: 0116 252 5445/ 0116 258 8047 (nedp1@le.ac.uk)

NIHR CLAHRC
Leicestershire, Northamptonshire and Rutland (LNR)

University of Leicester
Department of Health Sciences
New Academic Unit
Leicester General Hospital
Gwendolen Road, Leicester, LE5 4PW
Tel: 0116 258 8047

The 3-D Study: Diabetes, Depression and Distress
(Interview Study; Principal Investigator: Prof Kamlesh Khunti)

INITIAL EXPRESSION OF INTEREST AND PATIENT DETAILS FORM

To be signed by the volunteer:

I consent to my contact details being used for arranging and carrying out a research interview. I understand that I can change my mind about doing the interview, that the researcher will discuss this research with me again before starting the interview and that my contact details will be destroyed once they are no longer needed for getting in touch with me.

Name of volunteer (PRINT): _____

Signature (or mark): _____ Date: _____

.....

To be completed by researcher:

I confirm that it is my opinion that the volunteer has understood what is involved in taking part in this study. If the volunteer is unable to read the information sheet and this initial consent form, I confirm that the content has been fully explained verbally.

Name of researcher (PRINT): Signature: Date:

_____ _____ _____

(NOTE: Page 2 to be destroyed once contact and other details are no longer required for arranging and conducting the interview).

To be completed by researcher:

Name of volunteer (PRINT):_____

Address:

Contact telephone number: _____

To be completed by volunteer:

It would also be helpful for us to know the following (where appropriate, please tick *one* box for each question):

1. Your age group:

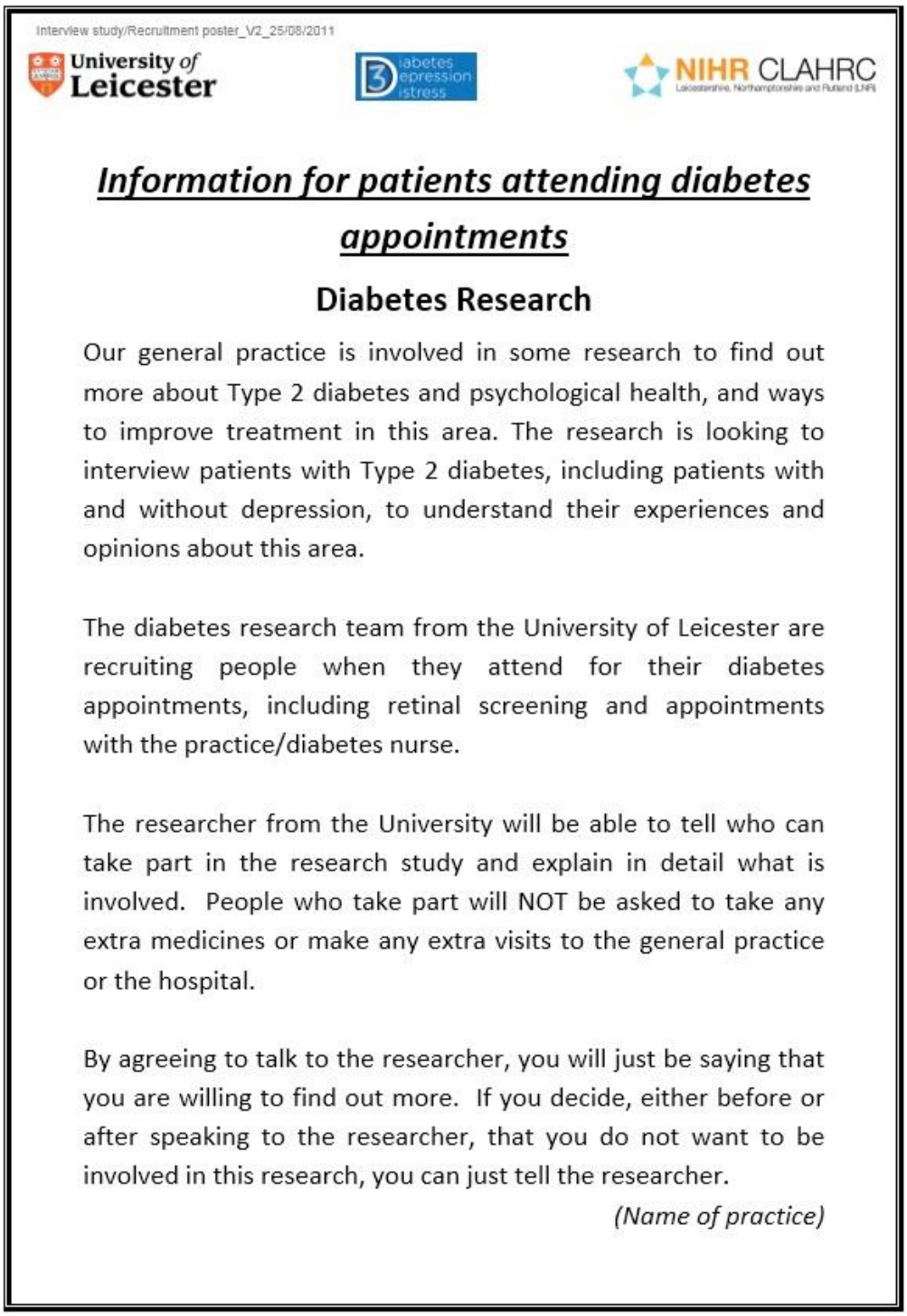
Below 30 ☐ 30-39 ☐ 40-49 ☐ 50-59 ☐ 60 or over ☐

2. Male ☐ Female ☐

3. How would you describe your ethnic origin?_____

4. Which of the following statements best describes you:
   I have *recently* been diagnosed with depression ☐
   I have *previously* been diagnosed with depression ☐
   I have *never* been diagnosed with depression ☐

Appendix 17: Poster displayed in general practices for the recruitment of patients in a qualitative interview study to elicit and explore the understanding, perceptions and experiences of Type 2 diabetes with depression and/or diabetes-specific distress (Chapter 4)



Interview study/Recruitment poster_V2_25/08/2011

University of Leicester

Diabetes Depression Distress

NIHR CLAHRC Leicestershire, Northamptonshire and Rutland (LNR)

Information for patients attending diabetes appointments

Diabetes Research

Our general practice is involved in some research to find out more about Type 2 diabetes and psychological health, and ways to improve treatment in this area. The research is looking to interview patients with Type 2 diabetes, including patients with and without depression, to understand their experiences and opinions about this area.

The diabetes research team from the University of Leicester are recruiting people when they attend for their diabetes appointments, including retinal screening and appointments with the practice/diabetes nurse.

The researcher from the University will be able to tell who can take part in the research study and explain in detail what is involved. People who take part will NOT be asked to take any extra medicines or make any extra visits to the general practice or the hospital.

By agreeing to talk to the researcher, you will just be saying that you are willing to find out more. If you decide, either before or after speaking to the researcher, that you do not want to be involved in this research, you can just tell the researcher.

(Name of practice)

Appendix 18: Written consent form for healthcare professional participants in a qualitative interview study to elicit and explore the understanding, perceptions and experiences of Type 2 diabetes with depression and/or diabetes-specific distress (Chapter 4)

Interview study/HCP consent form_V1_15/07/2011

NIHR CLAHRC
Leicestershire, Northamptonshire and Rutland (LNR)

University of Leicester
Department of Health Sciences
New Academic Unit
Leicester General Hospital
Gwendolen Road, Leicester, LE5 4PW
Tel: 0116 258 8047

The 3-D Study: Diabetes, Depression and Distress
***(Interview Study;* Principal Investigator: Prof Kamlesh Khunti)**

HEALTHCARE PROFESSIONAL CONSENT FORM

[Please write your initials in each box]

1) I confirm that I have read and understood the Healthcare Professional Information Sheet (Version 2, dated 25/08/2011) for the above study and have had the opportunity to ask questions. [1]

2) I understand that taking part is voluntary and that I am free to withdraw at any time, without giving a reason and without my medical care or legal rights being affected. [2]

3) I understand that the interview will be audio-recorded but that the recording will be destroyed at the end of the study and all information will remain strictly confidential. [3]

4) I agree that any information collected about me as part of the study can be stored and analysed by the research team at the University of Leicester, and that small parts of what I say may be quoted anonymously when the results of the research are reported. [4]

5) I agree to take part in this study. [5]

Name of volunteer (PRINT):	Signature:	Date:
_____	_____	_____
Name of researcher (PRINT):	Signature:	Date:
_____	_____	_____

Appendix 19: Written consent form for patients in a qualitative interview study to elicit and explore the understanding, perceptions and experiences of Type 2 diabetes with depression and/or diabetes-specific distress (Chapter 4)

Interview study/Patient consent form_V1_15/07/2011

NIHR CLAHRC
Leicestershire, Northamptonshire and Rutland (LNR)

University of Leicester
Department of Health Sciences
New Academic Unit
Leicester General Hospital
Gwendolen Road, Leicester, LE5 4PW
Tel: 0116 258 8047

The 3-D Study: Diabetes, Depression and Distress

(Interview Study; Principal Investigator: Prof Kamlesh Khunti)

PATIENT CONSENT FORM

[Please write your initials in each box]

1) I confirm that I have read and understood the Patient Information Sheet (Version 2, dated 25/08/2011) for the above study and have had the opportunity to ask questions. [1]

2) I understand that taking part is voluntary and that I am free to withdraw at any time, without giving a reason and without my medical care or legal rights being affected. [2]

3) I understand that the interview will be audio-recorded but that the recording will be destroyed at the end of the study and all information will remain strictly confidential. [3]

4) I agree that any information collected about me as part of the study can be stored and analysed by the research team at the University of Leicester, and that small parts of what I say may be quoted anonymously when the results of the research are reported. [4]

5) I agree to take part in this study. [5]

Name of volunteer (PRINT): Signature: Date:

_____ _____ _____

.....

To be completed by person taking consent:

I confirm that it is my opinion that the volunteer has understood what is involved in taking part in this study. If the volunteer is unable to read the information sheet and consent form, I confirm that the content has been fully explained verbally.

Name of researcher (PRINT): Signature: Date:

_____ _____ _____

Appendix 20: Post-interview sheet for patients in a qualitative interview study to elicit and explore the understanding, perceptions and experiences of Type 2 diabetes with depression and/or diabetes-specific distress (Chapter 4)

NIHR CLAHRC
Leicestershire, Northamptonshire and Rutland (LNR)

Diabetes Depression Distress

University of Leicester
Department of Health Sciences
New Academic Unit
Leicester General Hospital
Gwendolen Road, Leicester, LE5 4PW
Tel: 0116 258 6047

The 3-D Study: Diabetes, Depression and Distress
(Interview Study; Principal Investigator: Prof Kamlesh Khunti)

Thank you for agreeing to be interviewed for this study.

If talking with the researcher has raised any issues that you would like to discuss with someone, please contact your doctor or nurse for advice and support.

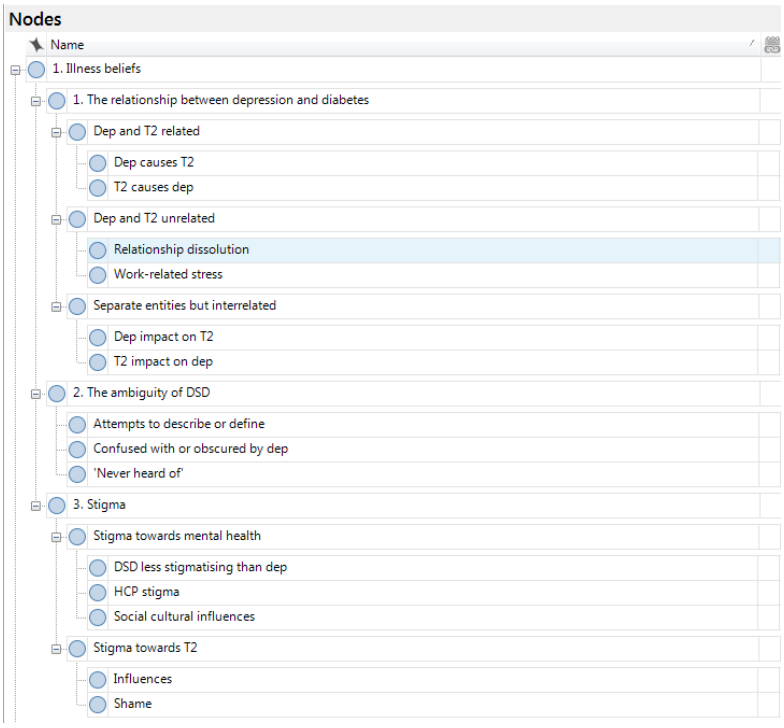
You may also find the following telephone numbers helpful:

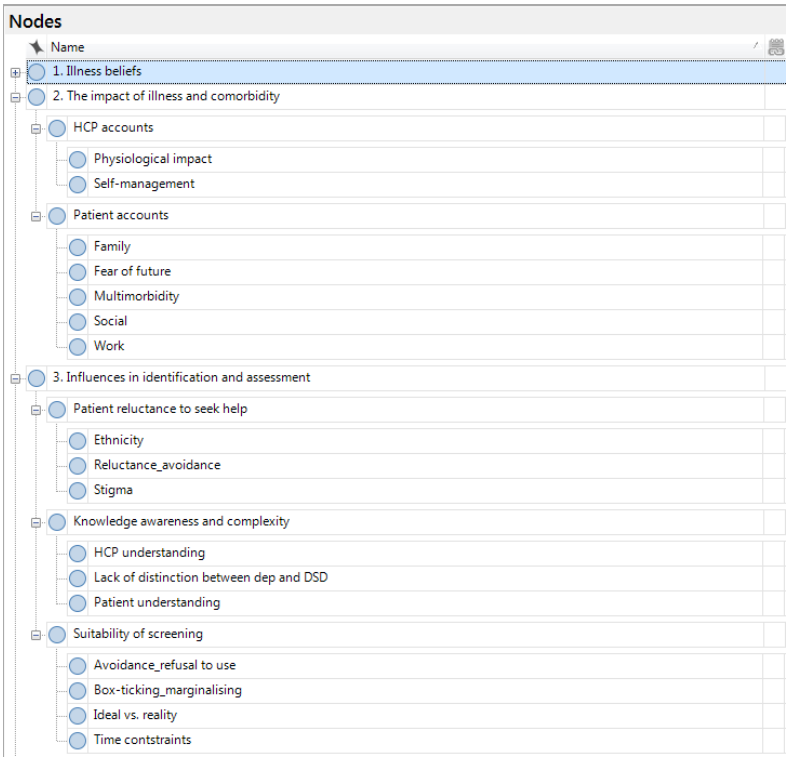
- **Samaritans (08457 90 90 90).** They are able to support people who may be feeling distressed and perhaps want to talk to someone about it;

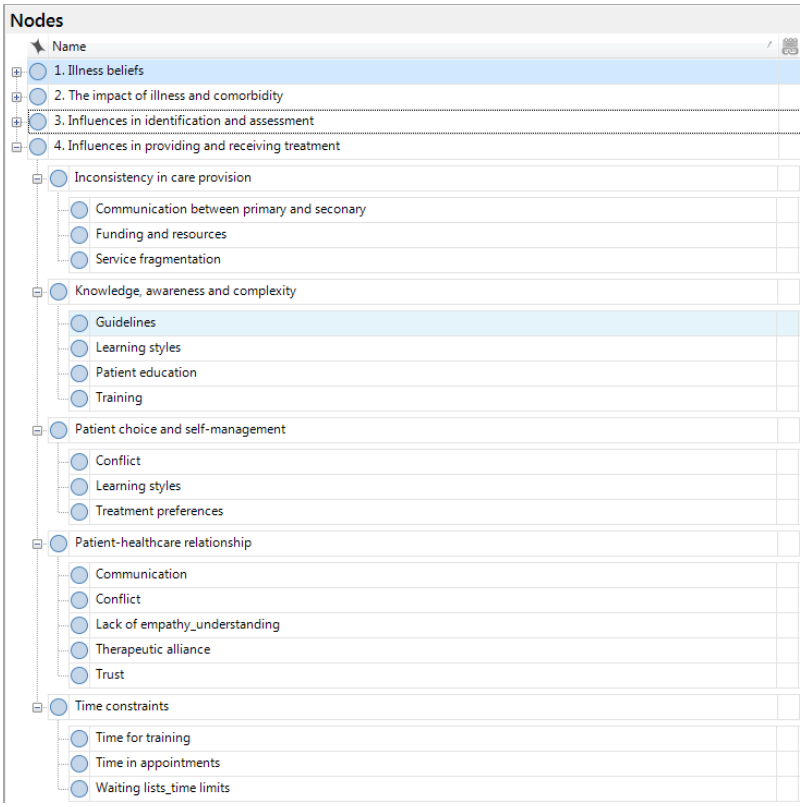
- **LAMP Direct (0116 255 6286)** or **MIND (0300 123 3393)**. They are able to talk to people about mental health issues and where they can find support in their local area;

- **Patient Advice and Liaison Service (PALS) (0116 295 7011)**. They are able to tell people about NHS services for people that may have health problems, and support groups where they could find help.

Appendix 21: Example of coding in the data analysis for a qualitative interview study to elicit and explore the understanding, perceptions and experiences of Type 2 diabetes with depression and/or diabetes-specific distress (Chapter 4)






Nodes
Name
1. Illness beliefs
2. The impact of illness and comorbidity
3. Influences in identification and assessment
4. Influences in providing and receiving treatment
Inconsistency in care provision
Communication between primary and seconary
Funding and resources
Service fragmentation
Knowledge, awareness and complexity
Guidelines
Learning styles
Patient education
Training
Patient choice and self-management
Conflict
Learning styles
Treatment preferences
Patient-healthcare relationship
Communication
Conflict
Lack of empathy_understanding
Therapeutic alliance
Trust
Time constraints
Time for training
Time in appointments
Waiting lists_time limits

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