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Improving the care of people with diabetes and severe mental illness

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Declaration

I, Tracey Dorey confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

Abstract

Background

There is an increased prevalence, morbidity, reduced quality of life and excess mortality in adults with a severe mental illness (SMI) and type 2 diabetes (T2D). While the origins of these disparities are multifaceted, health care system and delivery factors emerge as a noteworthy contributing element.

Aim

The aim of this PhD was to develop a theoretically informed and evidence-based behaviour change intervention to support improved T2D care for adults with an SMI.

Method

This PhD consists of five studies. A systematic review (*Study 1*) of the perceived barriers and enablers of delivery and organisation of T2D care for adults with an SMI. A theoretical congruence assessment (*Study 2*) of existing interventions targeting health professional delivery of T2D care. The design of an intervention informed by the 8 steps of the Behaviour Change Wheel. A Delphi study (*Study 3*) with 21 service users, health professionals, and carers supported completion of steps 1 -3 to identify and specify a behaviour target(s). A qualitative interview study (*Study 4*) with 10 health professionals which through a deductive (using Framework Analysis) and inductive analysis (using Codebook Thematic Analysis) identified the important domains of the Theoretical Domains Framework to be targeted in a resulting intervention. Final steps 5-8 of the Behaviour Change Wheel were completed through mapping exercises, existing literature, and a Delphi study (*Study 5*) with 6 mental health professionals resulted in a draft intervention strategy.

Results

The expansive systematic review of 28 studies, consisting of 2,243 participants identified that health professionals perceive barriers to the provision of T2D care for adults with an SMI across individual, interpersonal, and organisational levels. The domains *Environmental Context and Resources, Social influence, Social/professional role and identity, Knowledge, Skills,* Goals and *Beliefs about* capabilities were identified as important determinants. Existing interventions were limited in number (n=8) but targeted many of the identified domains. It was identified however that there was scope to expand on existing interventions by considering a wider range of theoretically congruent intervention content, ensuring more detailed intervention descriptions, and developing rigorous evaluations. The INDEX guidance and the eight steps Behaviour Change Wheel were used to guide the development of a theoretically informed and evidence-based intervention over three studies. It was identified that T2D care for adults with an SMI could be improved by focussing on 1) HbA1c monitoring, 2) provision of lifestyle advice and 3) referral, delivered during relapse of severe mental illness by mental health nurses working in community mental health teams. Across all three target behaviours eight domains were identified as important. The centrality of *social/professional role and identity* and the need to shift responsibility was highlighted. Intervention development resulted in the selection of 6 intervention functions, 3 policy categories, and 14 behaviour change techniques which were combined into four overarching intervention strategies - 1) a training session, 2) appointment of a T2D relapse champion, 3) goals and feedback and 4) changes to care planning and the environment

Conclusion

This PhD has provided a clear understanding of the perspectives and priorities of service users, carers, and health professionals resulting in a novel, evidence-based and theory-informed intervention. The intervention strategies collectively aim to improve the knowledge and skills of mental health nurses, enhance teamwork and support systems, set goals, and provide feedback, and modify the care planning process and environment to facilitate the provision of three target behaviours (1. HbA1c monitoring, 2. referrals and 3. lifestyle advice) during a relapse of SMI. Whilst these strategies demonstrate promise it is important to consider contextual factors such as staff readiness for change, the emotional response to feedback and the overall context of community mental health care. Ongoing evaluation and refinement of these strategies will be needed and can be progressed through post-doctoral feasibility testing.

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List of abbreviations

6SQUID	Six essential Steps for Quality Intervention Development;
AACCODS	Authority, Accuracy, Coverage, Objectivity, Date, Significance
AACTT	Action, Actor, Context, Target, Time
APEASE	*Affordability, Practicability, Effectiveness and Cost-effectiveness, Acceptability, Side-effects,* and *Equity*
APMS	Adult Psychiatric Morbidity Survey
AXIS	Appraisal tool for cross-sectional studies
Behaviour Change Technique	Behaviour change technique
BCW	Behaviour Change Wheel
BMI	Body mass index
CASP	Critical appraisal skills programme
COM-b	Capability, Opportunity, Motivation – behaviour
CONSORT	Consolidated Standards of Reporting Trials
COVID-19	Coronavirus 2 (SARS-CoV-2)
DIAMONDS	Improving diabetes self-management for people with severe mental illness
EBCD	Experience-based co-design
ELFT	East Lonon Foundation Trust
GUIDED	Guidance for reporting of intervention development
HbA1c	Glycated haemoglobin
IDEAS	Integrate, Design, Assess and Share;
IM	Intervention Mapping
INDEX	IdentifyiNg and assessing different approaches to DEveloping compleX interventions;
IQR	Interquartile range
JBI	Joanna Briggs Institute
JLA	James Lind Alliance
LTP	Long term plan
MAP-IT	Matrix Assisting Practitioner's Intervention Planning Tool
MOST	Multiphase optimization strategy;
MRC	Medical Research Council
NHS	National Health Service
NHS	National health service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health and Care Research
NPT	Normalisation Process Theory

ORBIT	Obesity-Related Behavioural Intervention Trials;
PAR-BCP	Participatory Action Research based on theories of Behaviour Change and Persuasive Technology
PPIE	Patient and public involvement and engagement
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT	Randomised controlled trial
RE-AIM	Reach, effectiveness adoption implementation maintenance
SMI	Severe mental illness
SPIDER	(Sample, phenomenon of interest, design, evaluation, and research type
T2D	Type 2 diabetes
Theoretical Domains Framework	Theoretical Domains Framework
TIDierR	Template for Intervention Description and Replication
UK	United Kingdom
USA	United States of America

1 Chapter 1: Background

1.1 Severe mental illness and type 2 diabetes

1.1.1 Severe mental illness

Severe mental illness (SMI) is a collective term which is used to describe a range of disorders that severely impair an individual's ability to engage in functional and occupational activities[1]. SMI is separated by the National Institute for Health and Care Excellence (NICE) broadly into schizophrenia and bipolar disorder[2]. Other psychoses include schizoaffective disorder, schizophreniform disorder and delusional disorder[3], which often include symptoms of both schizophrenia and bipolar disorder[4].

SMI is characterised by altered perceptions, mood, thoughts and behaviours[3]. Symptoms are divided into 'positive' symptoms, which includes hallucinations and delusions; and 'negative' symptoms such as a lack of drive, self-neglect and social withdrawal[3]. The early course of an SMI is characterised by frequent relapse, with pooled cumulative risk of relapse reported as 28 – 54% at 1-3 years for positive psychotic symptoms and 26-83% for hospital readmission at 1-7.5 years[5].

Schizophrenia represents a major psychiatric disorder, or cluster of disorders that affects a person's perceptions, thoughts, mood, and behaviour[3]. A large-scale meta-analysis indicates that the typical peak age of onset of schizophrenia for both males and females is 20.5 years (IQR 21- 33 for females and IQR 20-31 for males)[6]. The incidence of schizophrenia globally ranges from 2.7 (1.4–5.3) to 75.9 (74.4-77.5) per 100,000-person years[7]. The Adult Psychiatric Morbidity Survey [APMS][8], a robust population-based series of UK surveys initially conducted in 1993 (and since 2007 restricted to the population of England), identified the prevalence of schizophrenia and psychosis as 0.5% (2007) and 0.7% (2014)[8]. Bipolar disorder is a severe chronic mood disorder which is characterised by periods of mania or hypomania and episodes of severe depression[9]. Individuals may also experience features of psychosis including hallucinations and delusions[9]. The peak age of onset is 15 to 19 years, there is however substantial delay between onset and first contact with mental health services[9]. Global incidence is 1.4 (1.0-2.0) to 28.5 (28.0-29.1) per 100,000-person years[7]. Overall, 2% of the UK population screened positive for bipolar disorder in the APMS in 2014[8].

Throughout this thesis, SMI will be used as a collective term to refer to any of the above outlined diagnoses. This will be unless otherwise stated, where findings have been outlined to be indicative of an individual diagnosis and not necessary representative of all the diagnoses under the umbrella term of SMI.

1.1.2 Physical health outcomes for people with severe mental illness

Alongside mental and functional effects, all-cause mortality is substantially worsened for individuals with an SMI. Estimates vary but findings suggest a reduced life expectancy of 15 to 20 years, which has been consistently demonstrated across decades[10–13]. There have been increases in premature mortality in adults with an SMI in England when comparing data from 2015-2020[14]. This occurs across all person populations (14.5% increase), as well as in males (15.7%) and females (12.7%)[14]. Additionally, evidence suggests that these effects may be worsening in some regions of the UK[15], with premature mortality rates highest in the most deprived quintile at 200 per 100,000 population and lowest in the least deprived quintile at 53.9 per 100,000 population[14].

Physical ill-health has been identified as a considerable contributor to this increased mortality[15–17]. The susceptibility to cardiovascular diseases, type 2 diabetes (T2D), respiratory disorders, and specific cancers is elevated by 2 to 3 times in people with an SMI, when compared to individuals without an SMI[18,19]. Furthermore, there is evidence of an increasing association between SMI and mortality from cardiovascular disease, with T2D a significant risk factor for cardiovascular disease development[20].

Reducing premature mortality by improving physical healthcare for people with an SMI remains a priority for NHS England[2]. The NHS Long Term Plan (LTP) [21] sets out the healthcare priorities for 2019-2029. The priorities were created with stakeholders, including members of the public, NHS staff, local and national NHS leaders and the organisations that represent them. The LTP focuses on preventing and reducing health inequalities,[21]with the Core20PLUS5 (adults) the national approach to addressing health inequalities[22]. One of the 5 key clinical areas of the Core20PLUS5 is SMI, highlighting the need for improvements in physical health outcomes for adults with an SMI, as well as acknowledging the impact of deprivation on outcomes[22]. Furthermore, a recognition of the challenges faced in managing multimorbidity, with one in four adults now living with at least two conditions, means that there is an accepted need to adapt the current model of care to tackle this challenge[23].

The NHS therefore has a strong commitment to enhancing the physical healthcare provisions for those affected by SMI, aiming not only to extend life expectancy but also to rectify the unsettling health disparities that persist. Whilst these inequalities are evident across many physical health conditions, T2D contributes significantly to this inequality[17].

1.1.3 Type 2 diabetes mellitus

Diabetes, both diagnosed and undiagnosed, is estimated to affect 8.5% of people in England[24]. Rates of diagnosis are rising, and current modelling suggests that by 2035 more than 4.9 million people will be diagnosed with diabetes[25]. Furthermore, this modelling suggests that approximately one in four people with diabetes are undiagnosed. T2D contributes to approximately 90% of the diagnoses, with the number of people diagnosed doubling in the last 20 years[26]. It is estimated that the cost of diabetes care is 5% of the UK healthcare expenditure and 10% of the annual NHS budget and that as prevalence increases, the cost of treating complications will grow if current care regimes are maintained [27]. The NHS LTP has placed an increased focus on improving the management of diabetes owing to its leading position as a cause of premature mortality[21].

Typical symptoms of T2D include increased need to urinate, feeling thirsty, feeling tired and indeliberate weight loss[28]. It is a life-long condition, which impacts daily and if uncontrolled can lead to several short and long-term health complications[28]. T2D has an associated increased cardiovascular risk; it is associated with obesity, decreased physical activity levels, raised blood pressure, disturbed lipid profile and an increased risk of thrombosis[29,30]. Individuals diagnosed with T2D are at increased risk of macrovascular and microvascular complications, including gastroparesis, painful diabetic neuropathy, autonomic neuropathy, diabetic foot problems, diabetic kidney disease, erectile dysfunction and eye disease.[31]

Treatment of T2D is complex, often requiring the input of multiple health professionals to ensure optimal management. Clinical guidelines[32] and medical service contracts (NHS England/General Practitioners Committee England, 2019) mandate that individuals with T2D should receive an annual health check, consisting of nine T2D care processes, which includes a review of blood glucose levels (measured by glycated haemoglobin - HbA1c), blood pressure, monitoring of serum cholesterol, serum creatinine and urine albumin/creatinine ratio, foot risk surveillance, body mass index (BMI) measurement, smoking history and referral for retinopathy screening. Key treatment priorities for adults with T2D include structured patient education, the provision of dietary advice integrated with other aspects of lifestyle modification including physical activity, weight loss and smoking cessation, blood pressure management, blood glucose management and drug treatment[32]

In summary, T2D poses a significant and growing health challenge, with rising rates of diagnosis and an impending surge in cases predicted for the future. The economic burden of diabetes care is also substantial, highlighting the urgent need for effective management strategies to mitigate both financial and health-related consequences.

1.1.4 Severe mental illness and type 2 diabetes mellitus

A meta-analysis of 41 studies comprising 161,886 participants reported 9% (95% CI 7.3% - 11.1%) diabetes prevalence in SMI[33]. In the UK, the prevalence of T2D in people with an SMI is twice as high compared to the general population[34]. It is challenging however to obtain accurate prevalence rates because estimates suggest up to 70% of T2D is undiagnosed in people with SMI[35]. Evidence demonstrates increased T2D diagnosis across all age groups[1]. Those who experience multiple episodes of psychosis have a prevalence that is double that of the general population and an earlier onset[36].

Although there is evidence to suggest a genetic component to the development of T2D in people with schizophrenia[37], there appears to be a complex and multifactorial mechanism of association, and many of the identified risks are modifiable. The use of antipsychotic medication is linked to metabolic side effects, such as weight gain and raised blood sugar, blood pressure, cholesterol, and triglyceride levels, with these factors suggested to be contributory to a higher prevalence of T2D[1]. Although medication side effects are important, a focus solely on this overlook other crucial factors and might even hinder attempts to prevent T2D in this population[35]. Other factors potentially contributing to the higher incidence include traditional risk factors for diabetes, which are more common among people with SMI, such as being overweight and obese[1], smoking, poor diet, and physical inactivity [38]. Additionally, broader social determinants of health, such as poverty and a poor-quality neighbourhood environment disproportionately affect people with SMI[35].

Beyond an increased T2D prevalence, individuals with an SMI also experience greater T2D complications[39,40], are more likely to need emergency appointments for these complications[41], have a poorer quality of life and higher mortality associated with their T2D when compared to individuals without a comorbid SMI[42–44]. Adults with an SMI and T2D incur higher health-care costs (mean: £26363.90 per person per year), compared to those solely with T2D, which is primarily attributed to increased secondary care costs[45]. These secondary care costs are often associated with an elevated admission rate for emergency macrovascular complications (e.g. myocardial infarction)[45], identified in those with an SMI and T2D. The purported reasons for this are complex and multifactorial[15], and include non-compliance with the care process[46] and the effect of SMI on self-management[47]. Evidence does however demonstrate that for individuals with an SMI, mortality remains elevated after adjusting for behavioural risk factors such as smoking, physical activity and body mass index[48]. This suggests that other factors play a role in the T2D outcomes for people who have comorbid SMI/T2D, including accumulating evidence that the suboptimal organisation and delivery of physical health care for people with an SMI may be a contributory factor [15,35,40,49,50].

Throughout this thesis the term ‘organisation and delivery of care’ is used to define both the act of delivering care by a health professional and the organisation of the care pathway, e.g. the structures and guidelines designed to “house” the act of delivering care.

1.2 Health and care system and the impact on type 2 diabetes outcomes for people with SMI

Health system factors are purported to explain 10 to 25 percent of the variation in excess mortality for people with an SMI and comorbid physical illness[51,52], yet evidence suggests comparable monitoring of T2D in adults with an SMI. A 2018 clinical audit in England and Wales evaluated diabetes care quality, focusing on eight of the nine recommended care processes, excluding retinopathy screening (See section 1.1.3 for details of the care processes)[53]. The audit found 58% of all adults had received all eight care processes, compared to 48.9% adults with an SMI and T2D[53]. More recently a longitudinal observational study (2021) conducted on a comprehensive and representative sample within the primary care setting in England, identified comparable levels of monitoring of T2D in adults with and without an SMI [54]. They did however identify that despite this comparable monitoring and an elevated frequency of general practitioner (GP) consultations there is a discernible pattern of under-diagnosis pertaining to cardiovascular illness[54]. This diagnostic oversight was accompanied by an escalation in the incidence of unscheduled, emergency admissions for cardiac care[54]. Further evidence highlights that whilst a high proportion of service users received appropriate T2D care (HBA1c measurements, blood pressure, cholesterol, foot, and eye examinations) there were moderate levels of sub-optimal self-management behaviours, low well-being, limited T2D support from mental health professionals and high levels of diabetes distress[55]. Given the excess mortality in adults with an SMI, these comprehensive analyses collectively suggest that the critical concern needs to be focused not simply on the monitoring of T2D but on factors outside of these processes, such as the appropriateness of the current proposed T2D monitoring for this vulnerable population.

Physical health care for individuals with an SMI are covered by NICE guidance. The NICE guidance (NG28) and Quality Statement 6 (Assessing Physical Health) of the related quality standards, outlines care provision for those with an SMI, covering physical health[3]. It recommends that comprehensive physical health assessments are undertaken at 12-weeks post diagnosis, 1 year post treatment and annually thereafter. This check consists of weight, waist circumference (annual only), pulse and blood pressure, fasting blood glucose, or HbA1c and blood lipids and overall physical health. The responsibility for this is initially with the secondary care team who should assess the physical health of service users for the first 12 months or until their SMI symptoms stabilise, whichever is longer. Following this, under shared care arrangements responsibility shifts to general practitioners and other primary health professionals[3]. This involves an annual check of recommended physical health measurements as well as a focus on common physical health problems in this population, including T2D[3]. Whilst the treatment of T2D for adults with an SMI should follow the appropriate NICE guidance[56], this does not take into consideration the unique challenges people with an SMI may have in managing their T2D, such as systems which separate T2D and mental health care, more frequent psychotic relapse, excessive weight gain caused by antipsychotic treatment, and psychotic symptoms affecting cognition and decision making[45].The influence of psychotic and negative symptoms on self-management is evident with reported difficulties including managing fluctuations in bloods sugars related to stress or paranoia[57,58] and perceived altered reality impacting body awareness[57,59]. This highlights the need for additional support from health professionals, with increased support during times of mental illness relapse and instability[57–60], i.e. at time beyond that which is currently outlined the NICE guidance[61–63]. Service users have suggested that this is particularly relevant to emotional or unhealthy eating[55,57,58]. The dual threat of both impaired self-care behaviours during relapse, coupled with poorer eating habits results in poorer glycaemic control and an increased risk of T2D complications developing over the long term, even with appropriate medication management[64].

Further to the specific needs of people with an SMI that merit greater attention than is directed in current clinical guidelines, health professionals have been found to attribute physical symptoms to the pre-existing SMI, and so miss the identification of comorbid conditions and delay treatment opportunities[65,66]. This misattribution or overlooking of symptoms is termed "diagnostic overshadowing" [65,66]. Diagnostic overshadowing has been described as stigma in action[67] and is suggested to occur due to clinical reasoning errors underpinned by unconscious negative biases[68]. Diagnostic overshadowing is implicated in initial recognition and ongoing management of T2D in adults with an SMI[69]. A systematic review of service user and health professional experience of diagnostic overshadowing highlighted that beyond stigma, it is underpinned by communication, the knowledge of health professionals and an ill-suited healthcare system[70].

Challenges in communication may play a role in the increased levels of diabetes distress in adults with comorbid SMI/T2D[55]. Diabetes distress refers particularly to an adverse emotional or affective state stemming from the difficulties of managing diabetes[71]. The way health professionals communicate may exacerbate the distress, or even contribute to its development, with inattention from health professionals resulting in missed opportunities for relevant and connected communication targeting the concerns of the individual[71]. Service users perceive this to result from a lack of knowledge, both of SMI and its impact on T2D in physical health professionals, resulting in potentially dangerous consequences such as inappropriate guidance on medication management[60]. Service users report feelings of frustration at having to be the 'expert' in the other condition when engaging with either a physical or mental health professionals[60,72], which can result in feeling 'left alone' to make decisions about T2D care[73]. These experiences of care may further increase feelings of isolation as service users report not being able to speak to family or friends about their T2D[58,60]. Feelings of isolation, reconceptualised as a lack of social support, may contribute to the poorer outcomes experienced by adults with an SMI and T2D. Evidence suggests a positive relationship between support and diabetes self-management[73] particularly relating to dietary behaviours[74]. Although this research was in populations without an SMI, given the evidence that increased social support can benefit recovery in SMI[75] it appears likely that social support can be equally as valuable for adults with an SMI and T2D. This is underscored as experiences of positive social support highlighted by service users as beneficial in monitoring and managing their T2D[59,60].

An ill-suited health system, characterised by the separation of health services for mental and physical conditions may influence professional behaviour towards prioritising psychosis over T2D.[45] The need for better integrated care is supported by a growing evidence-base[15,70,76], not least to address issues around uncertainty as to who has responsibility for the physical health of service users[76]. This will need to move beyond simple colocation of services, which has demonstrated variable impact[77], addressing issues such as communication between different professionals.[61,66]. Ultimately these issues contribute to inappropriate treatment delays, exposure to untreated illness and development of complications[72] and may partly explain the inconsistency between the comparable monitoring of physical health conditions yet under-diagnosis of cardiovascular disease[54], as well as the increased risk of T2D complications[39,40].

In summary, increased health professional support beyond that which is currently mandated and provided, as well as the need to address multifaceted challenges such as better T2D/SMI care integration, addressing an ill-suited health and care system, enhanced health professional knowledge, and communication are important for improving T2D care for those with comorbid SMI. Targeting care provision must however be done sensitively as the NHS is facing worsening workforce challenges, increased costs, and on-going impacts on productivity. The next section will provide a brief summation of the current NHS context as well as highlighting how improving T2D care for adults with an SMI fits into the broader context of NHS policy and service.

1.2.1 NHS context and provision of community mental health care

As highlighted earlier in this chapter, the NHS LTP[21] focuses on improving the physical health of adults with an SMI paying particular attention to reducing inequalities as well as targeting diabetes in the general population. These targets are interrelated given the higher prevalence of T2D in adults with an SMI, as well as high levels of inequalities in T2D outcomes for this vulnerable population. The LTP[21] suggests that there needs to be a focus on the training and skills development of professionals but also on their ability to deliver care, which indicates an acknowledgement that in order to improve care provision, and outcomes, there needs to be a focus on the workforce and their abilities, but also on the wider context and 'enabling productive working'[21].

Mental health services in the UK are currently undergoing significant modernisation and changes. The Community Mental Health Framework details how the LTPs vision for a community-based mental health model focussed on the delivery of comprehensive and holistic care can be practically delievered[78]. The framework is a direct response to the perceived stagnation and fragmentation in the existing mental health care model[78]. Such structural limitations may be inextricably linked to the experiences of service users who encounter issues such as diagnostic overshadowing and feelings of frustration at being the "experts" in their medical conditions[60,72]. Notably, the Community Mental Health Framework underscores a heightened emphasis on individuals with an SMI and coexisting physical health conditions, advocating for integrated services that support enhancement of physical health outcomes[78]. Furthermore, the framework highlights the need for flexible provision, affording the capacity to escalate care when the need for more specialised or intensive care is required[78]. This evolving landscape of the mental health services in the UK signifies a promising opportunity to address long-standing issues including the poor outcomes of adults with both an SMI and T2D.

Since the inception and publication of the NHS LTP[21] and the Community Mental Health Framework[78], the landscape of care provision has considerably changed owing to the COVID-19 pandemic. Beyond the 'peak' pandemic years of 2020 and 2021 there is an enduring impact on both provision of service and those who provide the service[79]. There were record levels of staff sickness reported in 2022, with mental illness contributing substantially to the recorded levels[80]. Furthermore, record levels of staff leaving the NHS owing to increased burnout and workloads, which is self-perpetuating owing to high levels of staff turnover[81]. This highlights a need for sensitive and considered approaches to T2D care improvements and underscores the importance of interventions developed in collaboration with the workforce to ensure suitability given the challenges faced by staff. The recently published NHS Workforce LTP[79] outlines three interrelated factors *train, retain and reform*. The focus on reform[79,81] highlights the need to increase productivity through working and training differently, focussing on building broader teams with flexible skills which will provide the care needed more efficiently and effectively[79].

In summary, improving T2D care for individuals with an SMI is of paramount importance. The elevated prevalence of T2D among those with SMI, coupled with increased morbidity and excess mortality, underscores the urgency for improved healthcare delivery. Examination of evidence of current care creates a picture of T2D requiring additional support, beyond annualised health checks, which is not currently being met in by the health and care system. Furthermore, diagnostic overshadowing underpinned by communication, knowledge, and skills of the existing workforce all potentially play a role in the impact of the health and care system on the poorer outcomes for adults with an SMI and T2D. The next section will explore approaches and/or interventions that have been designed to improve delivery of T2D care and T2D outcomes for people with an SMI.

1.3 Interventions targeting health professionals and/or the health and care system to improve type 2 diabetes outcomes for people with severe mental illness

Throughout this thesis the term ‘intervention’ is used to identify components or activities introduced into an environment which are designed to change behaviour. A comprehensive systematic review and meta-analysis of randomised controlled trials of pharmacological and behavioural interventions for improving diabetes outcomes in adults with an SMI, did not identify any specific interventions which focussed on health professional behaviour[82]. Systematic and mapping reviews of interventions targeting the delivery of physical health care more broadly, by health professionals to adults with an SMI[83–86] can however provide important context to inform an intervention to improve T2D care for adults with an SMI.

In the systematic reviews[83–85] identified interventions were predominantly educational - targeting the knowledge, skills, attitudes, and confidence of mental health professionals in providing physical health care. Overall, these studies indicate that educational interventions can significantly improve health professionals' knowledge and skills, as well as demonstrate improvements in their attitudes and confidence in providing physical health care for adults with an SMI.

Impacts on clinical practice or service user outcomes were infrequently reported, but one study found a reduction in waist circumference measurement[87] and another reduced diabetes-related medical emergency reports, neither were examined for significance[88]. Whilst the outcomes of interventions across these reviews is promising, i.e., improvements in knowledge, skills, attitudes and confidence of professionals, there is a need to rigorously examine whether this translates into objectively better clinical practice and outcomes for service users[83,85]. The interventions included in the reviews varied considerably, for example in duration and mode of delivery (e.g., simulations, self-directed learning, didactic teaching workshops), which are moderators of intervention effectiveness[89]. Understanding and accounting for these moderators is essential and can be enhanced using theory, and clear and detailed descriptions of interventions, both of which were minimal in those interventions identified in this review.

The focus on knowledge, skills, attitude, and confidence assumes that these are key factors which affect delivery of T2D care; but addressing these issues alone may be insufficient as models of behaviour propose factors beyond knowledge and skills to be influential in driving behaviour[90]. Given the evidence suggests that health professional behaviour is influenced by factors such as availability of evidence, individual motivation, clarity of roles and the culture of specific healthcare practices[91]; there is clearly the opportunity to explore and design interventions which consider and target factors beyond those targeted in the reported interventions. This assertion is supported by the narrative synthesis from the mapping review[86] which identified that the empowerment of existing staff, removal of everyday barriers such as poor IT systems and bureaucracy surrounding referrals, as well as the training and confidence-building of the existing workforce were all central to improving physical health care for adults with an SMI.

Finally, within the systematic reviews[83–85], it was possible to identify three education-based intervention studies [88,92,93] that specifically targeted T2D based knowledge and clinical judgement of mental health nurses. These pre- and post-test design studies found improved clinical judgement, measured by the Lasater Clinical Judgment Rubric[88], and T2D-related knowledge[92,93], however the outcomes were measured immediately following training[92,93] thus it is not possible to discern the long-term impact of these outcomes. A reduction in diabetes-related medical emergencies comparing the month before and after intervention delivery[88] was identified, however this relationship was demonstrated through correlation only and should be interpreted with caution. Cumulatively, reviews suggest there are no interventions which target the organisation and delivery of T2D care and a minimal number specifically targeting T2D care in SMI populations. Interventions which have been identified target only the knowledge and skills of mental health professionals and have limited demonstrable impact on T2D outcomes suggesting a need to develop an intervention which aims to improve T2D care for adults with an SMI,

1.4 Summary, aim and objectives

This PhD aims to develop an intervention to improve T2D care for adults with an SMI. There are profound inequalities in physical health outcomes for adults with an SMI resulting in a 15–20-year reduced life expectancy. This has been identified for several decades and is worsening. A substantial contributor to this is cardiovascular disease for which T2D is a critical risk factor. The prevalence of T2D in SMI populations is elevated, with symptoms often affected by the fluctuating nature of SMI symptomology.

While the origins of these disparities are multifaceted, health and care service provision emerges as a noteworthy (10-25%) contributing element. Existing evidence suggests the need for care beyond that which is dictated in current guidelines and a nuanced understanding to the challenges of delivery of T2D care for adults with an SMI including an ill-suited health system, suboptimal knowledge, and communication challenges. These collectively contribute to diagnostic overshadowing, diabetes distress and social isolation experienced by individuals with an SMI and T2D. While a specific review of interventions targeting T2D care for adults with an SMI was not identified, reviews of interventions targeting physical health care more broadly did include and identify three interventions specific to this project. These reviews can provide context for T2D care and highlight that educational interventions exhibit promise in enhancing mental health professionals' knowledge, skills, attitudes, and confidence, yet it was argued that a more comprehensive approach encompassing various influencing factors is pivotal for enhancing clinical practice and outcomes. An intervention designed to improve T2D care for adults with an SMI is warranted to provide more equitable and effective healthcare delivery and support improved T2D outcomes for adults with an SMI and T2D. This however must be approached cautiously, given the escalating challenges within the NHS context.

The aim of the research reported in this thesis was to develop a new intervention to support improved T2D care for adults with an SMI and T2D. This was achieved through the following objectives:

- ***Objective 1:*** Explore intervention development literature to clarify the most appropriate approach to intervention development (Chapter 2)
- ***Objective 2:*** Identify the barriers and enablers of the delivery and organisation of T2D care for adults with an SMI (Chapter 3)
- ***Objective 3:*** Identify the active components of existing interventions targeting the delivery and organisation of care for adults with an SMI (Chapter 4)
- ***Objective 4:*** Assess the extent to which identified intervention components target the theoretical determinants of the delivery and organisation of T2D care for adults with an SMI (Chapter 4)
- ***Objective 5:*** Develop an understanding of the behaviour(s) which will be targeted by the intervention to improve T2D care for adults with an SMI using consensus methods with service users, carers and health professionals, and existing evidence. (Chapter 5)
- ***Objective 6:*** Develop an in-depth understanding of the behaviour target (Chapter 6)
- ***Objective 7:*** Design an intervention in collaboration with stakeholders to target the important domains (Objective 6) underpinning the target behaviour (Objective 5). (Chapter 7)
- ***Objective 8:*** Outline the programme theory and clearly describe the intervention to support creation of a rigorous evaluation plan (Chapter 8)

2 Chapter 2: Overall Theoretical and Methodological Approach

2.1 Prologue

The previous chapter highlighted the importance of improving T2D care for adults with an SMI. This included the vast, and increasing, inequalities in prevalence, morbidity and mortality associated with T2D in adults with an SMI. It was proposed that the current guidance on T2D care for adults with an SMI was suboptimal and that diagnostic overshadowing likely impacted by the knowledge and skills of health professionals, communication challenges and an ill-suited health and care system were central. The limited number of interventions was highlighted, as well as the minimal impact on T2D care, although it was concluded that educational interventions show promise in enhancing mental health professionals' physical health skills. It was concluded that a new intervention would be needed to address these gaps. This chapter will follow detailed published guidance on the development of complex interventions, and the theoretical and methodological underpinning of the intervention development process will be explored and implications for this PhD outlined.

2.2 Intervention Development

Intervention development has been described as the process between an idea or inception of an intervention and formal feasibility, piloting or efficacy testing prior to a full evaluation[94]. Whilst in practise it is acknowledged that intervention development never really ends as changes occur through its lifecycle [95], it is this definition which is utilised throughout this thesis as the demarcation of the start and end points of this project. This definition is congruous with the initial phase of the guidance provided by the Medical Research Council

(MRC) for the development of complex interventions[96,97]. The MRC framework emphasises the importance of intervention development and design and draws heavily on the comprehensive INDEX guidance[98], which was published to provide some key considerations for intervention development, these will be explored in relation to this PhD research for the remainder of this chapter.

2.3 INDEX Guidance

The INDEX guidance was developed from a systematic methods overview of published approaches[99], a systematic review of primary research[100], qualitative interviews[101,102], a consensus exercise, expert panel, the experience of the authors and discussion with researchers[95]. These activities resulted in the publication of the *Extended Guidance on Developing Interventions to Improve Health and Health Care*[98]. The guidance describes 11 considerations when designing an intervention, with authors noting that it may not be possible nor desirable for developers to address all these actions during the development process, but that consideration of relevance should be made at the start of and throughout the development process[98]. The authors provide a set of questions for developers to consider under each key issue - an overview is provided in Table 1. The table provides detail of each key issue and considers them in relation to this PhD, where key issues require further exploration these are discussed in section 2.4 to 2.9. Whilst presented in this format, the authors are clear that development is not a linear process, and it is expected that developers will continually return to the key issues through development, therefore the influence of the INDEX guidance on each aspect of development will also be highlighted at the end of each chapter in the thesis.

Table 1: Key consideration of intervention development (Adapted[1]) and how they have been applied in this PhD

Key Issue	What the issue entails	Consideration for the PhD
Plan the development	This key issue focuses on identification of the problem and may contain initial ideas of content, format, and delivery of the proposed intervention. These early ideas may be refined and challenged throughout the development process. Consideration of whether an intervention is required/cost-effective/appropriate can be made at this stage. A key decision is whether to be guided by published approaches to intervention development or undertake a more pragmatic self-guided approach.	This issue is considered in section 2.4
Involve stakeholders throughout the development process	There was consensus (>70%) about developing interventions iteratively with stakeholder input throughout. Consideration of which stakeholders and how they are involved are promoted as important issues	This issue is considered in section 2.5
Bring together a team and establish decision making processes	Decisions should be made on the team required to develop an intervention and whilst there is no consensus on the *optimum* size of team it is recognised that it is important to agree a process for making decisions	The team consists of a PhD student and supervisory team (MH, KM, HM). Further support from other professionals was sought where needed. Where appropriate this is detailed and discussed throughout the thesis.
Review published research evidence	Reviews of previous research evidence can help to define the health problem and its determinants, understand the context in which the problem exists, clarify who the intervention should be aimed at, identify whether effective or cost-effective interventions already exist for the target population/setting/problem, identify facilitators and barriers to delivering interventions in this context and identify key uncertainties that need to be addressed using primary data collection. It is suggested that this	Published evidence has been used in Study 1 to identify the barriers and enablers to the provision of T2D care for people with SMI (Chapter 3).

	process is undertaken throughout intervention development, with flexibility in approach to incorporate new findings. It is also highlighted that systematic reviews may not be necessary, nor possible; however, undertaking some review is important to ensure that there are no existing interventions that would make the one under development redundant.	Study 2 was a content analysis and assessment of theoretical congruence has been undertaken of existing interventions (Chapter 4).
Draw on existing theories	Experts recommend consideration of which theories are relevant at the start of the development process, however these should be continually reviewed.	This issue is considered in section 2.6
Articulate programme theory	A programme theory describes how a particular intervention is expected to lead to its outcomes [103]. Articulation early in development can support communication with stakeholders and funders and can be informed by existing theory. Programme theory should be flexible, tested and refined throughout the development process using primary and secondary data, as well as stakeholder input.	This issue is considered in section 2.7
Undertake primary data collection	This will usually involve mixed methods and can be informed through a review of the evidence base which identifies key uncertainties that primary data collection can then address.	This section is considered in section 2.9
Understand the context	Recent guidance identified that contextual features include those relating to population and individuals; physical location or geographical setting; social, economic, cultural and political influences and factors affecting implementation, for example, organisation, funding and policy[96]. The rationale for understanding context is based on this need to design interventions which can operate within existing structures, resources, and constraints.	This issue is considered in section 2.8 as well as alongside *involvement of stakeholders* in section 2.5
Pay attention to future implementation of the intervention in the real world	Developers may pay attention, early on, to factors that may affect the use of the intervention, 'scale-up' and sustainability. This is important owing to the need to develop interventions which can be utilised in the *real world* and not just shown to be effective or cost-effective within controlled environments.	This issue is considered alongside *involvement of stakeholders* in section 2.5
Design and refine the intervention	Design, which is often used interchangeably with development, is a distinct phase of the development process where ideas are generated and decisions made about intervention components, how it will be delivered, by whom and where. Following this a	This section is considered alongside *undertake primary data*

	prototype of the intervention can be created to share with stakeholders to enable them to consider and present their views. Once designed the intervention can be refined through a series of rapid iterations with each modification assessed for feasibility, acceptability, and engagement. The programme theory is important at this point to assist developers to test some of the proposed mechanisms of action.	*collection* in section 2.9
End the development phase	Whilst this may seem artificial, owing to the ongoing nature of refinement of interventions, developers need to decide when to stop the first intensive development phase. This can include abandoning the intervention or moving to the next phase of feasibility/pilot testing or full evaluation.	The first intensive development phase will end upon completion of the intervention as part of the PhD

2.4 Plan the Development Approach

2.4.1 Taxonomy of Intervention Development

It is considered important to draw on published approaches for intervention development[98], however a recent systematic review of interventions developed between 2015 and 2016 found that 43 of the 87 interventions did not use a published approached but followed a 'pragmatic' self-selected set of steps[100]. For interventions focused on changing health professional behaviour it appears that published approaches are used more frequently[104]. The use of a published, as opposed to pragmatic, approach was judged to be appropriate for this PhD as it supports a structured, systematic, and transparent process of intervention development. There are eight proposed categories of published intervention development, from which a theoretically informed and evidence-based approach was selected. A theory and evidence-based approach to intervention development should enable a transparent, systematic and reportable intervention development process, which is limited in existing interventions (Section 1.3).

The guidance identified six published theory and evidence-based approaches[95], 1) MRC framework for developing complex interventions, 2) Behaviour Change Wheel, 3) Intervention Mapping, 4) Matrix Assisting Practitioner’s Intervention Planning Tool, 5) Normalisation process theory, and the 6) Theoretical Domains Framework. The MRC framework for developing complex interventions[96,97,105] highlights non-linear development through four phases, 1) development or identification of an intervention, 2) assessment of feasibility of the intervention and evaluation design, 3) evaluation of the intervention, and 4) impactful implementation. The revised MRC guidance incorporates the INDEX guidance in the development phase[106] and thus broadly supports development of this intervention by providing the framework for development considerations being outlined within this chapter. This was not however utilised alone as more detailed guidance on the intervention development process was required and thus the five remaining approaches were considered. The Matrix Assisting Practitioner’s Intervention Planning Tool and Normalisation Process Theory were judged to have insufficient detail to support development. The Theoretical Domains Framework was also judged to be limited in detail, however the more explicit links to theory and its combination with the Behaviour Change Wheel were important in supporting the chosen approach.

The remaining two approaches, Intervention Mapping [107] and the Behaviour Change Wheel [90], were considered in more detail. Both are comprehensive frameworks to support intervention development[95], although review of the INDEX taxonomy (Appendix 1) highlights that Intervention Mapping is potentially more comprehensive, this can be contested as some action points not listed may be present within the Behaviour Change Wheel. For example, Intervention Mapping is documented as including consideration of real-world issues such as cost and delivery, to avoid implementation failure. This is not documented within the INDEX appraisal of the Behaviour Change Wheel. The use however of the Affordability, Practicability, Effectiveness/Cost-effectiveness, Acceptability, Side-effects and Equity (APEASE) criteria for guiding intervention content decisions arguably fulfils this criterion with a focus on real-world implementation issues outside of the effectiveness of an intervention[108]. These two frameworks both have been identified in reviews of interventions that target health-related outcomes[100] and in interventions targeted at health professionals[104] highlighting their appropriateness for the research in this PhD. Thus, given similar levels of comprehension and their demonstrated utility in this research field, the two approaches are described and further explored below.

2.4.2 Behaviour Change Wheel

The Behaviour Change Wheel was developed from a synthesis of 19 frameworks of behaviour change, focussing on moving from behavioural analysis to intervention design[90]. It was developed in three steps, 1) a systematic literature review and evaluation of existing behaviour change intervention frameworks supported through consultation with behaviour change experts, 2) the development of the new framework (Behaviour Change Wheel) and 3) the testing of the reliability of a new framework[90]. It proposes three broad stages of intervention development[108], which are illustrated in Figure 1.

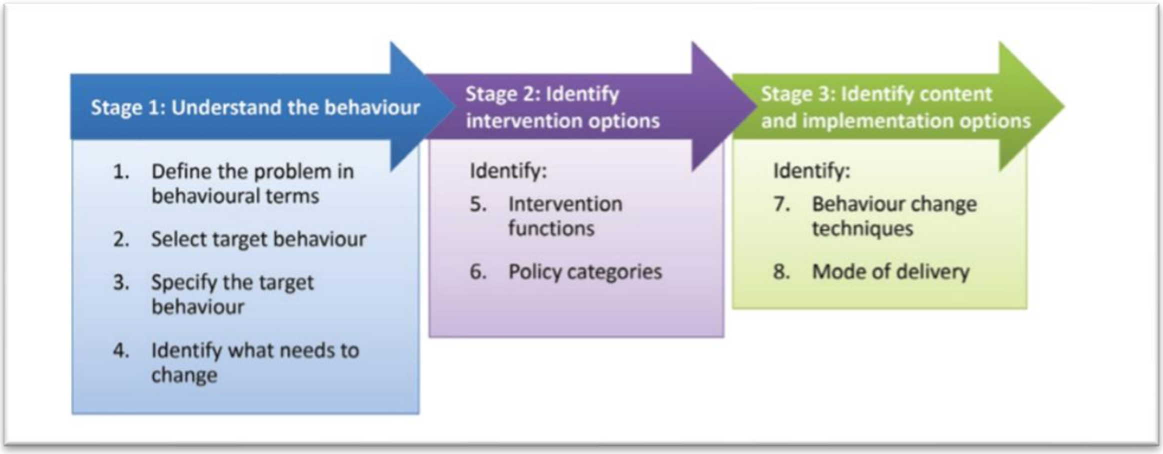


Figure 1: Intervention Development Phases of the Behaviour Change Wheel

Whilst this is presented in a linear format, the authors stress the need for a flexible approach to intervention development, returning to previous steps as required[108]. Stage 1 requires an in-depth behavioural analysis that will result in a clearly specified behavioural target and understanding of the barriers and enablers of the target behaviour, achieved through four steps. The four steps are detailed in Table 2.

Table 2: Table outlining the four steps of the first stage of the Behaviour Change Wheel (adapated[108])

Step	Purpose	Actions
1	Define the problem in behavioural terms	Identify the target individual, group or population involved in the behaviour and specify the behaviour itself.
2	Select a target behaviour	Acknowledging behaviours do not exist in isolation, produce a long list of candidate target behaviours. Prioritise the target behaviour(s) considering the potential for impact, likelihood of change, spillover effect and ability to measure change.
3	Specify the target behaviour	Specify the target behaviour(s) in appropriate detail and context. Focus on who needs to perform the behaviour, what needs to be done differently, when will it be done, where will it be done, how often and with whom.

4	Identify what needs to change	Identify what needs to change, particularly within the individual and/or environment to achieve the desired change in behaviour.

2.4.2.1 COM-B model of behaviour and the Theoretical Domains Framework

Identifying what needs to change in the fourth step can be supported by using either the COM-B model of behaviour and/or the Theoretical Domains Framework (Theoretical Domains Framework). The COM-B model of behaviour proposes that three components (***c****apability,* ***o****pportunity,* and ***m****otivation*) interact to influence behaviour. Where a more detailed understanding of behaviour is required the Theoretical Domains Framework can be used, as the domains map onto the components of the COM-B model[108], demonstrated in Figure 2.

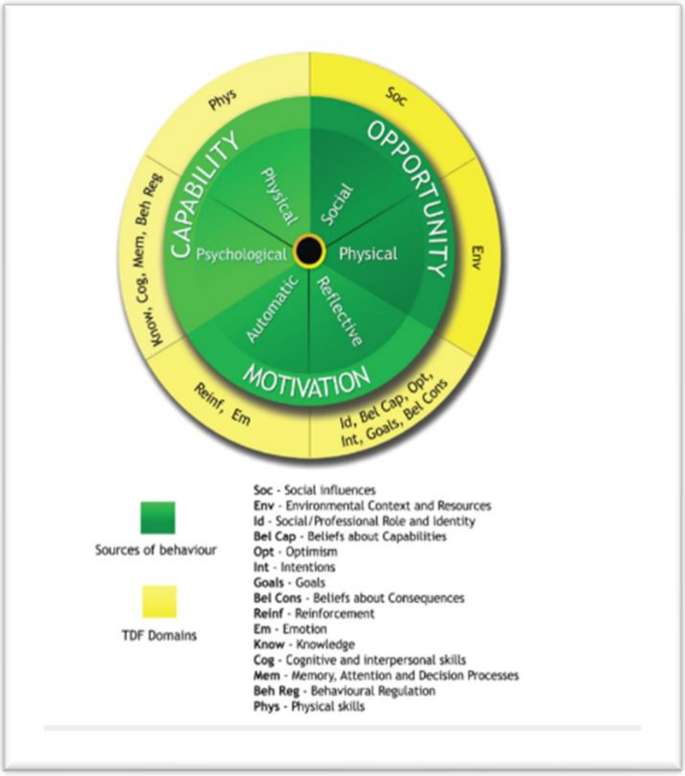


Figure 2: Figure showing the overlap between the COM-B and the Theoretical Domains Framework

The Theoretical Domains Framework was developed by a team of behavioural scientists in collaboration with implementation researchers in order to make theories more accessible to those working in implementation research[109]. The Theoretical Domains Framework is synthesised from 33 theories of behaviour and behaviour change, consisting of 14 domains, covering 84 theoretical constructs[91]. The development of the Theoretical Domains Framework was supported though 1) identification of theories and theoretical constructs relevant to behaviour change, 2) simplification of these into overarching theoretical domains, 3) evaluation of the importance of the theoretical domains, 4) a cross-disciplinary evaluation and synthesis of the domains and constructs, 5) validation of the domain list, and 6) piloting a series of interview questions to elicit views about the constructs and domains[109]. The Theoretical Domains Framework was subject to a validation exercise with an independent group of behavioural experts to investigate the optimal structure and content of the framework, which demonstrated similar structure and content but extrapolation into 14, rather than the original 12 domains[91]. The domains, definition and constructs are provided in Table 3.

Table 3: Table detailing the domains of the Theoretical Domains Framework including description, and proposed constructs (adapted[91,110])

Domain	Description (Definition and *constructs provided in italics)*
Knowledge	Awareness of the existence of something *Knowledge of condition/scientific rationale, procedural knowledge, and knowledge of task environment*
Skills	An ability or proficiency acquired through practice *Skills, skill development, competence, ability, interpersonal skills, practice, skill assessment*
Social professional role and identity	A coherent set of behaviours and displayed personal qualities of an individual in a social or work setting

	Professional identity, professional role, social identity, identity, professional boundaries, professional confidence, group identity, leadership, organisational commitment
Beliefs about capabilities	Acceptance of the truth/reality about or validity of an ability, talent, or facility that a person can put to constructive use *Self-confidence, perceived confidence, self-efficacy, perceived behavioural control, beliefs, self-esteem, empowerment, professional confidence*
Optimism	Confidence that things will happen for the best or that desired goals will be attained *Optimism, pessimism, unrealistic optimism, identity*
Beliefs about consequences	Acceptance of the truth/reality about or validity of outcomes of a behaviour in each situation *Beliefs, outcome expectancies, characteristics of outcome expectancies, anticipated regret, consequents*
Reinforcement	*increasing the probability of a response by arranging a dependent relationship, or contingency, between the response and a given stimulus* *Rewards (proximal/distal, valued/not valued, probable/improbable), incentives, punishment, consequents, reinforcement, contingencies, sanctions*
Intentions	Conscious decision to perform a behaviour or a resolve to act in a certain way *Stability of intentions, stages of change, TTM*
Goals	Mental representation of outcomes or end states that an individual wants to achieve *Distal/Proximal goals, goal priority, goal/target setting, autonomous controlled goals, action planning, implementation intention*
Memory attention decision processes	Ability to retain information, focus selectively on aspects of the environment and choose between two or more alternatives *Memory, attention, attention control, decision making, cognitive overload*
Environmental Context and Resources	Any circumstances of a person's situation or environment that discourages or encourages the development of skills and abilities, independence, social competence, and adaptive behaviour

	Environmental stressors, Resources/material resources, organisation culture/climate, salient events/critical incidents, person x environment interaction, barriers, and facilitators
Social influences	Interpersonal processes that can cause an individual to change their thoughts, feeling or behaviours *Social pressure, social norms, group conformity, social comparison, group norms, social support, power, intergroup conflict, alienation group identity, modelling*
Emotion	A complex reaction pattern, involving experiential, behavioural and physiological elements, by which the individual attempts to deal with a personally significant matter or event *Fear, anxiety, affect, stress, depression, positive/negative affect, burn-out*
Behavioural regulation	Anything aimed at managing or changing objectively observed or measured actions *Self-monitoring, breaking habit, action planning*

Following completion of an in-depth understanding of the behaviour developed through stage 1, stage 2 supports selection of intervention functions and policy categories, which are thought to be most likely to bring about behavioural change[108]. Intervention functions are defined as the broad categories by which an intervention can change behaviour and policy categories are the policies which can support their delivery[108]. The Behaviour Change Wheel suggests links between these intervention functions/policy categories and the Theoretical Domains Framework, detailed in mapping matrices[108]. The intervention functions and policy categories are defined and described in Table 4.

Table 4: Definitions of each intervention function and policy category (Adated from the Behaviour Change Wheel[108]P.91 and P. 111)

Intervention Functions	
Education	Increasing knowledge or understanding

Persuasion	Using communication to induce positive or negative feelings or stimulate action
Incentivisation	Creating an expectation of reward
Coercion	Creating an expectation of punishment or cost
Training	Imparting skills
Restriction	Using rules to reduce the opportunity to engage in the target behaviour (or to increase the target behaviour by reducing the opportunity to engage in competing behaviours)
Environmental restructuring	Changing the physical or social context
Modelling	Providing an example for people to aspire to or imitate
Enablement	Increasing means/reducing barriers to increase capability (beyond education and training) or opportunity (beyond environmental restructuring)
Policy categories	
Communication/marketing	Using print, electronic, telephone or broadcast media
Guidelines	Creating documents that recommend or mandate practise. This includes all changes to service provision
Fiscal regulation	Using the tax system to reduce or increase the financial cost
Legislation	Making or changing laws
Regulation	Establishing rules or principles of behaviour
Environmental/social planning	Designing and/or controlling the physical or social environment
Service provision	Delivering a service

The third stage of development focuses on the identification of behaviour change techniques and the mode of delivery. Behaviour change techniques are the smallest components of behaviour change interventions, which are observable, replicable and can be used alone or in combination[111]. They are organised in the behaviour change techniques taxonomy(v1) of 93 consensually agreed distinct techniques[112], which has been recently revised into an ontology consisting of 281 techniques[113]. The mode of delivery for the intervention refers to the methods used to deliver the intervention such as face-to-face[108]. The mode of delivery has also been subject to further research with the creation of an ontology[114]. This completes the eight-step (3-stage) process of the Behaviour Change Wheel. In contrast Intervention Mapping proposes six-steps of development which are outlined in the next section.

2.4.3 Intervention Mapping

The six-steps of Intervention Mapping are illustrated in Figure 3. Although presented in a linear fashion the process is designed to be iterative, fitting with the guidance of the MRC and similar in ethos to the Behaviour Change Framework. Each step involves several tasks which guide the developer to complete each step

Figure 3: Steps of Intervention Mapping

Three fundamental rules underpin intervention mapping, 1) the socio-ecological approach, 2) multi-theory and evidence-based approach and 3) stakeholder participation.

A socio-ecological approach highlights the importance not only of the individual but of the context and environment of the behaviour. The use of multi-theory and evidence-based research to inform development is argued to promote change; alongside this stakeholder participation enhances in the acceptability and feasibility of a designed intervention[107].

The Behaviour Change Wheel (incorporating the Theoretical Domains Framework) and Intervention Mapping are both theory and evidenced-based approaches to intervention development, with proven utility in interventions to change health professional behaviour[104]. There is no consensus as to which of these approaches is the most appropriate, thus selection can be pragmatically made based upon the requirements of the intervention and discussed in the next section.

2.4.4 Comparison of Intervention Mapping and the Behaviour Change Wheel

Both Intervention mapping and the Behaviour Change Wheel acknowledge the role of the individual and the context in the resulting behaviour, through the centrality of the socio-ecological approach of Intervention Mapping[107] and the *opportunity* component of the Behaviour Change Wheel [90]. This focus is important as 'human behaviour is defined as the product of individual or collective human actions, seen within and influenced by their structural, social and economic context'[115]. Thus, an intervention that seeks to change behaviour is arguably improved by considering all these factors. Furthermore, the role of external/environmental factors has been highlighted as central to improving integrated care for people with mental and physical ill-health[15,83,86]. Yet, interventions which are designed to target health professional behaviour infrequently attend to this important aspect of behavioural change[104]; a limitation identified in T2D care interventions described in Chapter 1 (Section 1.3). The use of either Intervention Mapping[107] or the Behaviour Change Wheel[90] can therefore be used to support the development of an intervention with awareness of the contextual conditions.

The tailoring of complex interventions can be supported with the involvement of stakeholders as they can provide an understanding of context, which is key to interpreting findings of a specific evaluation and generalising beyond it[116]. It is acknowledged that there is often a failure to achieve expected outcomes or improvements from implemented interventions and it has been suggested that this can result from a lack of understanding of what is required to make them work[117]. This may be because there is a lack of understanding of the context within which the intervention is being delivered or is expected to work. A core principle of Intervention Mapping[107] is the involvement of a planning group comprised of stakeholders[107]. Whilst arguably less prominent in the Behaviour Change Wheel[108] there is a focus on the importance of stakeholders and 'designers are encouraged to pilot review and amend the intervention as necessary with input from key stakeholders before launching the intervention'[108]. Thus, both approaches enable involvement of stakeholders in the development process.

Both Intervention Mapping[107] and the Behaviour Change Wheel[90] advocate the use of theory to support in the design of interventions, however selection of theory and methods to guide the content of an intervention differs between the frameworks. A recent review of interventions targeting health professional behaviour utilising Intervention Mapping [118] found a lack of documented rationale for the selection of determinants, a finding reflected in a previous Cochrane review exploring tailoring of interventions to change health professional practice[119]. Previous employers of Intervention Mapping in health and healthcare[120–122] have highlighted that the process is "time-consuming and resource intensive"[121] and the full Intervention Mapping methodology may not be suitable for all situations[122]. It may be that the sheer volume of theories and change methods from which to reference is overwhelming and additional support is needed to determine appropriate theory and operationalisation beyond that provided by the approach. The clear links to the Theoretical Domains Framework within the Behaviour Change Wheel[108] may ameliorate this issue as it was designed, in part, to address the often-cited issue of theory overload which developers faced when designing interventions [109]. Therefore, the Behaviour Change Wheel provides a more pragmatic approach to theory use in the intervention development process.

In summary, both the Behaviour Change Wheel[108] and Intervention Mapping[107] offer a structured approach to intervention development and selection of specific intervention approaches during the *plan the development phase*. Whilst it is acknowledged that spending too little time in development may result in a flawed intervention, there is a danger that too much time spent on development may result in the intervention becoming obsolete owing to changes in context[95]. This is perhaps particularly pertinent in the field of healthcare given the extent and range of factors influencing changes in need and approaches for care as well as the need to produce plans to reduce inequalities in an expedited manner, as is outlined by the LTP-[21]. The Behaviour Change Wheel provides a systematic and theoretically informed, yet parsimonious, method for identifying components of an intervention[108], it was therefore selected ahead of Intervention Mapping to guide intervention development in this PhD.

2.4.5 Application of these theoretical frameworks in related health areas

The Behaviour Change Wheel and Theoretical Domains Framework have been utilised to identify barriers and enablers and to develop interventions in similar fields, such as severe mental illness and smoking cessation, improving attendance and delivery of diabetic retinopathy screening and diabetes quality improvement interventions, described further below. These examples underscore the appropriateness of the selection of these frameworks and provide valuable lessons for this PhD.

Examination of barriers and enablers using the Theoretical Domains Framework and the Behaviour Change Wheel for intervention development have been used to support smoking cessation in mental health settings[123,124]. The research identified five theoretical domains important to this topic 1) *Environmental Context and Resources, 2) Knowledge, 3) Social Influence, 4) Intentions and 5) Emotion.* The authors identified that integration of services and overcoming competing demands on staff time and resources are crucial[123]. In addition, clearer referral pathways, consideration of the additional challenges faced by those with an SMI and the availability and accessibility of preference-based support are central to supporting smoking cessation in this population[123]. Following on from this work, the Behaviour Change Wheel was used to develop an intervention to support smoking cessation targeting four of the identified domains which is now ready for formal testing in a randomised feasibility study[124]. Collectively this suggests the utility of the frameworks for developing a behaviour change intervention in a mental health setting.

These frameworks have also been used extensively in the topic of diabetic retinopathy screening for both Type 1 and Type 2 diabetes, generally[125–127] and in young adults (18-34 years)[128,129]. This literature highlights the importance of a nuanced approach to identifying barriers and enablers as different domains were identified as salient for the different populations. For example, in young adults the domain *Goals* was identified as salient[128], which was not highlighted in the literature generally[126]. Conversely, the domain *Memory, Attention and Decision Processes* was identified as salient in the general literature[126] but not in young adults[128,129]. Exploration of the themes within the domain highlight differences which are arguably related to age such as forgetting appointments, competing health demands and attribution of vision-loss to age related changes rather than diabetic retinopathy[126]. These findings underscore the importance of nuance in understanding barriers and enablers, as different intervention strategies would be appropriate to address these determinants. This can be achieved by following the third step of the Behaviour Change Wheel or using a framework such as the Action, Actor, Context, Target, Time (AACTT) framework. Both approaches allow behaviour specification to support a nuanced understanding of barriers and enablers.

These frameworks have demonstrated the ability to cope with multiple care behaviours, an important consideration given the complexity of T2D care. This has been demonstrated within T2D care with six guideline-recommended health professional behaviours the focus of an intervention using behaviour change techniques. These behaviours included prescribing for blood pressure and glycaemic control, providing physical activity and nutrition advice, providing updated T2D education and foot examination. The ability of these frameworks to support behaviour change of health professionals across multiple behaviours further underscores their utility in this PhD.

Finally, use of these frameworks to develop a behaviour change intervention in T2D care[127] highlight the importance of considering a range of delivery formats of behaviour change techniques. An implementation intervention designed to improve delivery of six clinical behaviours of T2D management by healthcare professionals reported a lack of statistically significant improvement[127]. The authors suggested this may have resulted from suboptimal delivery intensity (a single 90-minute session). Alternative intervention delivery (e.g. environmental restructuring) and modes of delivery (e.g. the use of computerised prompts within the clinical environment) offered by the Behaviour Change Wheel should be considered. This will however require consultation with appropriate stakeholders to support acceptability. The role of stakeholders in this PhD is considered in the next section.

2.5 Involvement of stakeholders and pay attention to future implementation

Two linked key issues in the INDEX guidance is the involvement of stakeholders and pay attention to future implementation. There are few evaluations of the impact of the involvement of stakeholders on research, practice, policy, or population outcomes[130] and together with limited empirical evidence on outcomes, there is a lack of clarity about how stakeholders are involved[131]. The extent to which stakeholders are involved in research is acknowledged to be variable[132]; equally the terminology used to describe stakeholder involvement is fluid. The literature, in common with the findings of other systematic reviews in health care[133,134], indicates that multi-stakeholder health services research collaborations, whilst intended to support the actualisation of evidence-based principles, are relatively unverified in their efficacy[135]. There are also potential costs associated with their involvement which are often unacknowledged[136]. It is suggested that there are five cost ‘types’ including 1) risk to the research itself, 2) risk to the research process, 3) professional risks for stakeholders and researchers, 4) personal risk for stakeholders and researchers and 5) risks to the wider cause of scholarship[136]. These were suggested to result from misunderstandings[136], or arguably a misalignment of expectations of what constitutes stakeholder engagement. To overcome these difficulties clarity over the level of involvement and actualisation of the principles of stakeholder involvement are needed. This assertion guided consideration of involvement of stakeholders.

In this project, stakeholders, identified as health professionals providing care (including those who can implement ideas such as service leads and team managers), and service users and carers, participated in all phases of the work, supporting the design of the intervention following the steps of the Behaviour Change Wheel. The active involvement of stakeholder inherently addressed other key considerations in the INDEX guidance, *understanding context* and *pay attention to future implementation,* through stakeholders' expertise and knowledge of the NHS context which was used to refine the proposed intervention strategy. The involvement of stakeholders in each of the primary data collection studies is detailed in Chapters 5 (Section 5.4.7), 6 (Section 6.3.4) and 7 (Section 7.3.1.3)

2.6 Draw on Existing Theories

The INDEX Guidance identified four considerations related to the use of theory in intervention development; 1) select a theory or theories at the start, 2) draw on more than one theory, 3) use existing theory to guide collection of published evidence and 4) the periodic consideration of theory during the intervention development process[98]. As outlined earlier in this chapter the clear links to the Theoretical Domains Framework within the Behaviour Change Wheel[108] are central to the decision to utilise this approach. Frameworks of theories, such as the Theoretical Domains Framework, have an advantage as they can bring together disparate and overlapping theories providing a broad overview of potentially relevant factors[98]. This includes a focus beyond individual behaviour change to factors that reside at social and organisation levels, which can be beneficial in complex interventions[95].

The recent MRC update clearly highlights the important role of theory in intervention development[97] . There is however ongoing debate as to whether the utilisation of theory results in effective intervention design. Interventions underpinned by theory are advocated by the MRC, suggesting that its use will likely result in a more effective intervention than one which is purely informed by empirical evidence or a solely pragmatic approach[96]. Reviews have found positive associations between theory use and efficacious outcomes for interventions across the social and behavioural sciences[137,138], yet others have suggested that theory-based interventions are no more effective than non-theory-based[139]. Reducing the use of theory in intervention design to an efficacy argument diminishes other potential benefits. These involve the use of theory as a coherent and explicit framework for designing, evaluating, and optimising interventions; the provision of a common language to clarify key aspects of interventions; and a logical and systematic way to consider and interpret accumulating evidence - which over time allows predictions in new or uncertain contexts[140]. Whilst these differences may result from variable application of theory[139], equally there may be limitations in intervention reporting[141]. The use of the GUIDED (Guidance for reporting of intervention development) reporting checklist[142], an intervention development reporting checklist, could ameliorate the latter issue by providing a clear structure for reporting intervention development. In particular item 6 focuses on reporting if and how published theory was used to inform the intervention development process[142].

Finally, the use of theory can support detailed examination of the barriers and enablers of T2D care for adults with an SMI, exploration of the proposed theoretical content of interventions and assess the congruence between these two outcomes. This is beneficial for identifying the potentially effective content of current interventions which can be utilised in future intervention development. Use of theory in this manner, can enable elucidation of what theory-based behaviour change techniques, delivered in which way, are effective in promoting behaviour change, for whom and in what circumstances and through which mechanisms of action[140]. Therefore, theory will be utilised to support the development of this intervention as well as guiding development of a proposed programme theory, discussed further in the next section.

2.7 Programme theory

Programme theory describes how a specific intervention is expected to lead to its outcomes[103]. It supports articulation of proposed causal mechanisms between the content of interventions, intermediate and long-term outcomes, and how these interact with contextual factors[95]. It is suggested that cumulative progress in the design of more effective interventions could be achieved through developing a more widely shared understanding of the "mechanism of action", or programme theory, through which interventions bring about change[143]. The Behaviour Change Wheel[108] contains a process for identifying potential mechanisms of action and behaviour change techniques to bring about change[144]. This was used to inform early development of the proposed programme theory, reported in Chapter 7 (Section 7.6).

2.8 Understand context

Developing an understanding of the contextual aspects surrounding the implementation of interventions is a significant consideration. Exploring context throughout the development process can minimise the risk of failure during later phases such as feasibility, evaluation, and implementation[98]. Context encompasses a wide range of factors, including those related to populations, physical location, social, economic, cultural, political features, and implementation-related factors[145]. Context was considered and understood in three ways in this PhD; 1) the active involvement of stakeholders throughout the PhD (detailed in Section 2.5 and 2.9), 2) the focus on identifying potential contextual moderators in the qualitative study (Chapter 6. Section 6.3.6.4) and 3) the use of the APEASE criteria to select intervention content in Chapter 7 (Discussed in more detail in section 7.3.1.2).

2.9 Undertake primary data collection and design and refine the intervention

This section covers two of the INDEX key considerations 1) undertake primary data collection and 2) design and refine the intervention as these informed each other in this PhD. Intervention design is a discrete component of the development process whereby ideas are generated, and decisions made about the intervention components including how these will be delivered, and by whom and in what context and setting[95]. The intervention was designed following the steps of the Behaviour Change Wheel[108], and potential contextual moderators of intervention effectiveness were identified in conjunction with stakeholders to inform and refine programme theory development. This was achieved through three mixed method studies, which followed on from study 1 (systematic review reported in Chapter 3) and study 2 (content analysis and assessment of theoretical congruence reported in Chapter 4).

- Study 3 supported completion of stage 1 (steps 2-3) of the Behaviour Change Wheel. It involved a research prioritisation study, using a Delphi method, with service users, health professionals and service delivery leaders to select and specify a behavioural target of importance to stakeholders.
- Study 4 supported completion of stage 1 (step 4) of the Behaviour Change Wheel and identified what needed to change to change the target behaviour i.e., the barriers and enablers of the identified targeted behaviour organised using the Theoretical Domains Framework. It also identified potential contextual moderators of intervention effectiveness.
- Study 5 supported completion of stage 2 and 3 (steps 5-8) of the Behaviour Change Wheel. It will involve a further Delphi with health professionals to create appropriate applications of candidate intervention functions, policy categories, behaviour change techniques and modes of delivery.

The development of the intervention was reported using the GUIDED reporting checklist[142], (Section 7.7). Further details of each study, including method and outcomes will be presented in each of the subsequent chapters (5, 6 and 7). Finally, refinement of the intervention is proposed to continue beyond completion of this PhD through post-doctoral work. This is discussed further in Chapter 8 (Section 8.4.1).

2.10 Conclusion

This chapter has considered the available guidance on developing complex interventions to shape key decisions surrounding the development of an intervention to improve delivery of T2D care for adults with an SMI. A theory and evidence-based approach using the Behaviour Change Wheel and the underpinning Theoretical Domains Framework was used provide a framework for developing the intervention. The involvement of stakeholders was identified as paramount; therefore, stakeholders were involved throughout intervention development. The articulation of programme theory and clear description of interventions also emerged as central to intervention development and were used to address gaps identified in existing interventions reported in Chapter 1 (Section 1.3).

Finally, to support intervention development prior to undertaking the steps of the Behaviour Change Wheel a theory-based evaluation of existing interventions was undertaken (Study 2) as identified in Table 1 (Section 2.3) and is reported in Chapter 4. This process enabled identification behaviour change techniques, which are potentially promising for intervention development. To support a theory-based evaluation of existing interventions it was first necessary to identify the perceived barriers and enablers of the delivery and organisation of T2D care (Study 1) which is detailed in the next chapter.

3 Chapter 3: A Systematic Mixed-Method Synthesis using the Theoretical Domains Framework

Study 1: What are the barriers and enablers of the delivery and organisation of T2D care for adults with an SMI?

3.1 Prologue

The previous chapters outlined the profound inequalities in T2D prevalence, morbidity, quality of life and excess mortality in adults with an SMI. Healthcare service provision was identified as a substantial contributor to this inequality with limited interventions identified which targeted T2D care for adults with an SMI. The interventions identified focussed on a narrow range of factors including knowledge and skills of mental health professionals. Evidence suggests that a broader range of factors is potentially implicated including diagnostic overshadowing, communication challenges underpinned by a lack of knowledge, the unique challenges faced by adults with an SMI, and a lack of integrated services. The second chapter outlined selection of a theory and evidence-based approach to intervention development to support transparent, replicable development with a focus on theory to articulate potential causal mechanisms. This selection also offered the opportunity to integrate theory into an examination of existing interventions to improve T2D care of adults with an SMI. This chapter will report a systematic review of the literature to identify barriers and enablers that healthcare professionals experience to delivery of T2D care for adults with an SMI. Undertaking this systematic review will enable a theory-based evaluation of existing interventions. The output of this chapter was published in the peer-reviewed journal Diabetic Medicine with the article available in Appendix 2.

3.2 Introduction

In Chapter 1 (Section 1.3) it was outlined that existing interventions, identified in prior systematic reviews, target the T2D knowledge and skills of mental health professionals. Beyond these important influences or determinants of behaviour, it was suggested that the complex health and care system likely impacts the delivery and organisation of T2D care resulting in diagnostic overshadowing (Section 1.2). This impact was suggested to result from an interplay between challenges in communication perceived to be underpinned by a lack of knowledge, and an ill-suited health and care system. These can be described as barriers to T2D care for adults with an SMI, as they interfere with the desired behaviour. Factors which support behaviour can be described as enablers of practice[119].It is widely assumed that efforts to change health professional behaviour will be less successful if they do not consider barriers to and enablers of practice. As yet however, there has not been a comprehensive review of the perceived barriers and enablers of the delivery and organisation of T2D care for people with an SMI.

Whilst identification of barriers and enablers is recommended, the method for their identification is less prescriptive[119]. A broad theoretical framework can support identification and synthesis of barriers and enablers from multiple sources. A frequently utilised framework that would enable sufficient breadth in the identification of barriers and enablers of health professional behaviour is the Theoretical Domains Framework[109], described in Chapter 2 (Section 2.4.2.1 and Table 4). The Theoretical Domains Framework was chosen as it has sufficient breadth to analyse a wide range of potential barriers and enablers of care. This includes individual, social, and environmental factors, which is important given the need for a broader consideration of factors underpinning health professional behaviour, e.g., knowledge (individual) and care integration (environmental). Furthermore, its utility as an *a* *priori* framework for synthesis has been demonstrated in syntheses of qualitative and mixed study reviews[27,55,56] all of which aimed to understand and/or change health professional behaviour. Thus, demonstrating the suitability of this framework for the systematic review.

The use of the Theoretical Domains Framework and identification of the potential significance of the domains in relation to T2D organisation and delivery of care for adults with an SMI could also offer insights into why certain interventions prove more successful than alternative approaches. The findings of this review will enable examination of existing interventions to identify whether they target the perceived barriers and enablers of T2D care. The findings of this review can also empower intervention creators to enhance their strategies by focusing on the most important determinants of T2D care for adults with an SMI.

3.3 Aim and Objectives

This systematic review aimed to identify barriers and enablers of the delivery and organisation of T2D care for adults with an SMI, from the health professionals' perspective, using the Theoretical Domains Framework. The objectives were to:

- Identify published and grey literature which reports or explores the barriers and enablers of the delivery and organisation of T2D care for people with an SMI as experienced by health care professionals
- Extract barriers and enablers and map these onto the 14 domains of the Theoretical Domains Framework
- Identify key themes within the 14 domains
- Assess the relative importance of each domain in relation to the delivery and organisation of T2D care

- Where possible, identify differences in barriers and enablers of T2D healthcare for people with SMI. This will include comparisons made between different health professionals (e.g., General Practitioners (GPs), mental health nurses etc), the nine recommended care processes (detailed in Section 1.1.3) and different health care settings (e.g. community, inpatient settings) depending on data availability

3.4 Method

3.4.1 Eligibility Criteria

Selection criteria were identified using the SPIDER (sample, phenomenon of interest, design, evaluation, and research type) question format[37], detailed in Table 5.

Table 5: Spider Criteria

SPIDER Criteria	Eligibility
Sample	Health professionals
Phenomenon of Interest	Reported or explored perceived barriers and enablers of the delivery and organisation of T2D care for adults with an SMI (as per NICE guidance NG28 and QS6)
Design	Any design
Evaluation	Any evaluation
Research Type	Any qualitative, quantitative, or mixed method design.

Only original primary research studies were included (i.e., no commentaries or reviews). No studies were excluded on the basis of country or publication date, however literature was excluded if it was not in English, where it only included the perspective of service users, where the focus was only on the management of mental health or where it was not clear that the reported barriers and enablers pertained to T2D care for adults with SMI.

A key focus of included studies had to be the perspectives of health professionals on the delivery and organisation of T2D care for adults with an SMI

3.4.2 Terminology

For this synthesis, the definitions outlined in Table 6 were utilised to identify eligible studies:

Table 6: Terminology Definitions

Concept	Definition
Health Professionals	Any health professional who delivers information, guidance, screening, or treatment to adults with SMI and/or T2D. This includes mental health professionals (e.g., mental health nurses), physical health professionals (e.g., diabetes nurse specialists) and general health professionals (e.g., GPs)
Severe Mental Illness	SMI definition as per Chapter 1 (Section 1.1) covers schizophrenia, bipolar disorder and other psychoses[2]. Other psychoses include schizoaffective disorder, schizophreniform disorder and delusional disorder[3] Studies that did not state explicitly individual diagnoses but specified severe or serious mental illness were included.
Type 2 Diabetes	If provided, the validation of the diagnosis of T2D should be consistent with the standard classification criteria valid at the time of the study (e.g., ADA 1999; ADA 2008; WHO 1998).
T2D Care	The focus of care can be 1) T2D care generally i.e., not specified by the authors but discussed as ‘type 2 diabetes care’ or ‘metabolic care’, or 2) a specific T2D care process, such as those specified in standard guidelines for treating T2D e.g. National Institute for Health and Care Excellence, American Diabetes Association; International Diabetes Federation)

3.4.3 **Search Strategy**

The comprehensive search strategy (see Appendix 3 for the full strategy) for published literature, was informed by an initial basic search using the terms demonstrated in Table 7.

Grey literature search engines do not enable such a comprehensive search strategy and therefore the simpler strategy (Table 7) was utilised.

Table 7: Basic Search Strategy

Source	Search
Published Literature	*Health professionals AND severe mental illness AND barriers/enablers AND T2D terms OR general physical care terms AND T2D terms*
Grey Literature	*Health professional AND severe mental illness AND type 2 diabetes AND barrier or facilitator or enabler*

A combination of key words and mesh terms were used and combined using Boolean operators as it is acknowledged that identifying qualitative evidence can be challenging, requiring this comprehensive combination[46]. The search terms were informed by a prior Cochrane[42] and systematic review[30]. Both were comprehensive and in a similar field supporting identification of appropriate health professional and T2D care terms. Terms pertinent to barriers and enablers specifically in the field of type 2 diabetes and SMI research were also included (e.g., engagement, communication) informed by previous research[43,44]. Additionally terms related to the Theoretical Domains Framework domains were included, for example representing the domain *emotion* were the terms *anxiety* and *fear*. These terms were identified previously, by seven research psychologists familiar with the Theoretical Domains Framework[45]. The MEDLINE search strategy was reviewed by two members of the supervisory team (KM and AS), as well as a Health Sciences Librarian with expertise in the development of systematic review search terms. After the MEDLINE strategy was finalised, the search was adapted to the syntax and appropriate headings of each database. All search strategies are provided in Appendix 3.

3.4.4 **Information Sources**

Searches were conducted in Medline, EMBASE, PsycINFO, CINAHL, OVID Nursing, Cochrane Library, Google Scholar, OpenGrey, PsycEXTRA, Health Management Information Consortium and Ethos, with reference list, forward and backwards citation searching of included literature. The reference lists of excluded reviews were searched to identify any potentially relevant studies[24,38–41]. All databases were searched from inception to March 2019 with repeat searches in September 2019 and January 2023, to ensure the review was current. All searches were carried out using the same method i.e., no changes made to the search terms nor sources. Notifications were set for subsequent publications.

3.4.5 **Study Selection**

Initial search results from published and grey literature were imported into EPPI-Reviewer 4. Following duplicate removal, the titles and abstracts were independently screened by TD and HM against the eligibility criteria. Any discrepancies in independent screening were resolved through discussion without the need for additional input. Full text screening was independently undertaken by TD for 100% of all papers and compared to the screening decision by another member of the review team (HM, MH & KM) who each screened one third of papers The references identified through citation searching were imported into Excel and subject to the same review process for both title and full text screening.

3.4.6 **Data Extraction**

The data for extraction was agreed in discussion prior to extraction and a data extraction file was created in Excel. Data extraction items and format was adapted from available published examples and piloted prior to use in this review.

The following data were extracted:

- Author
- Year of publication
- Country
- Setting
- Profession
- Age
- Service duration
- Staff grade
- Number of service users under care
- Broad study aims
- Sampling frame
- Sampling method
- Sample size
- Diabetes care process (e.g., care generally or a specific process)
- Study design
- Analysis method
- Data: participant quotations, survey results or statistical test results
- Author interpretations/conclusions

All extraction was undertaken by TD with a second independent reviewer (AZ) performing extraction for 20% of the included articles. Differences of opinion were resolved through discussion without the need for a third reviewer.

3.4.7 **Critical Appraisal**

3.4.7.1 Method

The Critical Appraisal Skills Programme (CASP) tool for qualitative studies[146] was used to appraise qualitative studies. It forms part of a number of critical appraisal tools and was developed and piloted by experts and has been utilised in Cochrane reviews of qualitative evidence [147]. The CASP is a ten-question checklist, which focuses on assessments of the aim, suitability of the methodology, recruitment, adequate and appropriate data collection, consideration of the relationship between the researcher and participant, ethics, clarity of findings and value of the research.

The Appraisal tool for cross-sectional studies (AXIS) tool[148] was used to appraise cross-sectional studies. It was created to assess the quality and risk of bias of cross-sectional studies by an expert panel using Delphi methods[148]. The tool was created to address the increasing importance of cross-sectional studies in the field of evidence-based medicine and the identified lack of appropriate tools to assess both risk of bias and study quality [148]. The twenty-question tool focuses on the presented methods and results of included studies and attempts to overcome issues of quality of design versus quality of reporting by incorporating both with the tool assessment [148].

The Joanna Briggs Institute (JBI) checklist for case reports[149] was utilised to critically appraise the case study. The eight-item checklist focuses on rationale for the inclusion of the patient and clarity of the assessment methods, intervention/treatment, adverse events and learned lessons.

There is no known tool designed specifically to assess pilot randomised controlled trials (RCTs) therefore the Consolidated Standards of Reporting Trials (CONSORT) extension for reporting of pilot RCTs [150] was used to guide critical appraisal. Although the Cochrane Risk of Bias 2 [151] was identified as appropriate for critical appraisal of RCTs it was judged to be inappropriate owing to the differences in aims, outcomes and reporting requirements between RCTs and pilot studies [152] . Each of the 26-item reporting criteria were reviewed to appraise whether the pilot RCT had considered these aspects.

Grey literature should be subject to critical appraisal and the AACODS checklist[153] focuses on assessing the *Authority, Accuracy, Coverage, Objectivity, Date* and *Significance* of the resource. It has been utilised in other systematic reviews[126] and is suggested to be appropriate owing to its broad applicability but sufficiently concise framework for critically appraising alternative sources.

3.4.7.2 Assessment

No scoring system is recommended for any of the chosen appraisal tools therefore outcomes of the assessments are portrayed to provide an indication of relative strengths and weaknesses of the body of evidence. Each of the proposed questions in the assessment tools were appraised and a response of yes, no, unsure and not applicable were applied. No studies were excluded based on the outcome of the critical appraisal; the outcomes however were used to gain an understanding of whether any of the identified Theoretical Domains Framework domains were solely informed by a weak evidence base to address confidence in the findings. All studies were subject to critical appraisal by TD and a random 20% sample were independently assessed by AZ and differences resolved through discussion.

3.4.8 Data Analysis and Synthesis

A framework synthesis was undertaken to analyse the data using the following five steps 1) familiarisation, 2) identifying a framework, 3) indexing, 4) charting and 5) mapping and interpretation[154], with an additional assessment of relative domain importance.

Framework synthesis[154] is based on the principles of framework analysis. It was initially designed for analysis of qualitative data in an attempt to address the volumes of data produced by such research; it involves a largely deductive process of organising and analysing data utilising a pre-identified framework to structure analysis[155]. Framework analysis, and similarly synthesis, are best suited to research which has specific questions, a pre-designed sample and pre-identified issues[156] all of which are pertinent within this synthesis. Furthermore, a framework synthesis offers a sufficiently flexible yet soundly organised mechanism for the synthesis of heterogenous data [154], important in this review given the heterogeneity of the data.

3.4.8.1 Familiarisation

Familiarisation was achieved by reading each paper several times to ensure that salient information was identified.

3.4.8.2 Identification of a framework

The Theoretical Domains Framework was selected as the organising framework for this synthesis. Selection of the *a priori* framework was made by focusing on the instrumental contribution of the theories or framework, which is described as how the framework can make it easier to conduct a meaningful and insightful review[154]. As previously highlighted, the selection of the Theoretical Domains Framework was based on its comprehensive scope, its effectiveness as a pre-established framework for synthesis in multiple reviews[27,55,56] and the ability to act as an evidence base for theoretical congruence analysis of existing interventions (described in Section 4.4.5.3).

3.4.8.3 Indexing

Both qualitative and quantitative data were extracted from the studies and entered in an Excel spreadsheet. The extracted data units relating to factors that influenced delivery of T2D care for adults with an SMI were indexed by assigning a label which best described the overall sentiment of the extracted data unit and whether it was a barrier and/or enabler to T2D care provision.

3.4.8.4 Charting

A matrix was created in Excel to allow data units to be grouped by health professional groups and care processes where possible, utilising separate tabs.

3.4.8.5 Mapping and Interpretation

The data units were assigned to the domain(s) of the Theoretical Domains Framework identified through either, 1) identification by the study author who had employed the framework[157,158], or 2) interpretation of the data unit and assignment to one or more domains by TD. The coding of the first three studies was used to produce the coding protocol (Appendix 4), which provided examples of data units framed under each domain. The coding protocol was discussed with the supervisory team and disagreements discussed; upon approval of this the remaining studies were coded by TD. The use of the coding protocol was to support consistency of coding across the remaining studies.

The data units assigned to each domain were reviewed and labels assigned to the data units. These were influenced by the study objectives i.e., focussing on identifying barriers and enablers to the provision of T2D care as well as being informed by the constructs within each of the domains.

3.4.9 Synthesis of Qualitative and Quantitative Data

A 'data-based convergent synthesis'[159] was utilised whereby the extraction and analysis of qualitative and quantitative data was completed at the same time. As one synthesis method was used, data transformation was required[159], which involved quantitative data being 'qualitised'. Quantitative data was included in the framework and given a descriptive code to inform the themes. For example, a statement such as "providers don't have enough time" with a mean score of 4.03, on a Likert-type scale of 1= not a barrier to 5 = a strong barrier, would be coded as a barrier suggesting a lack of time. The transformation enabled the synthesis of findings from both qualitative and quantitative studies, using the Theoretical Domains Framework as the organising framework.

3.4.10 Assessment of importance

Domain importance was determined using an assessment of 1) frequency, 2) expressed importance and 3) discord within the domain[109,160–162]. The "frequency" for each domain was identified by examining the number of studies that were identified as highlighting a domain; this provided an ability to assess the relative importance of the domain and create a hierarchy. Expressed importance, was identified by exploring the included papers to identify whether the author of the original paper expressed that the data unit or domain was important to the study identified through an express statement of "importance" or explicitly by study participants. Discord was identified as any domain whereby the themes demonstrated opposing/conflicting views, for example mental health professionals articulate that T2D care is not their responsibility whilst physical health professionals express opposing views, i.e., T2D care *is* the responsibility of mental health professionals. These criteria have been utilised previously[160,161] and enable importance to be identified not only owing to prevalence or perceptions of importance, but identification of domains which may provide additional intervention targets caused by differences in professional opinions, for example differences in professional responsibility.

Domains that had a high frequency, defined as being identified in over 1/3 of the included studies, and met the criteria of expressed importance and discord were identified as the most important domains.

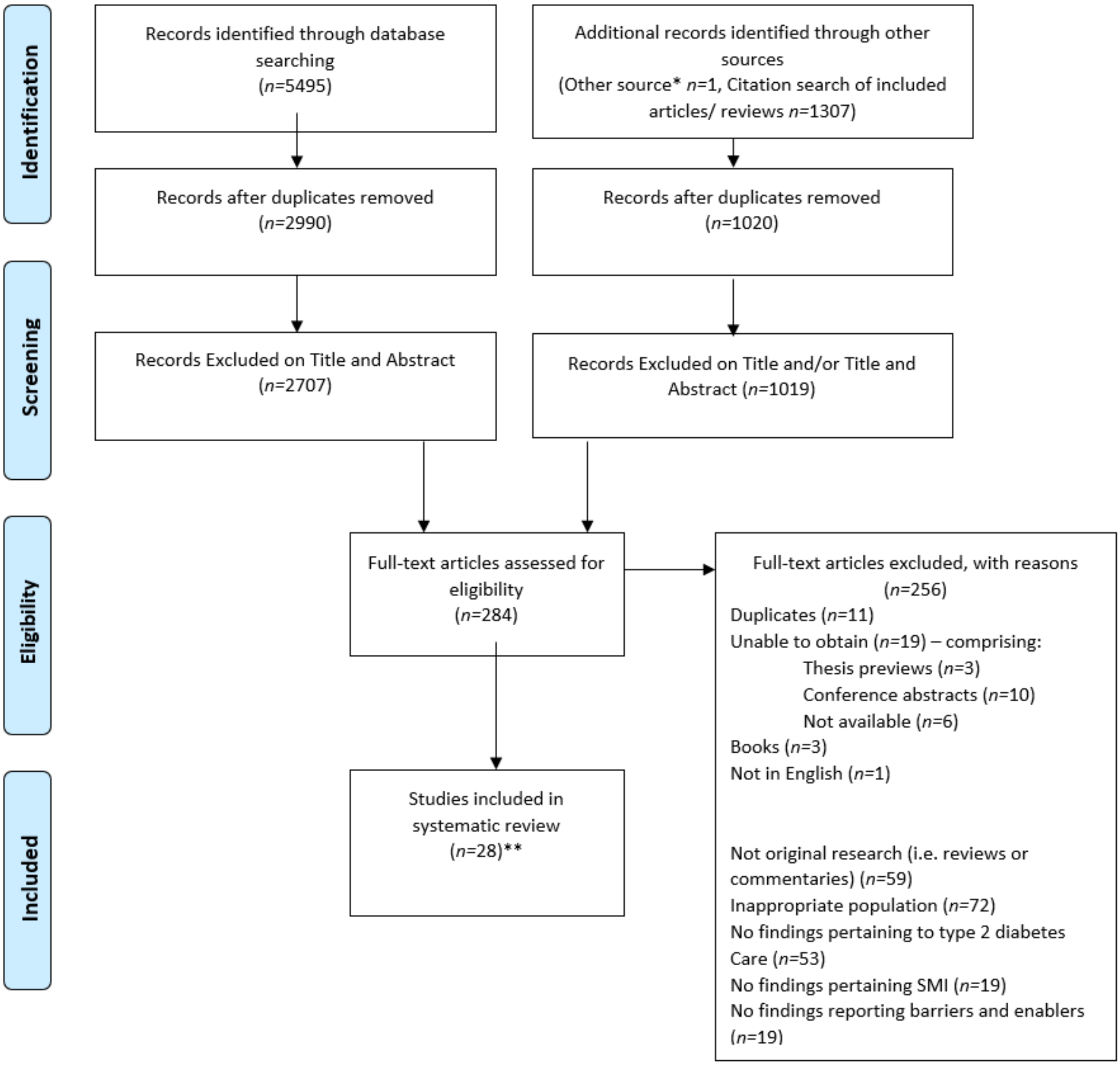
3.4.11 Registration

A protocol was produced, registered, and published on PROSPERO (CRD124491).

3.5 Results

3.5.1 Search Results

Titles and abstracts of 6802 references were screened across initial and citation chain searching of included articles and identified reviews[85,163–165], resulting in 284 full texts assessed for eligibility. One of the assessed studies was identified through knowledge of one of the supervisory team. Of these, 28 studies (*n*=27 database searches, *n*=1 other source) were included in the synthesis. Full study characteristics are provided in Table 8. The PRISMA diagram outlining the selection of articles at each stage of the search is presented in Figure 4.



*= Other source was the MSc student thesis known to one of the supervisory team. Agreement from student to provide thesis for assessment of inclusion in in the review

**= Studies included were *n*=27 from database searches and *n*=1 from other source

Figure 4: PRISMA of Studies Included and Excluded from the Review of Barriers and Enablers

3.5.2 Included Studies

3.5.2.1 *Study Setting*

The study settings are reported in Table 8. The sampled studies were conducted across seven countries with most included studies undertaken in the United Kingdom (n=11, 39%) and United States of America (n=8, 29%). Additionally, two studies were conducted in Australia, two in Canada and one contributing study conducted in each of the following Denmark, Sweden, Saudi Arabia, Uganda and China.

3.5.2.2 *Study Participants*

Seven studies[92,93,166–169] focussed specifically on mental health nurses, or student mental health nurses. Two studies[170,171] focussed on psychiatrists and one on nurse educators[172]. There were three single participant studies involving a student nurse[173], a cardiometabolic nurse[174] and a telephonic nurse case manager[175]. The remaining 15 studies utilised a mixed sample [157,158,176–188]. For this review professionals were grouped into mental health professionals - defined as those who focus on mental health solely (e.g., psychiatrist, mental health nurse), and physical health professionals (e.g., diabetologist, diabetes specialist nurse, general practitioner). Mixed samples were defined as samples containing both mental and physical health professionals that did not distinguish within their results and/or discussion whether the data was informed by a particular care group or profession. Full details are provided in Table 8.

3.5.2.3 *Research Methods*

There were 15 qualitative[157,167,172–175,177–180,182,184–186,188], and 12 quantitative studies[92,93,158,166,169–171,176,181,183,187,189], as well as one mixed-method[168] study included in this review. The methods are detailed in Table 8.

3.5.2.4 Care Process Focus

Most studies (*N*=22) focussed on T2D (or metabolic) care generally. Two studies[173,180] focussed on the provision of diet advice and four were focussed on T2D education[172,175–177] . Further details are provided in Table 8.

Table 8: Study characteristics of those included in the systematic review

No	Reference, date, status, identification	Country, Setting	Research Objectives	Topic or factor of investigation (relevant to synthesis)	Methodological approach (relevant to synthesis)	Data collection – (relevant to synthesis)	Data analysis – (relevant to synthesis)	Participants (relevant to synthesis)	Sample size & method (relevant to synthesis)	T2D Care Process
1	Adams (2008) *(Published)* Database search	UK, Setting not specified	A descriptive account of experience of nursing care to an individual with diagnoses of SMI and T2D	Reports experience of providing care	Qualitative – case study	Personal account of experience	Case Study	Student Nurse	*N*=1 Sample method not reported	Health promotion – diet for service user with T2D
2	Aloudah et al (2021)	Saudi Arabia, Tertiary Mental Health Hospital	Exploration of factors affecting T2D care for individuals with schizophrenia	Reports healthcare providers' attitudes and perspectives of diabetes care in people with schizophrenia	Qualitative - Based on the Theoretical Domains Framework	Semi-structured interviews	Themes	Physician n=4 Pharmacist n=2	*N=6* Sample method not reported	T2D care generally
3	Chwastiak et al., (2018) *(Published)* Database search	USA, Community Mental Health Centre-Outpatient	To assess the feasibility, acceptability, and preliminary effectiveness of a collaborative care model to improve T2D care and outcomes for service users with psychosis	The findings of the feasibility study provide reports of the ability to provide shared care	Randomized controlled Pilot study	Patient-focussed outcome measures. Brief reported statements from staff but unclear how these were obtained	Paired t-tests	Staff from the Community Mental Health Centre and the Washington Diabetes Centre	Sample size and method not reported	T2D education and general health assessment, health plan, medication adherence, healthy nutrition, physical activity
4	Cimo & Dewa, (2019) *(Published)* Database search	Canada, Setting not specified– various healthcare organisations	To explore perspectives of how T2D education can effectively address the challenges faced when people with SMI engage in T2D self-care behaviours	Reports on perceptions of tailoring of T2D education including perceived barriers and facilitators	Qualitative	Focus group – semi-structured questions/prompts	Themes	Nurse practitioner n (5%) Social worker n (38%) Registered nurse 14% Registered dietitian 5% Certified diabetes educator 14% Community worker 24%	*N*=21 Mixture of volunteer and snowball sampling	T2D self-care education
5	Coblentz et al., (2015) *(Published)* Database search	USA, Two rural communities	To investigate the barriers, strengths, and potential solutions for improving metabolic screening and treatment in adults diagnosed with schizophrenia living in rural communities	Reports on barriers and enablers (or improvement) of care of metabolic syndrome in service users with Schizophrenia	Qualitative	Semi-structured Interview	Inductive content analysis	Primary care providers *N*=7 Psychiatric care providers *N*=7	*N*=14 Voluntary - provided with study materials	T2D care generally

No	Reference, date, status, identification	Country, Setting	Research Objectives	Topic or factor of investigation (relevant to synthesis)	Methodological approach (relevant to synthesis)	Data collection – (relevant to synthesis)	Data analysis – (relevant to synthesis)	Participants (relevant to synthesis)	Sample size & method (relevant to synthesis)	T2D Care Process
6	Happell, et al., (2013) *(Published)* Database search	Australia, Setting not specified	To gain nurse views on a new cardiometabolic nurse role as well as advantages and disadvantages of such a role	Hypothesised role is to address some of the difficulties in providing cardiometabolic care (defined as e.g., cardiovascular disease and diabetes). Reports staff perceptions of how this may/may not work to address these issues	Quantitative, Cross-sectional	Survey – newly developed and piloted to check ease of completion and comprehension (Likert style)	Percentages, Mean scores	All members of the Australian college of mental health nurses (*N*=2852)	*N*=643 Voluntary, email invite sent to all members of the Australian College of Mental Health Nursing	Cardiometabolic care generally including assessment and treatment, taking primary responsibility tasks such as blood tests, referrals to specialists/GPs, monitoring of overweight, obesity and providing lifestyle advice.
7	Happell et al., (2015) *(Published)* Citation Search	Australia, Rural Mental Health Service *Intervention focussed*	As part of the study evaluation process – to seek the views of the CHN regarding the role to further develop the position for future studies and broader implementation. Specifically: 1. Initial understanding of the role of the CHN. 2. Organizational support. 3. Consumers, service, and personal outcomes. 4. Effect of the position on your view of the physical health of people with mental illness.	Reports on barriers and enablers of providing cardiometabolic care under a new specialist role of cardiometabolic health nurse	Qualitative	Semi-structured interview	Applied thematic analysis	Cardiometabolic Nurse	N=1 Purposive, recruited cardiometabolic nurse	Cardiometabolic care generally
8	Hemingway et al., (2013) *(Published)* Database search	UK, NHS Secondary Care Trust	Development and testing of training workshop for those who work with people with SMI/DM.	Reports on knowledge of DM	Quantitative, Pre-post test	Survey	Mean Percentages	Mental health nurses *N*=35 Student nurses *N*=26	*N*=35 Non-random convenience sample from qualified and student nurses attending workshop	T2D care generally

No	Reference, date, status, identification	Country, Setting	Research Objectives	Topic or factor of investigation (relevant to synthesis)	Methodological approach (relevant to synthesis)	Data collection – (relevant to synthesis)	Data analysis – (relevant to synthesis)	Participants (relevant to synthesis)	Sample size & method (relevant to synthesis)	T2D Care Process
9	Hemingway et al., 2015) *(Published)* Database Search	UK, NHS Secondary Care Trust	Increase understanding and skills of MHNs working with people with SMI and DM	Reports on knowledge of DM	Quantitative, Pre-post test Quantitative - descriptive	Survey – knowledge Survey – workshop content	Mean Percentages	MHN and student nurses	Pre-Test SN - *N*=30 MHN *N*=32 Post-Test SN *N*=22 MHN *N*=26 Survey: *N*=49 Non-random convenience sample from qualified and student nurses attending workshop	T2D care generally
10	Hultsjö, 2013 *(Published)* Database Search	Sweden, Psychosis outpatient centre	To explore and analyse MHNs experience of T2D care given to people with psychosis	Reports on barriers and enablers of T2D care	Qualitative	Semi-structured interview	Content Analysis	Mental health care staff at a psychosis outpatient clinic	*N*=12 Voluntary, study details provided at specific study meeting by the Principal Investigator	T2D care generally
11	Kahn et al., 2009) *(Published)* Database search	USA, Gold Choice Member Telephonic Nurse Case Management (TNCM) registry	Identify T2D self-management issues faced by Gold Choice members Explore the role of the TNCM in addressing the members' needs.	Reports on barriers and enablers of provision of DM care through telephonic nurse management	Qualitative	Progress note analysis Structured Interview (open-ended questions determined from progress note themes)	Content-driven immersion-crystallization Themes	Telephonic nurse case manager	*N*=1 Purposive – the professional involved in the care	T2D Education and self-management
12	Kaufman et al., (2012) *(Published)* Database Search	USA, Urban County Hospital	To enrich knowledge surrounding barriers and solutions to primary and metabolic care for service users with an SMI	Reports on barriers and enablers (solutions) to primary and metabolic care	Qualitative	Semi-structured interview	Content Analysis	Psychiatrists *N*=2 Case managers *N*=3 Nurse practitioners *N*=5	*N*=20 Voluntary, those who expressed interest contacted by research team	T2D care generally

No	Reference, date, status, identification	Country, Setting	Research Objectives	Topic or factor of investigation (relevant to synthesis)	Methodological approach (relevant to synthesis)	Data collection – (relevant to synthesis)	Data analysis – (relevant to synthesis)	Participants (relevant to synthesis)	Sample size & method (relevant to synthesis)	T2D Care Process
								Primary Care Physicians *N*=6 Primary Care Nurses *N*=4		
13	Lawless et al., 2016) *(Published)* Database Search	USA, Primary Care *Intervention Specific*	To assess the feasibility, acceptability, and implementation of nurse-led activities in a pilot study of Targeted Training and Illness Management (TTIM)	Reports on challenges and solutions to the provision of a targeted training and illness management programme for people with DM/SMI	Qualitative	Unclear – some quotes thus potentially some discussion plus observation	Narrative Description	Nurse Educators (employed specifically to deliver new trial programme)	*N*=3 Purposive – the professionals involved in the care	Structured Education Programme for people with SMI and T2D
14	Lowndes et al., (2013) *(Published)* Database Search	Canada, For-profit rural group home	To explore the social organisation of food provision and dietary intake in seriously mentally ill people with T2D	Reports on food provision and care of T2D in people with SMI in a residential facility	Qualitative	Institutional ethnography-semi-structured interviews, observation, and document analysis	Narrative description	Care providers *N*=3 Family physician *N*=1 Field/social workers *N*= 3 Home operator *N*=1 Social Night coordinator *N* =1	*N*=9 Sample method not reported	Diet
15	Mangurian et al. 2019	USA, Safety net clinics in one large urban public health system	To explore the opinions of primary care clinicians and psychiatrists on the monitoring of metabolic effects of antipsychotics	Reports the attitudes metabolic monitoring and treatment of	Quantitative – cross sectional	Survey	T tests, multivariate Logistic regression, logistic regression	Psychiatrist n=49 Physician n=99 Nurse practitioners n=57 Physician assistant n=4	N=209, Purposive, clinicians approach directly by research team and invited to participate	Cardiometabolic care generally
16	McBain et al. (2016) *(Published)* Database Search	UK, Inner City NHS Secondary Care Trust	To explore the barriers and facilitators health professionals experience when managing T2D in people with SMI	Uses Theoretical Domains Framework to investigate barriers and enablers of T2D care for people with SMI	Qualitative – Based on the Theoretical Domains Framework	Semi-structured interviews	Framework Analysis	Psychiatrists *N*=4 Community health nurses *N*=4 Diabetes nurse specialists *N*=2 GP *N*=3 Diabetologist *N*=1 Practice nurse *N*=1	*N*=16 Snowball and purposive	T2D Care generally

No	Reference, date, status, identification	Country, Setting	Research Objectives	Topic or factor of investigation (relevant to synthesis)	Methodological approach (relevant to synthesis)	Data collection – (relevant to synthesis)	Data analysis – (relevant to synthesis)	Participants (relevant to synthesis)	Sample size & method (relevant to synthesis)	T2D Care Process
								Primary care liaison nurse *N*=1		
17	McBain et al. 2018) *(Published)* Database Search	UK, Primary Care Practices, NHS Secondary Care Trusts	Identify the primary barriers and enablers that affect management of T2D in people with SMI	Uses Theoretical Domains Framework to investigate barriers and enablers of T2D care for people with SMI	Quantitative Cross-sectional	Survey – newly developed using consensus method and findings from previous interviews (McBain 2016)	Analysis of Variance, Regression Analysis	Mixed	*N*=273 Purposive, convenience and voluntary through targeted emails at nine NHS Trusts, GPs across the UK through Clinical commissioning groups, flyers at conferences and through professional bodies sharing on social media	T2D care generally and structured education, weight management, blood pressure, diet and nutrition, cholesterol, kidney function, foot examination, HbA1C target, retinopathy referral
18	McDonell et al., (2011) *(Published)* Database Search	USA Setting not specified	Assessment of the relative importance of service user, provider, and systemic barriers to metabolic syndrome management for persons with SMI	Reports on barriers to metabolic care for adults with SMI	Quantitative Cross-sectional	Survey – newly developed based on expert opinion, unclear if piloted	Mean, Paired t-test, One-way ANOVA, Post-hoc: Scheffé tests.	Medical *N*=39 (Physical Health Professional, ARNPs, Nurses, physician assistant and specialists) Mental Health *N*=22 (Psychiatrists, therapist/counsellor, psychologist, social worker, case manager) Other *N*=7 (Medicaid administrator,	*N*=68 Convenience – participants approached whilst attending a conference	T2D care generally

No	Reference, date, status, identification	Country, Setting	Research Objectives	Topic or factor of investigation (relevant to synthesis)	Methodological approach (relevant to synthesis)	Data collection – (relevant to synthesis)	Data analysis – (relevant to synthesis)	Participants (relevant to synthesis)	Sample size & method (relevant to synthesis)	T2D Care Process
								clergy/chaplains)		
19	[189] *(Published)* Citation Search	UK, Two NHS Secondary Care Trusts	Mental health nurses' current knowledge and past training in T2D care, their current T2D care activity and an analysis of their training needs.	Reports on DM knowledge and training need	Quantitative Cross-sectional	Survey, Newly developed – unclear on design and piloting	Percentages	Mental Health Nurses	*N*=138 Purposive sample of mental health nurses from two NHS Trusts	T2D Care Generally
20	Newcomer, (2005) *(Published)* Citation Search	USA, Setting not specified	Ascertain practice patterns and attitudes regarding metabolic disturbances during atypical antipsychotic therapy with an emphasis on how these perceptions impact therapeutic decision making.	Reports on psychiatrist response to metabolic issues and responsibility felt for medical care of service users	Quantitative Cross-sectional	Survey -Unclear on design and piloting	Percentages	Psychiatrists	*N*=300 Voluntary, nationwide survey	T2D care generally
21	Papachristou Nadal et al., (2019) *(Published)* Database search	UK, Primary Care, Community Care and NHS Secondary Care Trusts	Explore HCPs perspectives of barriers and solutions to supporting people with SMI and T2D.	Reports barriers and enablers of managing service users with SMI and DM	Qualitative	Focus group – open-structured interview	Thematic Analysis	Diabetologists *N=9* Diabetes Specialist Nurse *N=6* Psychiatrist *N=8* Mental Health care Coordinator *N = 11* GP *N=7* Care Home Pharmacist *N=2* Specialist Support Worker *N=3* District Nurse *N=4*	*N*=50 Convenience, targeting those that attended the workshop	T2D care generally

No	Reference, date, status, identification	Country, Setting	Research Objectives	Topic or factor of investigation (relevant to synthesis)	Methodological approach (relevant to synthesis)	Data collection – (relevant to synthesis)	Data analysis – (relevant to synthesis)	Participants (relevant to synthesis)	Sample size & method (relevant to synthesis)	T2D Care Process
22	Papachristou Nadal et al., 2022 *(Published)* Database search	UK, Community mental health unit South London	To explore the views of clinicians and people with severe mental illness and Type 2 diabetes on an integrated health service model with a focus on the care navigator to identify potential mechanisms of action	Reports the health professionals' experience of managing people with an SMI/T2D, barriers and facilitators of the intervention, what they thought worked and what could be improved	Qualitative	Semi-structured interviews	Thematic analysis	Care navigator *N*=2, Psychiatrist *N*=2, Diabetologist *N*=1, Dietician *N=1* Health Psychologist *N=1,* Community mental health team care coordinators *N*=3	*N*=10, Purposive targeting those who had participated in a prior intervention	T2D care generally (in the context of a pilot study assessing the integration of diabetes care into a community mental health team)
23	Parameswaran et al., (2013) *(Published)* Database search	USA, Two urban cities	Understand beliefs about roles, barriers to the screening and treatment of metabolic risks factors in people receiving antipsychotics	Reports on barriers to metabolic screening and monitoring in psychiatrist sample	Quantitative Cross-sectional	Survey - Unclear on design and piloting	Regression Analysis	Psychiatrists	*N*=134 Convenience of psychiatrists from affiliated academic medical centres	T2D care generally
24	Shannon (2017) *(Not Published: Thesis)* Identified by team member	UK, NHS Secondary Care Trust	To gain a deeper understanding of MHNs' attitudes and their impact on practice by 1) examining MHNs' attitudes to physical health and T2D care in people with SMI, 2) exploring the relationship between MHNs' attitudes and their delivery of physical health care.	Reports on barriers and enablers of T2D care	Mixed	Survey: PHASe (with additional questions to cover T2D care) Semi-structured Interview	Regression analysis Thematic Analysis	Mental Health Nurses	*N*=69, *N*=10 Voluntary, targeted those working in a local NHS Trust	T2D Care generally
25	Vaez et al., (2017) *(Published)* Database Search	USA, Single Federally Qualified Health Centre Clinic	Explore how well a federally qualified health centre clinic system aligns with the Chronic Care Model component, which components of the CCM are associated with T2D control and whether any additional factors contribute to service user outcomes	Association between chronic care model and DM care for people with SMI. Higher association with CCM is linked to improved outcomes	Quantitative Cross-sectional Chart Review	Survey - Assessment of Chronic Illness Care Survey	Mean Spearman correlation, t-test	Nurse Practitioners	*N*=4 Convenience, approached professionals working in an associated health clinic	T2D care generally

No	Reference, date, status, identification	Country, Setting	Research Objectives	Topic or factor of investigation (relevant to synthesis)	Methodological approach (relevant to synthesis)	Data collection – (relevant to synthesis)	Data analysis – (relevant to synthesis)	Participants (relevant to synthesis)	Sample size & method (relevant to synthesis)	T2D Care Process
26	Vancampfort et al., (2019) (*Published*) Database search	Africa, Three adult inpatient mental health facilities	Assess the barriers, attitude, confidence, and knowledge of nurses regarding metabolic health	Reports the barriers of health professionals regarding screening and care for metabolic health	Quantitative Cross sectional	Survey – M-BACK	Mean Spearman correlation	Nurses	*N=28* Voluntary with all professionals approached either in-person or via phone	Metabolic care generally
27	Wang et al., (2016) *(Published)* Database search	China, Two rural counties	To examine the effect of organisational integration on system-level care coordination and to identify factors influencing care coordination of county health care systems in rural China	Reports on the impact of structural integration on care coordination and the barriers to care coordination for promoting integration - analysed this in service users with comorbid T2D and schizophrenia	Qualitative	Semi-structured interview	Thematic analysis	Schizophrenia Doctors *N*=19, Diabetes Doctors *N*=23, Chiefs of Medicine *N*=29	*N*=71 Method not reported	T2D care generally
28	Wright et al., (2006) *(Published)* Citation Search	UK, Primary Care Practices, Community Care	Explored the views of people with SMI and health professionals from primary care and community mental health teams (CMHTs) on how best to provide services for primary CHD prevention	Reported views, barriers, and solutions to the provision of primary prevention for CHD, which covered T2D care and many T2D care processes	Qualitative	Semi-structured Interviews	Framework Analysis	Primary Care Staff *N*=10 Community Mental Health Team *N*=25	*N*=35 Purposive recruitment of professionals from a range of disciplines, approached with study details	CHD screening defined as including routine assessment of smoking status, elicitation of existing history of diabetes, total and HDL cholesterol, random glucose, body mass index and ECG (where relevant), and assessment of diet and exercise. Explored views on the following interventions: smoking cessation; weight reduction; diet and exercise advice; and drug treatment of hypertension, diabetes, and dyslipidaemia.

3.5.3 Critical Appraisal

As initially proposed, none of the primary studies were excluded based on their quality appraisal all were used to inform the discussion and limitations of this review. The individual appraisals of included studies can be found in Appendix 5, a summary of the appraisal is discussed below.

3.5.3.1 Qualitative Appraisal - CASP

Overall, the recruitment strategy was poorly reported, there was a limited consideration of the relationship between the researcher and participant a lack of clarity about ethical considerations, and a need for greater detail about the selection and application of approaches to analysis. There was little reporting of how the participants were selected, why those selected were most relevant and why some people chose not to take part. Most studies did outline their consent procedures but did not report their ethical approval nor provide sufficient detail as to how the research was explained to participants to demonstrate maintenance of ethical standards. There was relatively little reporting of the critical examination of the researchers' own role within the research. It was often difficult to ascertain how themes were derived and there was generally limited detail about the analysis process.

3.5.3.2 Cross-Sectional Appraisal - AXIS

Appraisal of the quantitative cross-sectional studies revealed many examples of appropriate reporting of the suitability of the study to address the hypothesised question as well as a clear presentation of results and discussion of study limitations. Limitations were frequently evident in justification of sample size making assessment of significance challenging, especially given the lack of statistical threshold statements and measurement rigour.

Additionally, bias was frequently difficult to assess as there was limited information on the sample frame, selection process and prevalence of non-responders.

3.5.3.3 Case Study – Checklist for case reports

There was insufficient information provided to enable a robust critical appraisal particularly relating to the description and justification of the items on the appraisal checklist. There was clear reporting of the treatment and lessons learned, however the lack of information makes judgement challenging. This lack of information is an acknowledged limitation of case study reporting [190] .

3.5.3.4 Pilot Randomised Controlled Trial

Critical appraisal highlighted appropriate reporting of objectives and outcomes. Limitations related to the lack of clarity over why a pilot study was utilised, a lack of clearly defined measures related to pilot studies, limited description of randomisation and a lack of information relating to pilot outcomes.

3.5.3.5 Grey Literature – AACODS

Appraisal of the grey literature demonstrated that there were many aspects of the thesis which were well conducted and reported. Limitations related to the limited appraisal through a formal peer-review, however the thesis was subject to appraisal by examiners who are experts in the field and therefore provide a form of peer-review. Additional limitations included the unknown qualification and experience of the author and unknown impact relative to literature as it is unpublished.

3.5.4 Deductive Analysis

In total, 628 units of data were extracted from 28 studies totalling 2,243 participants.

3.5.5 Assessment of Importance

Although all Theoretical Domains Framework domains were identified, assessments of Theoretical Domains Framework importance using the predefined criteria of frequency, expression and discord are detailed in Table 9.

Table 9: Table showing the outcomes of the predefined importance criteria for each domain of the Theoretical Domains Framework

./Theoretical Domains Framework Domain	Frequency *(n studies)*	Expression	Discord
Environmental Context & Resources	28	Yes	Yes
Social Influence	22	Yes	Yes
Knowledge	16	Yes	Yes
Social/Professional Role and Identity	16	Yes	Yes
Skills	15	Yes	Yes
Goals	12	Yes	Yes
Memory, Attention, Decision Processes	10	Yes	No
Beliefs about Capabilities	8	Yes	Yes
Beliefs about Consequences	7	Yes	No
Reinforcement	5	Yes	No
Emotion	5	Yes	No
Intentions	3	Yes	Yes
;Behavioural Regulation	3	Yes	No
Optimism	3	Yes	No

Seven domains met the importance criteria of frequency, i.e., were identified in more than 1/3 of all included studies. Eight domains met the criteria for discord, with Table 10 detailing the themes, and therefore domains, that have been identified as expressing a discordant belief within or between health professional groups. All domains met the criteria of expression of importance. It was clear owing to the statements made by the authors how to identify importance. One study[157] detailed that all domains were important, demonstrating author expression of importance, although it is arguable that this is owing to the use of the

Theoretical Domains Framework to design the interview questions. This study therefore had a considerable impact on the assessment of expression of importance.

Six domains met all three criteria: 1) *environmental context and resources 2) social influence*, 3) *skills*, 4) k*nowledge,* 5) *social/professional role and identity*, and 6) *goals.* Given the identified expression of importance, identification of discordant beliefs and the proximity to the achieving the frequency criteria (having one fewer study than the cut-off of 1/3 of studies), it was judged that evidence suggested the importance of *beliefs about capabilities* to the delivery and organisation of T2D care for adults with an SMI. This domain was therefore identified as a domain of importance. Overall, there was a good level of convergence across the three importance criteria, suggesting the seven domains are likely to be important to the delivery and organisation of T2D care for adults with an SMI.

Table 10: Themes identified within the domains of the Theoretical Domains Framework which contained discordant beliefs

Domain	Theme(s)	Discordant belief
Environmental context & resource Knowledge	1. Health professionals: time	Mental health professionals in two studies stated a lack of time to be a barrier to provide T2D care. In mixed samples there was variability with both an expression of sufficient and insufficient time to provide T2D care.
	2. Organisation priorities and culture	Both mental health professionals and mixed samples expressed variability in the degree to which they perceived the organisation they worked for as prioritising physical health care and the ability to overcome difficulties in providing T2D care.
Social influence	1. Working as part of a team (benefits and challenges)	Collaboration was identified by mental health professionals as enabling T2D care, however collaborative care viewed as a barrier owing to the conflict of interdisciplinary working.
Knowledge	1. Perceived lack of T2D knowledge 2. Having T2D knowledge	Mental health professionals perceived their lack of T2D knowledge to be a barrier to providing T2D care. This was not identified by psychiatrists in one study. Physical care professionals perceived their T2D knowledge as a care enabler.
Social/ professional role	1. Role responsibility	There were differences in the perception of responsibility to provide T2D care between professional group (e.g., physical care professionals and mental health professionals both felt the other was/should be responsible for T2D care and within professional groups.
Skills	1. Lacking in skills 2. Skill proficiency	Physical care professionals felt their lack of skills in working with individuals with an SMI was a barrier to providing T2D care, however their T2D skills presented as an enabler. Mental health

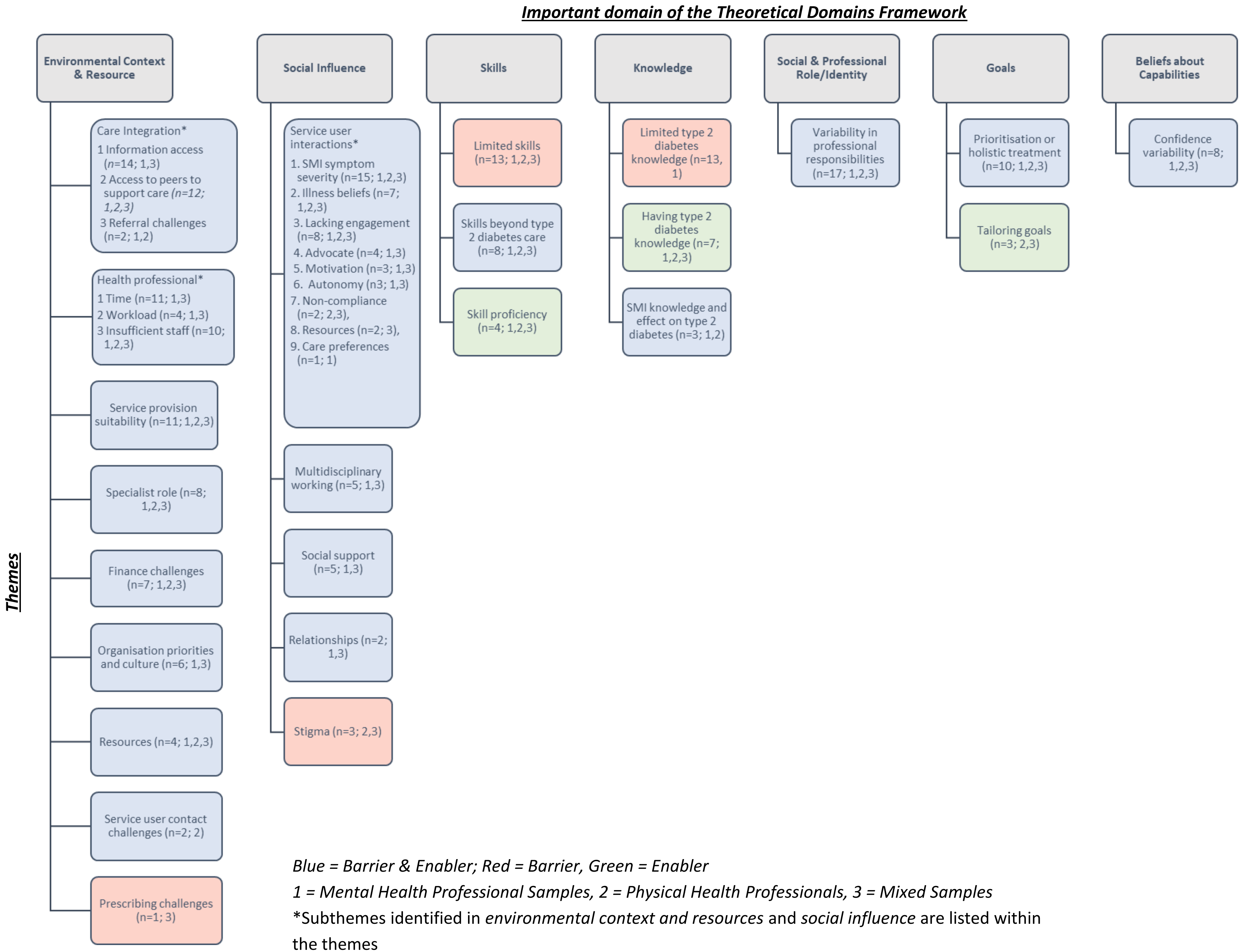
		professionals felt the converse of this, with their lack of T2D skills presenting a barrier to providing T2D care, and their skills working with individuals with an SMI as an enabler.
Goals	1. Prioritisation versus holistic care	Mental health professionals and mixed samples identified that there was variability in the prioritisation of mental health over the need for holistic care, applicable to T2D care generally. This sentiment was echoed by physical care professionals and mixed samples when providing T2D education and by mental health professionals when providing diet/nutrition advice.
Beliefs about capabilities	1. Having confidence 2. Lack of confidence	Mixed samples of health professionals expressed variability in their beliefs about their capabilities with some studies identifying professionals who felt confident, thus enabling T2D care. Others found a lack of confidence in their sample, presenting as a barrier to the provision of T2D care.
Intention	1. Intention variability	There was variability in intention to provide care across and within health professional groups.

3.5.6 Inductive Analysis – Themes

The themes from the seven domains rated as important are outlined in Figure 5; these are arranged in frequency order. The themes for the remaining domains can be found in the Appendix 6. A total of 23 themes and 15 sub-themes were identified within the important domains. *Environmental Context and Resources* had the greatest number of themes (Nine main themes with six sub-themes), followed by *Social Influence* consisting of five main themes and ten sub-themes. Reporting of these themes across health professional groups is also demonstrated in Figure 5.

The health professional groups are divided into mental health professionals, physical health professionals and mixed samples. The division of mental and health professionals was based on specialism, therefore for the purpose of this review GPs were assigned as physical health professional groups. Mixed samples occur when the studies have both mental and physical health professionals and do not distinguish within their results and/or discussion whether the data is informed by a particular care group or profession.

Of the 23 themes, 20 are informed by either all care groups, or at least two care groups (*n=7*) (i.e., mixed samples and mental health professional samples or mental health professional samples and physical health professional samples) and three informed by only one care group (n=3 mixed; n=2 mental health professionals). Mixed samples provided data for the greatest number of themes (*n*=20), followed by mental health professionals (*n=19*) and physical health professionals (*n=17*). The domain *beliefs about capabilities* was informed by all professional groups. The most important domains are summarised below, and a table of example quotes or quantitative data to support the themes are in Appendix 6.



Blue = Barrier & Enabler; Red = Barrier, Green = Enabler

1 = Mental Health Professional Samples, 2 = Physical Health Professionals, 3 = Mixed Samples

*Subthemes identified in *environmental context and resources* and *social influence* are listed within the themes

Figure 5: Themes coded to the important Theoretical Domains Framework domains

3.5.6.1 Domain 1: Environmental Context and Resources

Care integration across mental and physical health care providers, was identified as a barrier to the delivery of T2D care[157,170,171,176–179,181,182,184,185,191]. These challenges were linked to a lack of IT system integration, limited access to other care providers to support care (i.e., poor, and infrequent communication; attempted contacts commonly occurring at a time of crisis) and the challenge of referring service users to other care providers when needed. For example, mental health professionals' difficulties in accessing timely information, such as scheduled T2D care appointments, impacted their ability to motivate service users and support their clinic attendance. Both mental and physical health professionals noted that there were challenges in providing T2D care owing to pressures resulting from reduced staff levels[178,179,181–185,191], workload[182,184,185,185] and a perceived lack of time[157,171,178,179,181,185]; although in one study mental health nurses and support workers felt they had sufficient time, and more so than GPs[158]. The identified pressures were compounded by the complex needs of individuals with both T2D and SMI, who were deemed "undesirable"[179] due to the "large amount of resources required to treat them such as longer medical visits to explain treatment"[179].

Current approaches to service provision, including transportation challenges and inappropriate appointment times, were identified as a barrier to access for service users[18,157,167,171,178,179,181–183,191]; with a more flexible service, such as walk-in clinics or the development of a new care pathway, identified as a T2D care enabler[157,178,179,182,183,185,191].

A further suggestion was the development of a specialist role[166,174,178,179,182,185] with responsibilities including provision of T2D care and supporting service users to navigate the health system. The value of the role however was not unanimous as there were some concerns that the role would lead to service fragmentation or be unfeasible owing to cost implications[166].

Organisational priorities and culture created a barrier to T2D care[158,168,181,182,182,185]. An example included the paradox of the implementation of a designated physical health lead within a mental health team being hindered by bureaucratic issues and poor availability of equipment[168], suggesting an organisational culture which was not fully committing to the priority of physical health. This was not however identified universally[157].

Finance challenges created barriers such as insufficient health insurance for service users creating barriers to T2D care[178,184] or finances to provide appropriate dietary care[180], within 3 countries. Less frequently identified barriers included challenges in contacting service users to provide care over the phone[175] and laws prohibiting prescribing by certain US states[179].

3.5.6.2 Domain 2: Social Influence

Engagement of service users was reported to influence the delivery of T2D care; the most frequently identified sub-themes included the severity of service users' SMI creating a barrier to T2D care[158,158,166–168,171,178,179,181,182,185], with descriptions of treatment refusal owing to reasons which are not "rational because [service users] are not thinking clearly"[179]. Perceived severity of SMI also acted as an enabler, for example, where service users lacked capacity, health professionals felt individuals should be empowered to care for their own physical health[182]. Perceptions of service users' illness beliefs created barriers to T2D care[157,167,168,178–180,182], with examples including the perception that service users are not acknowledging their T2D, which affects their willingness to engage with services impacting attendance[182]. Finally, a perception of a general lack of engagement was also identified as both a barrier and enabler[157,168,178,182,185] (e.g. service user lack of interest [in T2D care] led to avoidance by some health professionals but inspired a more proactive approach in others[168]).

Collaborative care with good communication between health and social care providers was identified as an enabler to delivering T2D care[157,158,167,168]. Not all studies however identified positive relationships between professionals [167,171] with examples of mental health nurses receiving "chilly comments from the diabetes nurse when doing extra blood controls between diabetes appointments"[167]. The importance of social support received by service users particularly family support could enable care[157,158,167,178], for example if service users had supportive family care, professionals identified that they would 'use this'[157]. Other themes highlighted the importance of the relationship between service users and providers[167,179] and the possibility of stigma affecting care negatively[179,185].

3.5.6.3 Domain 3: Skills

Perceptions of inadequate T2D care skills were identified as a barrier, most frequently for mental health professionals [92,157,158,166,174,178,181,185,189]; who, beyond a general training need, expressed the importance of more 'practical skills', particularly foot care advice, weight management and medication management as well as basic insulin training. Having good communication skills when working with service users was labelled as an enabler[157,158,167,174,178], with a lack of specialist communication skills, a barrier to T2D care[179].The ability to communicate with other professionals about T2D care was also identified as a training need by mental health professionals[189]. No studies identified a lack of T2D skills as a barrier for physical health professionals, rather their skills were identified as an enabler[157,192].

3.5.6.4 Domain 4: Social/Professional Role & Identity

Physical health professionals more frequently identified that T2D care was their professional responsibility [158,185]. Some felt however that mental health professionals should take on more responsibility for the physical health of service users[185]. The importance of a positive relationship between service users and health professionals was cited as a reason as to why care would be better provided by mental health professionals – because of their greater rapport with and understanding of people with SMI[185]. Mental health professionals expressed more variability in their perceptions of responsibility both across and within studies. Reasons for this variability were diverse, and were linked to the date of graduation from residency[171], the presence/absence of primary care providers[171], caseload size and demands, and whether care was preventative or active treatment. Prevention was identified as the remit of the mental health professional, but following the diagnosis of T2D, care was seen as the responsibility of physical health professionals[167]. Additionally, differences in views about responsibility were linked to specific T2D care tasks[157,158] or individual practitioner differences[168]. It was suggested that T2D care could be improved if there was greater clarity in the division of labour between professional groups[183].

3.5.6.5 Domain 5: Knowledge

A lack of knowledge of T2D was commonly perceived as a barrier for mental health professionals in the delivery of T2D care [92,157,158,166–168,185,189]. This included limited knowledge of the T2D clinical guidelines, only a basic understanding of key aspects of T2D such as its causes, the types of diabetes and the differences between hypoglycaemia and hyperglycaemia. Increased T2D knowledge was however perceived as an enabler for physical health professionals [157,158,185]. Greater knowledge was associated with increased delivery of T2D education to service users[158]. The knowledge of SMI held by mental health professionals was a perceived enabler of T2D care[185]; with the limited experience of working with SMI service users was seen as a barrier for physical health professionals[167,178,185].

3.5.6.6 Domain 6: Goals

The prioritisation of mental over physical health was identified as a barrier to the provision of T2D for a range of health professionals [157,158,168,170,184,185]. This was linked to the immediacy of the issues faced by service users regarding their mental health compared to the chronicity of T2D. This did however cause conflict for mental health professionals owing to the known side effects of anti-psychotic medication in increasing the risk of diabetes. Some professionals noted that optimal care was holistic[185],[177], however whilst for telephonic nurse case managers it was identified that providing T2D education was their focus, this was conditional and was not prioritised when other issues emerged (e.g. troubleshooting housing emergencies)[175]. Setting individualised goals responsive to the needs of service users was perceived as an enabler of T2D care[157,158,177]; examples included setting smaller targets or focussing on one target behaviour. This was reported more frequently by physical health nurses than psychiatrists[158]

3.5.6.7 Domain 7: Beliefs about capabilities

A lack of confidence in providing T2D care was a barrier for mental health professionals[167,168] and mixed samples [158] attributed to limited knowledge and practical experience in delivering T2D care. Finally, physical health professionals perceived a lack of confidence concerning working with service users as a T2D care barrier[178,185], suggested to result from a lack of understanding of SMI.

3.6 Discussion

This systematic review explored health professionals' perceived barriers and enablers to the provision of T2D care for people with an SMI. The review incorporated quantitative and qualitative study findings from published and grey literature, identifying 28 papers for inclusion. The identified barriers and enablers to T2D care were coded to all fourteen Theoretical Domains Framework domains, however seven were identified as most important 1) *Environmental Context and Resources 2) Social Influence*, 3) *Skills*, 4) *Social/Professional Role and Identity*, 5) K*nowledge*, 6) Goals and 7) *Beliefs about* capabilities. The review suggests that health professionals perceive barriers and enablers to the provision of T2D care at the individual, interpersonal and system levels.

At an individual level, health professionals from mental health and physical health services reported barriers to the provision of T2D care, detailed within the domains *Knowledge*, *Skills,* and *Beliefs about capabilities*. Mental health professionals requested support to develop their T2D knowledge and skills; a finding largely congruent with the wider literature and the focus of identified interventions to improve T2D healthcare by mental health professionals [88,92,93] (described in Chapter 1. Section 1.3). It is noteworthy however that whilst the need to acquire knowledge and skills is important, without the confidence to put them into practice they may be insufficient. Mental health professionals, as well as other health professionals, identified that their lack of knowledge and skills affected their confidence to provide T2D care. Given that some professionals stated a need for improved communication skills, the perceived gaps in knowledge, skills and confidence may contribute to this perceived barrier. Wider literature suggests that a lack of knowledge, skills and confidence in ability affect the experience of T2D care by service users, with services users describing a lack of dialogue with mental health professionals about their T2D owing to their (mental health professionals) lack of understanding of T2D[57]. Equally the challenges of being treated by physical health professionals has also previously been highlighted with their ability to 'interact' with someone with an SMI questioned[57]. Poor communication, or interactions, can be harmful as health professionals are a form of social support; as a central element of social support is suggested to be the interpersonal exchanges we have with others which are meaningful to us[193]. A positive experience of T2D care provision for individuals with an SMI has been linked to optimal diabetes management[194]. Where health professionals find communication challenging, this may be perceived as a suboptimal form of social support, which can be more harmful than positive social support can be beneficial[193]. This is reflected in literature on service user experiences, who expressed that a barrier to self-management was poor communication with healthcare providers[195] or an unsupportive care environment[177]. Findings suggest that a multi-skill intervention, target knowledge, skills and confidence has the potential to be beneficial in improving delivery of T2D care. This will however need to that is sensitive to the needs of the different professionals involved in T2D care, and cognisant of service user experience and perceptions.

Health professionals also reported experiencing a wide range of interpersonal and organisational barriers and enablers to the provision of T2D care, highlighted in the domains *Environmental Context and Resources* and *Social Influence*. For example, positive team working was perceived to be an enabler to T2D care generally, but it was identified that team working is not always positive. Thus, interventions to support team working may support delivery of T2D care. Previous literature has identified that interpersonal conflict between health professionals may arise from communication breakdowns in the absence of timely and specified feedback to one another and clear expectations around task completion[196]. Whilst not explicitly identified as interpersonal conflict in this review, both issues surrounding improved communication need, and role boundaries were identified. For example, the need to improve communication with other health professionals was identified by one study in this review[189], suggesting a recognition of the importance of this skill and a need for improved ability. Additionally, conflicts triggered by unclear scope of practice, or workflow, have been reported to diminish job satisfaction, morale, or retention, and are also perceived to be detrimental to care[73] . These factors were also identified within this synthesis; with a variable, and at times contradictory belief, about professional responsibility identified. This suggests that interventions aimed at addressing these sources of ambiguity, providing role clarity and expectations, and supporting team working may be a focus with a greater potential for improving T2D care. A scoping review[197] of healthcare conflict factors advocated for interprofessional team training rather than silo training of professionals, a finding also reflected in a study in this review[182], which may provide a basis for changing behaviour. Such changes however will require support and championship from healthcare leaders, particularly in regards to changing organisational culture and more practically for scheduling to make such training a reality in healthcare organisations[197].

The interpersonal relationship between mental health professionals and service users was also perceived to influence T2D care. Mental health professionals identified that self-advocacy on the part of service users enabled them to deliver better care, however this can be challenging for people with SMI[198]. Challenges in self-advocacy therefore may be misconstrued as a lack of engagement as identified in this review. Whilst there is an important focus on improving self-advocacy for people with an SMI[199], this places responsibility solely with the service user and may mask interpersonal issues such as communication difficulties between service user and provider (as discussed above). These communication challenges may be causative in identified misaligned beliefs; for example, mental health professionals feeling that service users see their T2D as less important than their SMI which underpins the prioritisation of mental health over physical health. Prioritisation has been identified as important for self-management[200] and previous studies have reported that participants were aware of the importance of managing their diabetes, but found this challenging, often owing to the symptoms of their mental illness[201]. Further it was identified in this review, that mental health professionals wished to respect the choice and autonomy of service users particularly in reference to diet and lifestyle advice, despite diet and exercise being particularly challenging for people with an SMI [57,202] and an area in which additional support was wanted[55,57,58]. It may be crucial to support delivery of dietary advice, in light of this desire, particularly given the role of pessimism around such advice[203]. An intervention that focuses on the interaction between the provider and service user, potentially focussing on addressing issues of communication, may have the potential to improve care by aligning care wishes. DIALOG is a method designed to structure the communication between service users and health professionals, which has demonstrated favourable outcomes in community mental health care [204]. Whilst not T2D specific such methods could be investigated to achieve a supportive opportunity for service users to voice their preferences, such as the desire for dietary support[55,57,58], but also enable health professionals to gain a clearer understanding of these preferences. Furthermore, supporting this type of interaction could enable appropriate tailoring of care, a theme identified in the domain *Goals,* in the provision of T2D dietary advice; as well as setting individualised goals, identified as an enabler of T2D care.

Data coded to the domains *Goals* and *Environmental Context and Resources* highlighted organisational challenges to T2D care. Addressing service provision and ensuring accessibility and suitability for service users may also support improved T2D care. Beyond a more flexible service delivery model, there is also a need to provide more holistic and integrated care. The importance of holistic and integrated care is championed in the wider literature[15] as well as being supported by the literature on the experience of T2D care for people with an SMI who describe a lack of care integration[72] and disjointed care [195] as challenging. Recommendations for service change will however need careful consideration - whilst this review suggests that improved T2D care can be supported through improvements in information access, integrated IT systems, and ability to access staff to support care, previous literature has identified that co-location of mental and physical services has a variable impact on the delivery of T2D care[77]. Flexible service provision, including appointment times that are sympathetic to challenges that people with SMI face, may also support care improvement. Whilst a short appointment time and high workload will place demands on health professionals, there is a possibility that the perceived lack of time is also a result of prioritisation within the allocated time frame. It is possible that this may relate to a perceived lack of urgency for T2D care because of its chronic nature, with priority given to mental health issues perceived as urgent or time sensitive. Furthermore, a lack of prioritisation may send a message to service users that physical health is less important. This may be damaging as research with service users has identified that the ability to self-manage is associated with support received and prioritisation of T2D[201]. Additionally, this review suggests that organisational culture will need to be addressed as despite a shift to prioritise physical health within one organisation being identified as an enabler of care delivery - overwhelmingly a lack of such prioritisation was suggested to be a barrier [168,181,182,185,192]. Beyond espoused intentions of prioritisation, it will also be important for organisations to demonstrate an active prioritisation such as provision of resources, financial buy-in, statutory body recognition and reorganisation of care pathways, thus actively demonstrating that improving T2D care is a priority.

3.6.1 Strengths and limitations of the synthesis

A comprehensive search strategy was utilised including mixed studies from both published and grey literature to provide a wealth of perspectives on the barriers and enablers to T2D care provision for people with SMI. The use of the Theoretical Domains Framework as the *a-priori* framework for analysis has several strengths such as the retrospective application of a theoretical lens to data which has been collected allowing for an in-depth exploration of rich data. The coding of data was subjected to an agreed coding protocol and 20% independent data extraction, which although this will support the robustness of the results.

The synthesis was limited by the focus on T2D care in general (*n*=22) in most included studies and the participation of mixed professional samples, rather than a focus on more specific aspects of T2D care among individual professional groups. It was therefore not possible to distinguish from these studies which barriers and enablers related to which specific behaviours nor which health professional group. This was disappointing as a recent scoping review of service users' perceptions and experiences of living with co-existing T2D and SMI identified that diet and exercise, but not other diabetes self-care activities, are particularly compromised in SMI population[202].

The synthesis is also limited by the decision not to include the perspectives of service users. The decision not to include their perspectives was driven by a pragmatic need to ensure that the review was manageable. This provides opportunities for further work exploring service user perspectives of barriers and enablers of care as previous reviews (e.g. [126]), have demonstrated that this can provide important information on barriers and enablers relating to health professional behaviour and the organisation and delivery of care.

Although the review utilised multiple methods to identify Theoretical Domains Framework domains of importance, which is recommended[205], there is uncertainty as to the most appropriate methods to support this decision[161,162]. As discussed earlier, several methods have been used to identify domain importance (Section 3.4.10). The three criteria used in this review were selected to balance both quantitative assessment (frequency) and qualitative assessment (discordance and expressed importance). A limitation of this approach however is in the possibility of domains which did not meet the criteria still being impactful, as evidenced by the domain *Beliefs about capabilities*. This domain did not meet all three criteria yet arguably is important to the delivery and organisation of T2D care. This raises questions about whether the identified domains are the most important or whether they are those which health professionals can more readily identify, reflecting a broader limitation of this method[161]. It is arguably necessary to identify domains of importance for brevity in discussing outcomes and providing a more pragmatic base to selecting intervention components given their volume. This review treated the three criteria of frequency, discordance and expressed importance equally, however, the domain *Beliefs about Capabilities* met the criteria for discordance and expressed importance, but not the quantitative assessment of frequency (missing the cut off value of 9 studies). This highlights the need for flexibility in application of importance criteria. The qualitative criteria (discordance and expressed importance) may also be challenging to apply from a secondary perspective, i.e. judging existing literature as opposed to data collected by the researcher. Proximity to data may support making judgements on importance and discordance which are more difficult when judging secondary data. This may result in reporting bias affecting the outcomes, as the authors are limited both by space to discuss findings in their publications and may also be driven by findings perceived as interesting. These may all impact identification of domain importance. The assessment of expressed importance in this review was influenced heavily by one of the included papers, which had used the Theoretical Domains Framework and identified that all domains were important to the behaviour. This further highlights the challenges of identifying important domains. Finally, identifying domains in isolation and judging their importance may be problematic as this does not consider the possible relationship between domains, another criticism of this approach[206]. It may be a domain has an indirect effect, as its interaction with a domain labelled as "important" is crucial to behaviour. As an example in this review the domain *Beliefs about Capabilities* did not meet all three criteria for importance, however reviewing the data suggested that it was closely related to the domains *Knowledge* and *Skills*. It was concluded that although knowledge and skill development are clear targets for improving T2D care, without confidence to enact these they may be insufficient. Finally, it may be that rather than expressing domains as either important or not, a more useful approach would be to identify domains of greater and lesser importance in such circumstance. Those of greater importance would be clear targets for intervention development, however inspection of domains of lesser importance for their impact on domains of greater importance could be inspected to ensure they were included. Such an approach would be sensible for intervention development to support acceptability and resource utilisation, by ensuring a parsimonious intervention, whilst also arguably supporting greater effectiveness by not discounting domains labelled as of lesser importance.

The exclusion of studies that were not in English was necessary owing to the inability to translate findings. Whilst excluding studies based on language will potentially lead to bias only one was excluded and thus the impact is likely negligible.

3.6.2 Strengths and limitations of the papers included in the synthesis

Limitations of the synthesis are also informed by potential limitations in the primary studies included in the review. No studies were excluded based on critical appraisal, however there was considerable variability in individual study assessments with the potential for bias being the most challenging limitation. Sample selection was generally weakly reported and affects the validity, generalisability, and transferability of individual and synthesised findings. Additionally, there is potential for attribution bias by study participants as individuals are more likely to attribute failures to external (environment or others) and this may have influenced the prevalence of *Social Influence* and *Environmental Context and Resources* domains. For example, whilst stigma was identified in the domain *Social Influence,* it was in three studies only (11%) yet existing evidence suggests that diagnostic overshadowing, which is described as stigma in action[67], is an important contributor to the inequalities faced by those with an SMI and T2D. Such challenges could be overcome through the triangulation of data, achieved through observational data or the inclusion of perspectives beyond the health professional. Finally, three of the included studies made amendments to standard T2D care provision by adding in a new role [174], providing changed T2D education [172] and piloting a community mental health centre collaborative care model [176] , thus the reported barriers and enablers may be impacted by these changes. The findings from these papers are however congruous with the findings from literature utilising standard care, suggesting their appropriateness.

Three of the included studies utilised the Theoretical Domains Framework[157,158,186]. This allowed for a clear extrapolation of data into the domains for synthesis, as well as clarity around domains of importance. The remaining 25 studies did not explicitly state whether theory was utilised in the design nor analysis of data. This could have implications for the outcome of the review as the original studies may not have identified determinants which are important but were not considered explicitly by authors or participants. This is supported by evidence which has found that comparing the use of a non-theory versus theory-informed informed interview schedule can support identification of a wider range of determinants[207] . Conversely there is an argument that a non-theory informed interview schedule may support the identification of important domains as those discussed by participants may be those which they feel are the most important. Achieved through allowing a less confined approach to discussion, allowing spontaneous identification of determinants. This is however speculative and those determinants discussed may represent those most easily identified and not necessarily most important.

3.6.3 Future Research

Undertaking further exploration of the barriers and enablers of T2D care from other perspectives (e.g., from the perspective of service users or care commissioners) utilising varied methods of data collection (e.g., direct observation or consultation audio-recordings) may support data triangulation and increase the validity of findings. Most studies focussed on overall T2D care however T2D care is complex requiring many care processes. Identifying how, and whether, differences in barriers and enablers influence different care processes will be useful for future research. In particular, focussing on the provision of diet and exercise advice in future research has the potential to influence an area of care that service users find particularly challenging[202]. Additionally, the proposed links between the provision of care and the indirect impact on self-management offers opportunities for exploration.

3.6.4 INDEX key considerations

As outlined in Chapter 2 (Section 2.3) it is expected that developers will return to the key issues through development of an intervention; and it was proposed that this would be considered at the end of each chapter. Table 11 details the key issues considered within this chapter.

Table 11: INDEX key considerations of the systematic review of perceived barriers and enablers of T2D care for adults with an SMI

Key Issue	Included	Evidence
Plan the development	X	Not applicable at this stage
Involve stakeholders	X	Not applicable at this stage
Bring together a team and establish decision making processes	✓	Supervisory team supported search strategy, review of studies for inclusion, and assessment of quality of evidence
Review published research evidence	✓	Systematic review of evidence
Draw on existing theories	✓	Theoretical Domains Framework[91] used to code and understand extracted barriers and enablers
Articulate programme theory	X	Not applicable at this stage
Undertake primary data collection	X	Not applicable at this stage
Understand the context	✓	Support consideration of wider healthcare context for intervention development through strategies suggested and identification of wider issues influencing the delivery and organisation of T2D care.
Pay attention to future implementation of the intervention in the real world	✓	Discussion of how the outcomes could be relevant to future research and practise.
Design and refine the intervention	X	Not applicable at this stage
End the development phase	X	Not applicable at this stage

3.7 Conclusion

Whilst there are limitations of this synthesis, and all findings should be viewed considering these, it is the only known attempt to synthesise findings to explore the barrier and enablers to the delivery and organisation of T2D care in people with SMI. The findings demonstrate that it is possible to utilise the Theoretical Domains Framework to systematically identify the perceived barriers and enablers to the provision of T2D care for people with SMI with results suggesting seven important domains with barriers and enablers residing at an individual, interpersonal and system level. There is a need for a more detailed analysis of the different care processes in the complex provision of T2D care. Several recommendations were made including multi-skill training of healthcare providers delivered collectively, clarity over roles and responsibilities, a focus on the service user–health professional interaction, support for integrated and holistic care as well as demonstrable active prioritisation of T2D care for people with an SMI by organisations. This would suggest that there are many intervention opportunities which could support improved outcomes for those with T2D and an SMI through targeting the health care environment.

The seven domains identified as important to the delivery and organisation of T2D care for adults with an SMI (1) *Environmental Context and Resources 2) Social Influence*, 3) *Skills*, 4) *Social/Professional Role and Identity*, 5) K*nowledge*, 6) Goals and 7) *Beliefs about capabilities)* are proposed to be key determinants of the delivery and organisation of T2D care for adults with an SMI. As identified in Chapter 1 (Section 1.3) known interventions targeting provision of T2D care to adults with an SMI focus on knowledge and skills. They therefore do not appear to target all key determinants of T2D delivery and organisation for adults with an SMI, this however requires formal assessment. A theory-based evaluation of the extent to which existing interventions target the key determinants of the delivery and organisation of T2D care for adults with an SMI can assess this gap and is detailed in the next chapter.

4 Chapter 4: Content Analysis of Interventions

Study 2: Do existing interventions targeting the delivery and organisation of T2D care for adults with an SMI address the known barriers and enablers to these target behaviours?

4.1 Prologue

The previous chapter systematically identified barriers and enablers to the delivery and organisation of T2D care for adults with an SMI. Seven Theoretical Domains Framework domains were identified as highly important 1) *Environmental Context and Resources 2) Social Influence*, 3) *Skills*, 4) *Social/Professional Role and Identity*, 5) K*nowledge*, 6) *Goals,* and 7) *Beliefs about Capabilities*.

This chapter will identify promising intervention content by exploring the crossover between identified behaviour change techniques in studies which report effective outcomes and those which are feasible for delivery. It will also examine the extent to which the content of existing interventions are congruent with the key determinants (i.e., the important domains of the Theoretical Domains Framework) of the delivery and organisation of T2D care in SMI. The chapter concludes with a summary of how well the interventions to date have targeted the barriers and enablers of T2D care identified in the systematic review, as well as identifying promising intervention content for intervention design in this PhD, before highlighting where future research can continue to support improved T2D outcomes for people with an SMI.

4.2 Introduction

Interventions which contain content that experts consider to target the theoretical determinants (i.e., the important Theoretical Domains Framework domains) of the target behaviour are argued to be more effective[1]. The extent however to which existing intervention content targets the known barriers and enablers of the delivery and organisation of T2D care for adults with an SMI is currently unknown. This gap can be addressed through an assessment of theoretical congruence.

Theoretical congruence refers to the extent to which the identified theoretical content of interventions addresses the barriers and enablers to performing the targeted intervention behaviours[208]. Establishing the extent to which existing interventions are congruent with theory can be achieved by comparing the important Theoretical Domains Framework domains (theoretical determinants) identified in the systematic review (Chapter 3), with the theoretical content of existing interventions. It order to undertake an assessment of theoretical congruence; it is first necessary to clarify the content of existing interventions. It was detailed in Chapter 1 (Section 1.3) that the reporting of explicit theoretical content in known existing interventions was limited. To address this, the Behaviour Change Technique Taxonomy (V1) can be used to code and categorise existing intervention content[111]. Its utility in retrospective coding has been demonstrated previously[208,209], including in specific diabetes care processes (e.g., retinopathy screening attendance[125]) and diabetes care more generally[210]. Behaviour change techniques are the smallest replicable component of interventions that can be applied to change the theoretical determinants of behaviours[111]. An example of a technique is *behavioural practice/rehearsal, which is defined as "*prompt practice or rehearsal of the performance of the behaviour one or more times in a context or at a time when the performance may not be necessary, in order to increase habit and skill"[111]. This technique is proposed by experts to o be more likely to be effective when targeting a lack of skill as a barrier to target behaviours. This pairing would represent a 'high' theoretical congruence i.e., a match between the theoretical content (behaviour change technique: behaviour practice/rehearsal) and theoretical determinant (Theoretical Domains Framework domain: Skill). If, however the barrier was a lack of clarity around professional role and responsibility (Theoretical Domains Framework domain: *Social/professional role and identity)* this same technique would represent a 'low' theoretical congruence, or mismatch, as experts consider the technique *behavioural practice/rehearsal* to be less effective when targeting barriers related to social/professional role and identity. Identifying theoretically congruent behaviour change techniques in effective existing interventions can contribute to proposed intervention development in this PhD by identifying behaviour change techniques which are more likely to be effective in improving T2D care for adults with an SMI.

Assessment of theoretical congruence can also be used to make judgements as to whether there are any 'missed' opportunities, i.e., any behaviour change techniques or intervention content which experts consider likely to be effective, which have not been included in interventions. Whilst this cannot categorically state that these 'missed opportunities', if taken, would have led to successful outcomes, it can be used as an explanatory tool for differences in outcomes and may provide further guidance as to content for consideration in future intervention design.

Finally, the most recent of the three identified reviews[83–85] (described in Chapter 1. Section 1.3) was undertaken in 2019 therefore an updated search would ensure identification of any interventions targeting T2D care in adults with an SMI since this publication.

This chapter will therefore examine the extent to which the retrospectively identified theoretical content of existing interventions addressed the barriers and enablers of the delivery and organisation of T2D care for adults with an SMI that were identified in the systematic review reported in Chapter 3.

4.3 Aim and Objectives

This chapter sought to answer the research question: Do existing interventions targeting the delivery and organisation of T2D care for adults with an SMI address the known barriers and enablers to these target behaviours?

This analysis therefore had two overarching aims

Aim 1: Identify the active components of existing interventions targeting the delivery and organisation of care for adults with an SMI. The objectives were:

- Systematically identify interventions targeting the delivery and organisation of T2D care for adults with an SMI
- Code descriptions in identified interventions using the Behaviour Change Technique Taxonomy[112] and Behaviour Change Wheel[108]

Aim 2: Assess the extent to which identified intervention components target the theoretical determinants of the delivery and organisation of T2D care for adults with an SMI. The objectives are:

- Identify active components of interventions that reported effective outcomes to support intervention development
- Explore the level of theoretical congruence, by assessing the extent to which identified behaviour change techniques in existing interventions, target the important barriers and enablers of T2D care for adults with an SMI that were identified in the systematic review

- Identify whether there are any missed opportunities for intervention development by identifying behaviour change techniques that have not been used in existing interventions but are theoretically congruent with the important barriers and enablers of T2D care for adults with an SMI

4.4 Method

4.4.1 Eligibility Criteria

Selection criteria was informed by the **P**articipant, **I**ntervention, **C**omparator, **O**utcome, **S**tudy (PICOS) framework and designed to be as inclusive as possible given the anticipated limited number of interventions.

- **Participants:**

  Participants were health professionals who provide care to, or the organisation/delivery of T2D care for, adults with an SMI and T2D.

- **Intervention:**

  Interventions were any type of intervention or strategy to improve T2D care for adults with an SMI.

- **Comparator:**

  Comparator interventions were not necessary for inclusion in this review but where included, any compactor as described by the study author would be appropriate.

- **Outcomes**:

  Outcome measures could be either focussed on the health professionals such as their knowledge or outcomes resulting from health professionals' behaviour such as the reporting of HbA1c.

- **Study:**

  All study types were included

Studies were excluded where the sole focus of the intervention was on changing the behaviour of service users, such as self-management interventions. Studies would be eligible if they included other intervention strategies e.g., health professional education alongside self-management intervention, however the strategy would need to be explicitly stated and not a byproduct of implementing a self-management strategy e.g., new roles being implemented to deliver the self-management strategy. Literature was also excluded if they were reviews or not original research.

4.4.2 Search Strategy

Interventions were identified using the results of the search strategies detailed in Chapter 3 (Sections 3.4.3 and 3.4.4). In brief the comprehensive search strategy consisted of terms under each of the following in combination: Health professionals AND severe mental illness AND barriers/enablers AND T2D terms OR general physical care terms AND T2D terms. The full search strategy can be found in Appendix 3. Searches were undertaken in Medline, EMBASE, PsycINFO, CINAHL, OVID Nursing, Cochrane Library, Google Scholar, OpenGrey, PsycEXTRA, Health Management Information Consortium and Ethos, with reference list, forward and backwards citation searching of included interventions. This search strategy was deemed appropriate for simultaneous identification of interventions without the need for additional searching as it returned a significant number of references (n=6802), and identified the interventions from earlier reviews[83,85] further supporting its appropriateness.

4.4.3 Data Extraction

The AACTT framework[211] was used to organise data on study population and the care process(es) that were targeted in the intervention. The AACTT framework supports specification of a behaviour(s), detailing the actor, their behaviour(s) inclusive of details around the location and time of the behaviour(s) as well as with whom, or who for, the behaviour(s) are performed. The Form of Delivery[212] table was used for intervention content delivery. The following data was extracted:

- Author
- Date
- Country
- Setting
- Study Population (organised using the AACTT framework)
- Care process (organised using the AACTT framework)
- Sample size
- Intervention description (described using Form of Delivery table[212])
- Outcomes
- Results

4.4.4 Critical Appraisal

Critical appraisal of the interventions was undertaken using the Mixed Method Appraisal Tool (MMAT)[213], which enables comparison of the methodological appropriateness across differing study designs. The MMAT was developed from a literature review of systematic reviews that included both qualitative and quantitative data[213]. It focuses on methodological criteria across five core quality criteria across five categories of study design 1) qualitative 2) quantitative descriptive, 3) randomised, 4) non-randomised and 5) mixed methods. The revised tool does not advocate for scoring, rather a detailed description of the ratings on the core quality criteria are suggested. A 10% sample were independently appraised by a second reviewer (KM) with discussion used to resolve any discrepancies without the need for a third reviewer.

4.4.5 Data Analysis

Analysis was dictated by the two overarching aims and involved the following steps:

1. Code content in existing interventions
2. Identify intervention functions mapped to important domains of Theoretical Domains Framework identified in Chapter 3 (Section 3.5.5)
3. Identify behaviour change techniques mapped to important domains of Theoretical Domains Framework (Section 3.5.5)
4. Assess the theoretical congruence between content identified in existing interventions and mapped (1) intervention functions, (2) policy categories and (3) behaviour change techniques.
5. Identify potentially promising behaviour change techniques in the delivery of T2D care for adults with an SMI

4.4.5.1 Code content in existing interventions

A bespoke extraction table was created in Excel to code intervention content including the identified intervention functions, policy categories, behaviour change techniques and form of delivery (Appendix 7). The identified content within existing intervention was independently extracted and coded by TD and KM. Any discrepancies were resolved through discussion without the need for a third reviewer. Retrospective identification and coding of intervention functions and policy categories was made using the descriptions provided in the *Behaviour Change Wheel: Guide to Designing Interventions*[108]. Coding of behaviour change techniques was made using the Behaviour Change Technique Taxonomy v1[112].

It is acknowledged that often intervention descriptions are not sufficient to enable accurate identification of intervention content, therefore a minimum coding principle was utilised:

1. If the intervention function *Training* was identified, the intervention function *Education* was also coded. This was not the case in reverse, i.e., where *Education* was identified, unless specifically stated *Training* was not included.
2. If the intervention function *Education* was identified it was assumed that, even without express reporting, the behaviour change techniques: 1) *information about health consequences* and 2) *instructions on how to perform a behaviour*, as a minimum would have been used
3. If Tra*ining* was identified the behaviour change technique 1) *instructions on how to perform a behaviour* was assumed to have been utilised.

Rule one was included to reflect discussions between the first (TD) and second reviewer (KM) whereby it was noted that the separation of the intervention functions *Education* and *Training* can be challenging, as it was questioned whethe*r* training can ever take place without the provision of some sort of education, defined as increasing knowledge or understanding[108]. Rules two and three have been utilised previously in content analysis of diabetes interventions[210] and were chosen to provide a minimum content base to account for limited intervention descriptions.

The mean (and range) number of intervention functions, policy categories and behaviour change techniques identified across the interventions was calculated.

4.4.5.2 Identify potentially relevant intervention functions, policy categories and behaviour change techniques

Potentially relevant intervention functions were identified using a mapping matrix table in the Behaviour Change Wheel guide which links the domains of the Theoretical Domains Framework to intervention functions (Intervention functions are described in Section 2.4.2.1) that experts believe are likely to bring about change in those domains[108](P92-94). Using this method, it was possible to select the intervention functions considered likely to bring about change in the important domains identified in the systematic review.

Policy categories link to intervention functions and can be identified in a similar mapping matrix table[108] (P.114). The policy categories linked to those intervention functions identified as likely to bring about change were identified (Policy categories are described in Section 2.4.2.1).

Potentially relevant behaviour change techniques were identified using the Theory and Techniques tool[144]. This is an online tool which enables identification of hypothesised links between Behaviour Change Techniques and mechanisms of action (including the Theoretical Domains Framework)[143,214]. The tool enables identification of links which are documented as either present, absent, uncertain or unknown[214].

4.4.5.3 Assessment of congruence

Behaviour change techniques were assessed for congruence using previously identified parameters [209], which are:

1. Low Congruence – the identified intervention function/Behaviour Change Technique did not target any of the important domains identified in the systematic review (Chapter 3)
2. Medium Congruence – the identified intervention function/Behaviour Change Technique targeted at least one important domain
3. High congruence – the identified intervention function/Behaviour Change Technique targeted two or more of the important domains

Assessment of coherence can help to explain how and why existing interventions had an impact, as well as why they may not have had impact through the identification of highly congruent behaviour change technique/domain pairings.

Congruence was also examined qualitatively to explore whether the content of the behaviour change technique as delivered was optimal given the identified barriers and enablers described in Chapter 3 (Section 3.5.6). For example, examining whether the identified content of *Information about health consequences (*behaviour change technique), such as providing information about the long-term consequences of T2D, will target identified *Knowledge* (domain) barriers, such as mental health professionals limited T2D knowledge.

Alongside congruence, the ‘missed’ and ‘seized’ opportunities of intervention content were identified. This required comparison between the identified (in existing interventions) and mapped intervention functions and behaviour change techniques. A seized opportunity would be denoted by the identification of an intervention function or behaviour change technique in existing intervention content and a mapped identification of this content to a Theoretical Domains Framework domain of importance. For example, the domain *knowledge* was identified in Chapter 3 as an important domain, the behaviour change technique *Instructions on how to perform a* behaviour is mapped to this domain, therefore if *Instructions on how to perform a* behaviour is identified in existing interventions it would be classed as a seized opportunity. If it were not identified in existing interventions, it would be classed as a missed opportunity.

4.4.5.4 Identification of promising behaviour change techniques

Behaviour change techniques in existing interventions were defined as promising where they were identified in effective interventions. Interventions were defined as effective if they reported statistically significant effects (P<0.05) in any reported outcome. Furthermore, feasibility of the promising behaviour change techniques was assessed and confirmed where the technique was also delivered in over 25% of identified interventions. This approach has been utilised previously, and enables recognition of techniques that are likely to be achievable, well-received and suitable in future intervention development[123].

4.5 Results

4.5.1 Search Results

Titles and abstracts of 7034 references were screened across initial and citation chain searching of included studies and identified reviews[83,85,163–165,215–220]. The resulting 267 full texts were assessed for eligibility and eight studies were identified for inclusion. Of these eight studies, three[88,92,93] were identified in the earlier reviews detailed in Chapter 1 (Section 1.3). The additional number is likely to result from different search strategies and the updated search within this review. The PRISMA[221] diagram outlining the selection of articles at each stage of the search is presented in Figure 6.

4.5.2 Included Studies

4.5.2.1 Study setting

The studies were undertaken in three countries, four in the United States of America[88,176,222,223], three in the United Kingdom[92,93,224] and one in Australia[225]. Study characteristics are reported in Table 12.

4.5.2.2 Study participants (Actor)

All studies involved mental health professionals. The actors within the interventions were mental health nurses or students[92,93], psychiatric nurses[88], cardiometabolic nurse[225], care coordinator[222] and three targeted a mix of mental health professionals[176,222,223]. Study characteristics are reported in Table 12.

4.5.2.3 Study design

Two studies were randomised controlled trials[176,225] with comparators identified as usual care; one of which was a pilot study[176] Most utilised a pre-post test design[88,92,93,222–224], with one reported as a pilot study[223], another a feasibility study[224] and a final design an interrupted time-series design[222] . Study characteristics are reported in Table 12.

4.5.2.4 Intervention setting (Context)

Four studies were conducted in community settings including a primary care clinic linked to an outpatient mental health program[222], one in a community mental health service[225] and two in community mental health centres[176,223]. Two were conducted in inpatient settings including a secondary care mental health inpatient setting[224] and Veterans Affairs hospital[88]. Two studies did not adequately report the setting and included student nurses, thus potentially targeting inpatient and community settings[92,93]. Study characteristics are reported in Table 12.

4.5.2.5 Intervention descriptions (Target, Action and Time)

Target: Most targeted individuals with T2D and an SMI[88,92,93,222–224], one study targeted all users of community mental health services[225] and one targeted those with poorly controlled T2D and SMI[176]. This was defined as either HbA1c >8% or blood pressure >140/90). All studies targeted T2D care, with one also targeting dysglycemia[224]. **Action:** Intervention strategies were varied. Six studies focussed on the existing workforce with four interventions focussed on improving the knowledge, skills and clinical judgement of mental health nurses[88,92,93,223], through education and training workshops. Three studies focussed on changes to existing provision either through the addition of new roles[222,225] or implementation of a team-based care model[176]. A single study focussed on creating an alert system targeting existing staff[224].**Time:** Most studies did not focus on a specific time but on improving care generally[88,92,93,176,222,225], however one focussed on T2D care during the transition into community care[223] and another on care when an inpatient on a psychiatry ward[224] The full study details are provided in Table 12.

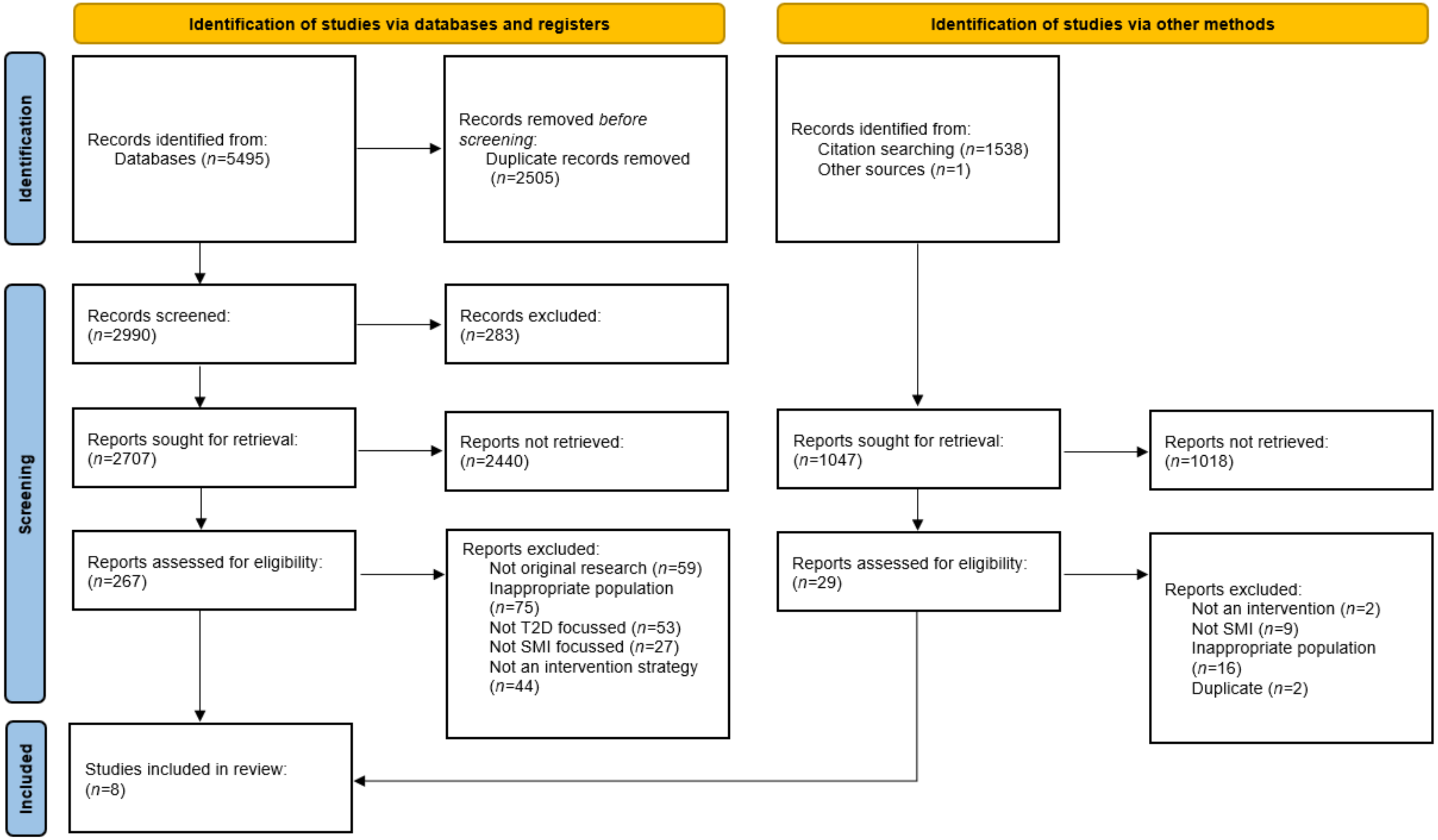


Figure 6: PRISMA diagram of the identification and selection of included studies

Table 12: Study Characteristics

Author (Year)	Intervention Strategy	Aim	Country, Setting (Context)	Study design	Number of recruited participants	Health professionals targeted (Actor)	Care Process (Target, Action, Time)	Outcome Measures	Outcome Measures Timepoint	Outcomes
Chwastiak et al. (2018)[176]	TEAMCare Collaborative Care Approach. Addition of tailored diabetes self-management education	Assess the feasibility, acceptability, and preliminary effectiveness of a collaborative care model on poorly controlled T2D in adults with psychosis	USA, Community Mental Health Centre-Outpatient	Randomised controlled trial (Pilot)	*n*=35 (service users)	Case Manager Psychiatrist Practice Nurse Endocrinologist	**Target:** Individuals with poorly controlled T2D (defined as either HbA1c >8% or blood pressure >140/90) **Action:** General T2D care **Time:** None specified	HbA1c (%) Low-density lipoprotein Blood Pressure Triglycerides PHQ-9 Body-mass Index Brief Psychiatric Rating Scale Fagerstrom Nicotine Dependence Scale	Baseline 3-months	Service user outcomes: HbA1c: M= -1.1 (t=2.17, df=13, p=.049) BMI: -1 kg/m2 and -.9kg/m2 (Reported as statistically significant) No significant results reported for BPRS or FNDS *No health professional outcomes reported*
Happell et al. (2014)[225]	Implementation of a new role: Cardiometabolic Nurse	Assess the effectiveness of a Cardiometabolic Nurse on cardiometabolic outcomes) of services users with an SMI who are at risk of	Australia, Rural Mental Health Service	Randomised controlled trial	*n=21* (Service users)	Cardiometabolic Nurse	**Target:** All users of community mental health service **Action:** General T2D care **Time:** None specified	Active Australia Survey (AAS) Daily intake of fruit and vegetables (F&V) Fagerstrom Nicotine Dependence Scale (FNDS)	Baseline (+2) 26 weeks (-2)	Service user outcomes: AAS: +4 (N/A) F&V +0.5(N/A) FNDS =19% (1,8) = 0.851; *p* = 0.38) Alcohol: +1 (N/A) AHBKAQ: +10% (N/S)

		cardiometabolic disease including targeting the behaviours of service users with T2D						Alcohol use disorders identification test Australian Health Behaviour Knowledge and Attitude Questionnaire (AHBKAQ)		*No health professional outcomes reported*
Hemingway et al. (2013)[93]	Diabetes care workshop	Increase the T2D knowledge base of mental health nurses	UK, NHS Secondary Care Trust	Pre-post - test	*n*=35	Mental Health Nurses Student Nurses	**Target:** Individuals with T2D accessing mental health services **Action:** T2D care generally **Time:** None specified	Diabetes knowledge scores	Immediately following workshop	Health professional outcomes: Pre-test (mean)= 4.76 - Post-test (mean) = 10.26 (P=<0.001, 4.67, 6.33 - 95%) *No service user outcomes reported*
Hemingway et al. (2015)[92]	Diabetes care workshop	Increase the health literacy of mental health nurses in T2D care of adults with an SMI	UK, NHS Secondary Care Trust	Pre-post - test	*n*=110	Mental Health Nurses Student Nurses	**Target:** Individuals with T2D accessing mental health services **Action:** T2D care generally **Time:** None specified	Diabetes knowledge scores	Baseline Post-intervention	Health professional outcomes: Pre-test: 5.90 (SD 2.17) - post-test 7.04 (SD 1.85) (P=0.004, 0.36, 1.91 - 95%) *No service user outcomes reported*

Wynn (2011)[88]	Simulation training workshop	Increase psychiatric nurses' diabetes medical knowledge and clinical judgement skills	USA, Inpatient Veterans Affair Medical Centre	Pre-post - test	*n*=20	Psychiatric Nurses	**Target:** Individuals with T2D accessing mental health services **Action:** T2D care generally **Time:** Inpatient	Clinical judgement score on Lasater Clinical Judgement Rubric	Baseline Post-intervention	Health professional outcomes: Not reported *t= 10.710, df = 19, p= 0.000* *No service user outcomes reported*
Crang et al. (2022)[223]	Educational workshop including a "booster" session	Increase mental health assessor's T2D knowledge	USA, Community Mental Health Centre	Pre-post - test (Pilot)	*n*=18	Mental health professionals	**Target:** Individuals with T2D accessing mental health services **Action:** T2D care generally **Time:** Transition back to community from mental health centre	Blood sugar steps, Diabetes Knowledge Test 2	Baseline post-intervention 3-months	Health professional outcomes: BS Steps pre 3.7 (2.23); Post 12.95 (1.93) DKT2 pre: 15.85 (3.22), post: 20.3(2.23) Both p<0.0001 *No service user outcomes reported*
Cook et al. (2021)[222]	Implementation of a care coordinator and diabetes registry. Addition of tailored diabetes self-management education.	Improve T2D outcomes by implementing a care coordinator and diabetes registry alongside tailored self-management education	USA, Primary Care Clinics in a Behavioural Health Home	Pre-post - test (interrupted time-series)	*n*=179 (service users)	Care coordinator Mental health professionals at the primary care clinic	**Target:** Individuals with T2D accessing mental health services **Action:** T2D care generally **Time:** None specified	HbA1 Low-density lipids, Triglycerides Systolic blood pressure Diastolic blood pressure	Baseline 12-months	Service user outcomes: HbA1c: -0.68 (p<0.001) LDL: –9.31 (p<0.001) Triglycerides: –16.79 (p<0.001) Systolic: –12.65 p<0.001 Diastolic –9.20 p<0.001

										No health professional outcomes reported
Patel et al. (2022)[224]	Implementation of an electronic clinical decision support system	Improve the management of dysglycaemia and diabetes in adults with an SMI in an inpatient setting	UK, NHS Secondary Care Trust	Pre-post - test (Feasibility)	*n*=198 (records)	Mental health assessors	**Target:** Inpatient on acute psychiatry ward (most have SMI) **Action:** Identification of dysglacemia and T2D generally **Time:** Admitted to secondary care service (mental health)	Number of alerts triggered (actual versus expected) in both the initial validation and an in-silico validation. Initial validation had 6 measures (1) whether alert triggered, 2) whether alerts received by end user, 3) if information clinically correct/ 4) incorrect, 5) whether HbA1c threshold information and 6) presence of alert flag if HbA1c above threshold). In-silico validation had 10 measures (1) alert trigger, 2) alert triggered in absence of HbA1c within 4 days of admission, 3) weekly reminders following no data	One month	Initial validation (expected/actual) Alert 1: 22/22 Alert 2: 22/22 Alert 3: 22/22 Alert 4: 0/0 Alert 5: 22/22 Alert 6: 9/9 In-silico validation Alert 1: 32/32 Alert 2: 49/49 Alert 3: 20/20 Alert 4: 101/101 Alert 5: 32/32 Alert 6: 101/101 Alert 7: 101/101 Alert 8: 101/101 Alert 9: 101/101 Alert 10: 0/0 *No service user nor health professional outcomes reported*

								input following alert 2, 4) summary of previous HbA1c, 5) provision of recent HbA1c plus threshold information, 6) recommends appropriate actions, 7) correct/ 8) incorrect clinical information included, 9) no additional or unexpected alerts including 10) post-discharge		

4.5.2.6 Intervention delivery

The interventions varied in their delivery across a range of parameters including whether the intervention was delivered directly to service users *n*=3[176,222,225]. Two of these contained specific references to providing personalised care to service users targeting their ability to self-manage, however they were eligible for inclusion as there were clear separate strategies targeting the delivery and organisation of care (e.g., introduction of new roles not only focussed on self-management strategies[222,225] and a focus on integrating care)[176]. Table 13 summarises the delivery features of the included studies.

Table 13: Summary of delivery features of included studies

Form of delivery	Summary n(%)
Provider	Non-personal *n*=3(37.5) Narrated powerpoint[223], DVD[93], Electronic decision support system[224] Mixed *n*=2(25)DVD/in-person delivery[92], Simulation/in-person delivery[88] Personal *n*=3(37.5) (Cardiometabolic nurse[174], care coordinator[222], mixed professionals[176]) Training in intervention delivery documented *n*=3(37.5)[88,174,176]
Delivery format	Face-to-face *n*=6(75) delivered to health professionals *n*=3(50)[88,92,93]or delivered directly to service user *n*=3(50)[174,176,222] Indirect *n*=2(25)(electronic prompts[224], narrated PowerPoint[223]) Target individuals *n*=4(50)[176,222,224,225] or group *n*=4(50)[88,92,92,223]
Materials	Non-clinical *n*=7(88) e.g.DVD[92,93], laminated handouts[223], email reminders[224], service user reports[222,224] Clinical equipment *n*=2(50)e.g. pen injectors[92] or simulation[88],
Setting	University *n*=2(25)[92,93] Healthcare site *n*=6(75)[88,176,222–225]
Intensity	Single session *n*=3(37.5)[88,92,93], Single session plus booster *n*=1(12.5)[223], Multiple interactions *n*=4(50)[176,222,224,225] 1-day *n*=3(37.5)[88,92,93], variable *n*=*2*(25) weekly then monthly[176], 22 alerts within 1-month[224] Not reported *n*=3(37.5)[222,223,225]

Tailoring	Tailored *n*=5(62.5) (service user focussed *n*=4(80)[176,222,224,225] professional focussed *n*=1(20)[88]) Not-tailored *n*=3(37.5)[92,93,223]

4.5.3 Critical Appraisal

The findings of the critical appraisal are detailed with a table of the outcomes provided in Appendix 8.

There were two studies which employed randomisation[176,225]. Overall appraisal identified variability in quality. Appraisal identified a lack of reporting of assessor blinding. It was possible in only one study[176] to ascertain the appropriate comparability and appropriate adherence to treatment; it was not possible for either study to assess the appropriateness of randomisation. The measurements and analyses were appropriate, however there were questions about the risk of non-response bias, representativeness and sampling strategy.

Five studies employed non-randomisation[88,92,93,222,223], and one mixed methods[92]. All studies were appraised as having variable quality. The main quality issues identified included a lack of representativeness, incomplete data and limited accounting for confounder variables. It was difficult to ascertain whether interventions were delivered as intended. Measurements of outcomes and intervention were judged to be appropriate.

The eighth study[224] reported the development and testing of an electronic clinical decision aid. It was therefore not possible to appraise the quality of this study. Although the findings were used to described the content of known interventions the content was not used to identify promising behaviour change techniques. Thus the inability to appraise quality was not assumed to negatively impact this study.

4.5.4 Content Analysis

Table 14 illustrates the intervention functions, policy categories and behaviour change techniques identified in existing interventions targeting the delivery and organisation of T2D care for people with an SMI.

Table 14: Identified intervention functions, policy categories and behaviour change techniques in existing interventions

	Intervention functions				**Policy Categories**			**Behaviour Change Techniques**								
Author (Year)	**Education**	**Enablement**	**Training**	**Environmental Restructuring**	**Service Provision**	**Environmental/Social Planning**	**Communication/Marketing**	**Feedback on behaviour (2.2)**	**Feedback on outcome(s) of behaviour (2.7)**	**Social support (practical) (3.2)**	**Instructions on how to perform the behaviour (4.1)**	**Information about health consequences (5.1)**	**Demonstration of behaviour (6.1)**	**Prompts/cues (7.1)**	**Behavioural practice/rehearsal (8.1)**	**Restructuring the social environment (12.2)**
Hemingway et al. (2013)	✓		✓				✓				✓	✓				
Hemingway et al. (2015)	✓		✓				✓	✓			✓	✓			✓	
Happell et al (2014)				✓	✓											✓
Wynn (2011)	✓		✓				✓									
Cook et al. (2021)		✓		✓	✓		✓		✓	✓				✓		✓
Crang et al. (2021)	✓						✓				✓	✓				
Patel et al. (2022)	✓			✓		✓	✓				✓	✓		✓		
Chwastiak et al. (2018)	✓		✓	✓	✓						✓	✓				✓

The intervention functions *Education, Environmental restructuring, Training and Enablement* were identified. On average interventions were coded as containing two intervention functions with *Education* the most frequently coded. The most common pairing was

Education and *Training*, identified in four studies in total; three [88,92,93] were coded as containing this combination alone, with one of the studies also coded as using *Environmental restructuring*[176]. *Training* was never identified without the presence of *Education*, however *Education* was identified alone[223] and in combination with *Environmental Restructuring*[224]. Finally, *Environmental restructuring* was identified as the sole intervention function in one study[225] and in combination with *Enablement*[222].

The average number of policy categories identified was one, with *Communication/marketing* most frequently identified. This was most frequently identified as the sole policy category[88,92,93,223], however it was also identified in combination with *Service provision*[222] and *Environmental and social planning*[224]. Finally, two studies utilised *Service provision*[176,225] alone.

Across the eight studies, nine individual behaviour change techniques were identified with *Instructions on how to perform a behaviour* and *Information on health consequences* most frequently identified (*n*=6). On average 3 (Range:1-4) behaviour change techniques were identified in each intervention. The application of behaviour change technique was extracted from each intervention. Table 15 provides examples of each behaviour change technique and application.

Table 15: Examples of how each Behaviour Change Technique was delivered

Behaviour Change Technique	Example identified in existing interventions
Restructuring social environment (12.2)	Addition of new role, such as a Cardiometabolic Nurse[225]
Behavioural practice/rehearsal (8.1)	Nurses were given the opportunity to opportunity to diagnose and administer treatment[88]
Prompts/cues (7.1)	Prompting guideline-based lifestyle interventions/advice regarding exercise, diet and smoking cessation[224]

Demonstration of behaviour (6.1)	Clinical demonstration provided [92]
Information about health consequences (5.1)	The long-term consequences of T2D were considered as part of the intervention [93]
Instructions on how to perform behaviour (4.1)	Participants attended an educational intervention that included a narrated PowerPoint presentation covering (a) the 15 steps in taking blood sugar reading with a glucometer, (b) identifying symptoms of hypo/hyperglycaemia along with diet and exercise and (C) the classes of diabetic medicines and their side effects.[12152152152152152151]
Social support (practical) (3.2)	The coordinator also facilitated specialty care by negotiating specific blocks of appointment time with university outpatient eye and podiatry clinics, arranging transportation with mental health case managers, and scheduling appointments with eye and foot specialists willing to conduct examinations on site.[222]
Feedback on outcome(s) of behaviour (2.7)	For providers, patient-specific reports generated before each visit summarized recent lab values and test results[222]
Feedback on behaviour (2.2)	Feedback from simulator[88]

4.5.5 Theoretical Congruence

4.5.5.1 Theoretical congruence across the interventions (on aggregate) assessed using intervention functions

On aggregate all important domains of the Theoretical Domains Framework reported in Chapter 3 (Section 3.5.5) were targeted by the identified intervention functions (Table 16) with all targeting a minimum of two domains demonstrating high theoretical congruence using the predefined criteria.

Table 16: Theoretical congruence of intervention functions aggregated

Intervention Function	**No. of studies**	**Important domains of the Theoretical Domains Framework which are mapped to the Intervention function (max *n*=7)**	**Theoretical Congruence**
Education	6	Knowledge	High

		Social/professional role & identity Beliefs about capabilities	
Training	4	Environmental context & resources Skills	High
Environmental Restructuring	4	Environmental Context & Resources Social Influence	High
Enablement	1	Environmental Context & Resources Social Influence Goals Beliefs about capabilities	High

Examination of domains targeted by behaviour change techniques however highlights that the domains *Goals* and *Social/professional role and identity* were not targeted by existing interventions. One of the behaviour change techniques (*Feedback on outcome(s) of behaviour)* was assessed as low theoretical congruence as it targeted no domains of importance. Two were assessed as moderate and the remaining six as having high theoretical congruence. Table 17 details theoretical congruence assessment of identified behaviour change techniques.

Table 17: Assessment of theoretical congruence of Behaviour Change techniques on aggregate

Behaviour Change Technique	**No.**	**Important domains of the Theoretical Domains Framework (max *n*=7) which are mapped to the behaviour change techniques and proposed link**	**Congruence**
Feedback on behaviour (2.2)	1	Knowledge (Inconclusive)	Moderate

Feedback on outcome(s) of behaviour (2.7)	1	None targeted	Low
Social support (practical) (3.2)	1	Environmental Context & Resources (Link) Social Influence (Link)	High
Instructions on how to perform the behaviour (4.1)	6	Knowledge (Link) Skills (Link)	High
Information about health consequences (5.1)	6	Knowledge (Link)	Moderate
Demonstration of behaviour (6.1)	1	Skills (Inconclusive) Beliefs about capabilities (Link)	High
Prompts/cues (7.1)	2	Environmental Context & Resources (Link)	High
Behavioural practice/rehearsal (8.1)	2	Skills (Link) Beliefs about capabilities (Link)	High
Restructuring the social environment (12.2)	3	Environmental Context & Resources (Inconclusive) Social Influence (Link)	High

4.5.5.2 Theoretical Congruence at individual study level

Assessment of theoretical congruence at individual study level demonstrates that seven of the studies have high theoretical congruence[88,92,93,176,222–224], and one moderate[225], when measured against pre-defined criteria. On average each study targeted 4.5 (Range: 2-6) of the seven important domains of the Theoretical Domains Framework. The most frequently targeted domains were *Beliefs about capabilities* and *Environmental Context and Resources*; the least frequently targeted was *Goals*. Table 18 illustrates all studies, the identified intervention functions, behaviour change techniques as well as outcomes of the theoretical congruence assessments.

The targeting of the important Theoretical Domains Framework domains (detailed in Section 3.5.5) is more comprehensive when mapped to intervention functions compared to individual behaviour change techniques, that is to say that more domains are targeted. Identifying solely though behaviour change techniques reveals an average of 2.6 (range 1-4) important domains were targeted. The domains *Goals* and *Social/professional role and identity* are not targeted when examined through Behaviour Change Technique mapping.

Table 18: Assessment of theoretical congruence at an individual study level

Author (Year)	**Intervention**	**Intervention Functions Identified**	**Behaviour Change Technique Identified**	**Important domains of the Theoretical Domains Framework which are mapped to the Behaviour Change Technique (max *n*=7)**	**Theoretical congruence**	**Qualitative Theoretical Congruence**
Hemingway et al. (2013) [93]	Diabetes care workshop	Education Training	Instructions on how to perform a behaviour Information about health consequences	***Knowledge*** ***Beliefs about capabilities*** ***Skills*** Social/professional role & identity Environmental context & resources	High	***Knowledge:*** Mental health professionals felt their limited T2D knowledge was a barrier, this is addressed though content in the training including the long-term consequences of T2D. There is however an opportunity for further BCT content to cover aspects of T2D care to improve knowledge including *NICE* guideline knowledge. **Skills:** The content of the described BCTs in the intervention do target the general training need identified as a barrier for mental health professionals. It does not however appear to target the specific barriers identified such as foot care, weight management or communication skills. ***Beliefs about capabilities:*** Targeting of the some of the barriers within the domains *Knowledge* and *Skills* may provide an impact on their belief about capabilities. As this was linked to limited knowledge and experience of delivering care. There are however opportunities to address more barriers within both domains which may confer additional benefit.

Hemingway et al. (2015)[92]	Diabetes care workshop	Education Training	Instructions on how to perform a behaviour Information about health consequences Demonstration of behaviour Behavioural practise/rehearsal	***Knowledge*** ***Beliefs about capabilities*** ***Skills*** Social/professional role & identity Environmental context & resources	High	***Knowledge:*** Mental health professionals felt their limited T2D knowledge was a barrier, this is addressed though content in the training including the long-term consequences of T2D. There is however an opportunity for further BCT content to cover aspects of T2D care to improve knowledge including *NICE* guideline knowledge. **Skills:** The intervention targeted the mental health professional skills around using blood glucose monitors and pen injectors. There are opportunities for additional 'practical' skills such as foot care, as well as targeting barriers around communication skills with other health professionals identified in mental health professionals. ***Beliefs about capabilities:*** Targeting of the some of the barriers within the domains *Knowledge* and *Skills* may provide an impact on their belief about capabilities. As this was linked to limited knowledge and experience of delivering care. There are however opportunities to address more barriers within both domains which may confer additional benefit.
Wynn (2011)[88]	Simulation training workshop	Education Training	Instructions on how to perform a behaviour	***Knowledge*** ***Beliefs about capabilities*** ***Skills***	High	**Knowledge:** General training in T2D addresses the general need for increased knowledge identified as a barrier in mental health professionals. There are

			Information about health consequences Behavioural practise/rehearsal Feedback on behaviour	Social/professional role & identity Environmental context & resources		however opportunities for additional content such as awareness of NICE guidelines. This is not covered as the intervention is based in the USA. **Skills:** General skills are addressed through the intervention however a focus on treating medical emergencies in people with T2D/SMI was not identified in the literature on barriers and enablers. Furthermore there is no explicit description of content which targets specific barriers such as foot care and communication skills. ***Beliefs about capabilities:*** Targeting of the some of the barriers within the domains *Knowledge* and *Skills* may provide an impact on their belief about capabilities. As this was linked to limited knowledge and experience of delivering care. There are however opportunities to address more barriers within both domains which may confer additional benefit.
Happell et al. (2014) [225]	Implementation of a new role: Cardiometabolic Nurse	Environmental Restructuring	Restructuring the social environment	***Social influence*** Environmental Context & Resources	Moderate	**Social Influence:** The introduction of a new role may be a match for barriers relating to service user interactions Barriers not addressed include the need for multidisciplinary working, increased social support, reduction in stigma and improved relationships.
Patel et al. (2022) [224]	Implementation of an electronic	Education	Instructions on how to perform a behaviour	***Knowledge*** ***Beliefs about capabilities***	High	**Environmental context & resources**. The study uses an IT prompt which combines integrated information

	clinical decision support system	Environmental Restructuring	Information about health consequences Prompts/cues	***Skills*** **Environmental context & resources** Social/professional role & identity		on T2D. This address issues of limited IT integration. There are however opportunities for additional content to target specific barriers identified such as service provision suitability, limited time and organisation priorities and culture. **Knowledge**: The provision of links to NICE guidelines, and required actions, partially address barriers around lack of knowledge of these guidelines. Similarly flagging up dysglycaemia may alleviate knowledge concerns around differences between hypo and hypers identified in the literature as a barrier for mental health professionals. **Skills:** The barrier of limited skills in medication management addressed by the provision of advice within the prompt. Skills however related to foot care, weight management and communication are not addressed. ***Beliefs about capabilities:*** Targeting of the some of the barriers within the domains *Knowledge* and *Skills* may provide an impact on their belief about capabilities. As this was linked to limited knowledge and experience of delivering care. There are however opportunities to address more barriers within both domains which may confer additional benefit.

Cook et al. (2021) [222]	Implementation of a care coordinator and diabetes registry. Addition of tailored diabetes self-management education.	Enablement Environmental Restructuring	Feedback on outcome(s) of behaviour Social support (practical) Prompts/cues Restructuring the social environment	***Environmental Context & Resources*** ***Social Influence*** Goals Beliefs about capabilities	High	**Environmental Context & Resources:** IT system workaround identified through the creation of a registry which may address the barrier of IT system integration. The new care coordinator role may also support issues of the limited suitability of service for service users by providing better integrated care and a link between different services. Opportunities for additional content include tackling barriers perceiving time and workload constraints, finance challenges and organisation culture and priorities. **Social Influences**: The role may ameliorate barriers related to service user interactions with content related to engaging those with an SMI/T2D. This included reminding people about appointments, as well as attending them and discussing results. Furthermore the focus on the involvement of family and friends targets the specific barrier (And enabler) of social support and relationships. The role also focuses on integrating care across specialities which targets the barrier (And enabler) of multidisciplinary working. Opportunities for additional content include the barrier of stigma.
Crang et al. (2022) [223]	Educational workshop including a "booster" session	Education	Instructions on how to perform a behaviour Information about health consequences	***Knowledge*** ***Beliefs about capabilities*** **Skills** Social/professional role & identity	High	**Knowledge:** Content identified targets the barrier of general knowledge of T2D for mental health professionals. There are opportunities for additional content around awareness of NICE guidelines. This is

						likely not targeted as the intervention was based in the USA. **Skills:** Content identified focuses on specific skill barriers including hypo/hyper differences, weight management though provision of diet and exercise information and medication management. There are opportunities for additional content around foot care and communication with other health professionals. ***Beliefs about capabilities:*** Targeting of the some of the barriers within the domains *Knowledge* and *Skills* may provide an impact on their belief about capabilities. As this was linked to limited knowledge and experience of delivering care. There are however opportunities to address more barriers within both domains which may confer additional benefit.
Chwastiak et al. (2018)[176]	TEAMCare Collaborative Care Approach. Addition of tailored diabetes self-management education	Education Training Environmental Restructuring	Instructions on how to perform a behaviour Information about health consequences Restructuring the social environment	***Knowledge*** ***Beliefs about capabilities*** ***Skills*** **Environmental Context & Resources** *Social influence* Social/professional role & identity	High	***Environmental Context & Resources:*** The creation of registry to overcome IT integration barriers and the provision of links to support integrated care between different members of multidisciplinary team. Opportunities for additional content include targeting barriers of staffing, workload, time constraints, finance challenges, organisation priorities and culture as well as a new specialist role. **Knowledge:** Content provided to improve general T2D knowledge addresses this barrier with opportunities

						for more specific content around the difference between hypos and hypers as well as knowledge of T2D clinical guidance. **Skills:** Content addresses barriers of medication management and weight inferred through diet/exercise training. Opportunities for additional content to address barriers of foot care skills. Mismatch in specifics such as guidelines and footcare identified as well as communication skills. ***Beliefs about capabilities:*** Targeting of the some of the barriers within the domains *Knowledge* and *Skills* may provide an impact on their belief about capabilities. As this was linked to limited knowledge and experience of delivering care. There are however opportunities to address more barriers within both domains which may confer additional benefit.

N.B. Domains in bold and italicized are targeted by both intervention functions and behaviour change techniques. Those without are targeted by the intervention functions only.

Qualitative assessment of the extent of match between the identified content (Section 4.5.4) and barriers and enablers from literature demonstrated variability. In most studies general T2D knowledge was identified matching existing barriers however there were instances (REFS) of mismatch where specifics were not identified predominantly guidelines and foot care. No studies focussed explicitly on communication between professionals within the multidisciplinary team a barrier within the domain *skills.* Variability in the match between content and the need for involvement of friends and family, as well as social support of professional peers was also identified. There was also a mismatch identified in the lack of focus on ensuring the service was appropriate for service users with T2D/SMI as well as professional perceptions of prioritisation and importance placed on T2D management by service users with an SMI.

4.5.5.3 Identifying promising behaviour change techniques

There were four behaviour change techniques that met the pre-defined criteria as demonstrating promise for future intervention development - 1) statistically significant effect in 2 or more studies and 2) identification in =>25% of studies (Table 19). Three techniques (*Instructions on how to perform the behaviour, Information about health consequence, Behaviour practice/rehearsal* are promising in demonstrating effects on health professional outcomes including improved knowledge scores[92,93,223]*,* of which one affected clinical judgement[88] (*Behaviour practice/rehearsal*). The fourth technique, *Restructuring the social environment*, was identified as having a promising effect on service user outcomes including reductions in HbA1c[176,222], low-density lipoprotein, Triglycerides and both systolic and diastolic blood pressure[222].

Table 19: Behaviour change techniques identified as promising

	Reported statistically significant effect	
Behaviour Change Technique	Health Professional Outcome(s) *N*(%)	Service User Outcome(s) *N*(%)
Feedback on behaviour (2.2)	1(12.5)[88]	0
Feedback on outcome(s) of behaviour (2.7)	0	1(12.5)[222]
Social support (practical) (3.2)	0	1(12.5)[222]
Instructions on how to perform the behaviour (4.1)	***4(50)***[88,92,93,223]	1(12.5)[176]
Information about health consequences (5.1)	***4(50)***[88,92,93,223]	1(12.5)[176]
Demonstration of behaviour (6.1)	1(12.5)[92]	0
Prompts/cues (7.1)	0	1(12.5)[222]
Behavioural practice/rehearsal (8.1)	***2(25)***[88,92]	0
Restructuring the social environment (12.2)	0	***2(25)***[176,222]

4.5.5.4 Opportunities for development (missed opportunities) for intervention functions and behaviour change techniques

Overall, there were four identified intervention functions. Mapping exercises highlight that the remaining five would represent potentially missed opportunities to target five important domains, illustrated in Table 20.

Table 20: Intervention functions linked to the important domains of the Theoretical Domains Framework but not identified in existing studies

Domains	Intervention functions
Social Influence	Restriction Modelling
Environment, Context & Resource	Restriction
Social/Professional Role	Persuasion Modelling
Goals	Persuasion Modelling Coercion

	Modelling
Beliefs about capabilities	Persuasion Modelling

In total nine behaviour change techniques were identified across the studies. Inspecting the Theory and techniques tool there are however 31 unique behaviour change techniques which have either evidence of a link or inconclusive evidence of a link that could be considered by developers, listed in Table 21.

Table 21: Behaviour change techniques linked to the important domains of the Theoretical Domains Framework but not identified in existing studies

Domain	behaviour change techniques
Knowledge	Biofeedback Information about antecedents Information about social and environmental consequences
Social Influence	Monitoring of behaviour by others without feedback Social support (unspecified) Social comparison Information about others' approval Social reward
Environment, Context & Resource	Problem solving Remove aversive stimuli Conserving metal resources Restructuring the physical environment Avoidance/reducing exposure to cues for the behaviour Adding objects to the environment
Social/Professional Role	Social support (Unspecified) Social comparison Credible source Identity associated with changed behaviour
Skills	Problem solving Generalisation of target behaviour Graded tasks Self-reward
Goals	Goal setting (outcome) Goal setting (behaviour)

	Review outcome goal(s) Review behaviour goal(s) Discrepancy between current behaviour and goal(s) Behavioural contract Graded Task Material reward (behaviour)
Beliefs about capabilities	Goal setting (behaviour) Problem solving Biofeedback Graded tasks Social reward Reduce negative emotions Verbal persuasion about capability Focus on past success Self-talk

Assessment of theoretical congruence suggests that, whilst behaviour change techniques were limited in number, they were highly congruent with the retrospectively identified important domains of the Theoretical Domains Framework. There was only one behaviour change technique (*Feedback on outcomes(s) of behaviour)* which was of low congruence as there is currently no suggested link between this technique and any of the domains of importance.

4.6 Discussion

4.6.1 Summary of Findings

Eight interventions were identified in this review of interventions targeting the delivery and organisation of T2D care for adults with an SMI. There was considerable heterogeneity in the overarching strategies including the provision of training for existing staff within their current role[88,92,93,223], reorganisation of the care pathways using existing staff [176], the introduction of new staff and/or programmes[174,222] and electronic support decision aids[224]. Retrospective content analysis of interventions collectively identified the use of four intervention functions, three policy categories and nine behaviour change techniques. Analysis suggests that four of the nine behaviour change techniques *(1) Instructions on how to perform the behaviour, 2) Information about health consequences, 3) Behavioural practice/rehearsal* and *4) Restructuring the social environment* are promising and can be considered a high priority in future intervention development.

There was a high theoretical congruence for both intervention functions and behaviour change techniques, both on aggregate and at an individual study level. On average, individual studies targeted 4.5 theoretical domains when assessed using intervention functions mapping and 2.6 when assessed using Behaviour Change Technique mapping. The decreased number of important domains targeted when using mapping to behaviour change techniques could result from the fact that as intervention functions are the general approaches to intervention development. That is to say that the existing interventions are broadly taking an appropriate overall approach, i.e., they are targeting a wide range of important Theoretical Domains Framework domains identified in Chapter 3 (Section 3.5.5) but are potentially missing out several important strategies, i.e., behaviour change techniques. Therefore, whilst the studies meet the criteria for high congruence there are opportunities to target a more comprehensive range of domains and thus behavioural determinants. Beyond the identified limited number of domains targeted, two domains (*Goals* and *Social/professional role and identity*) were not targeted by any interventions when mapped using the behaviour change techniques. Furthermore, a more nuanced qualitative exploration of congruence comparing the identified content of behaviour change techniques with barriers and enablers from literature highlighted further opportunities for development through mismatches. For example there is an opportunity to focus on communication and relationships between members of the multidisciplinary team as well as more specific knowledge and skill enhancement including foot care and awareness of appropriate guidelines. Thus, there is the scope for future interventions to consider a broader range of behaviour change techniques targeting all important domains, as well as ensuring that the content designed to deliver the techniques are tailored to the specific barriers and enablers within the domains. This can be achieved through a theory and evidenced based approach which supports systematic and transparent identification of determinants of behaviour (i.e., important Theoretical Domains Framework domains) which have been detailed in Chapter 3 (Section 3.5.5) and the prioritisation of targeted content in the development of interventions.

Whilst there is scope for consideration of a wider range of behaviour change techniques in future intervention development the Behaviour Change Techniques Taxonomy is based on the technique generally and not specific contexts, i.e., the techniques may not be applicable to the professional behaviour change in a healthcare context. A context-sensitive list of behaviour change techniques is available through a proposed subset of techniques identified as Continual Professional Development courses in a healthcare context[226]. This refined subset contains 43 of the identified behaviour change techniques which are pertinent to continual professional development of health professionals. All nine behaviour change techniques identified within the included studies are listed within this subset, supporting their appropriateness for this specific context (i.e., interventions targeting healthcare professionals).

Four behaviour change techniques were identified as promising in the current review, with one technique *Restructuring the social environment* linked to improved outcomes for service users, which highlights the potential of targeting the social environment in future interventions. The importance of exploring and targeting proposed social determinants of behaviour to improve T2D care for adults with an SMI is underscored through the identification of *Social/professional role and identity* and *Social influence* as important Theoretical Domains Framework domains. Social norm interventions are proposed to be an effective method for changing healthcare professional behaviour[227]. There is no set definition of social norm interventions, however five behaviour change techniques are proposed by the authors[227] to involve social norms, (*1) Social Comparison, 2) Information about Others' Approval', 3) Credible Source, 4) Social Reward* and *5) Social Incentive*)[227]. Further evidence for four of these behaviour change techniques can be found in the Theory and Techniques Tool, which proposes links between the techniques *Social* comparison, *Information about others' approval* and S*ocial* reward with *Social influence* and *Credible source* with *Social/professional role and identity.* Two of the identified interventions targeted *Social influence* but none targeted *Social/professional role and identity.* This indicates potential for future intervention development, however as differences have previously been identified in the effectiveness of the social norm interventions between professional groups (most strongly associated with doctors as well as other healthcare workers but not with nurses or other allied health workers[227]), thus some caution in this approach is required.

A further reason for the cautious interpretation of opportunities for future development is that whilst the mapping matrices provide guidance on the intervention content which could be utilised, the appropriateness for the specific context is largely untested. For example, the intervention function *Persuasion* was not identified in interventions included in this review. It is however mapped to the domains *Social/professional role and identity, Beliefs about Capabilities* and *Goals,* all identified as important domains in the delivery and organisation of T2D care for adults with an SMI. Given the mapping of *Persuasion* to these important domains, and its absence in identified interventions, it is classed as a “missed” opportunity and could be argued to be warranted for consideration in future intervention development. Its use however is not optimal as interventions which seek to reshape the attitudinal landscape in which professional behaviours are enacted, usually delivered using *persuasion* are less likely to lead to professional practice behaviour change[228]. It is therefore important to acknowledge that those intervention functions*,* and behaviour change techniques, identified as “missing” may not be optimal for the specific context of changing health professional behaviour. Therefore, future intervention development should view these results critically to ensure that choices are informed by evidence where possible.

There is contradictory evidence regarding an increased number of behaviour change techniques increasing effect size. Systematic review and meta-analysis of internet-based health behaviour change interventions reported that the inclusion of a greater number of behaviour change techniques increased effect size[229], however there was no evidence found of a link between an increased number of behaviour change techniques and effect size in physical activity interventions[230]. Therefore, future intervention development should carefully consider the number of behaviour change techniques ensuring a pragmatism in decision-making. Only two of the studies which reported a significant effect on outcomes[176,222] were randomised controlled trials, one of which was a pilot study[176] and therefore unlikely to be sufficiently powered, thus claims about the effectiveness of the promising behaviour change techniques is made with caveats. It is therefore important that future intervention development ensures a rigorous methodology and evaluation to support confidence in the evidence of behaviour change technique effectiveness in improving T2D care for adults with an SMI.

The eight interventions broadly supported general delivery of T2D care by mental health professionals, with the exception being care provided for those exhibiting poorly controlled T2D[176] or when admitted to a secondary mental health care provider[224]. All focussed on care generally and not on specific T2D care processes. This has implications for intervention design for two reasons, 1) the lack of clarity around roles and responsibilities is likely to be overlooked if professionals are not provided with clear guidance on when and where they should intervene in care. 2) literature on behaviour change[108] suggests that it is better in the first instance to intervene in one, or a small number of behaviours, to support behaviour change. Existing interventions lack such specification, particularly around the delivery of specific care processes (e.g., HbA1c measurement) as well as the time(s) when T2D care should or could be delivered. This offers an opportunity to explore T2D care in greater detail examining whether specific care processes and/or particular time(s) of T2D care delivery are more beneficial.

Overall, analysis of theoretical congruence suggests that whilst limited in the volume, the intervention functions and behaviour change techniques identified in existing interventions are appropriate, albeit with several caveats. There is however significant scope for considered intervention development utilising a theory-informed and evidence-based approach to selecting intervention content.

4.6.2 Strengths

To the best of my knowledge this is the first time that the Behaviour Change Wheel[108] and the Behaviour Change Technique Taxonomy v1 [112,231], Theory and Techniques Tool[214] and the Form of Delivery Framework [212] have been used to code content within interventions targeting the delivery or organisation of T2D care for people with an SMI. Additionally, this is the first known instance of the identified barriers and enablers being used to guide analysis and explore theoretical congruence between interventions and the identified barriers and enablers within the context of T2D care in SMI. This helps to identify, on aggregate, where future intervention developers could add to those existing interventions, as well as enable in-depth analysis of individual studies.

The search strategy used for the systematic review, and used to identify interventions, was comprehensive, therefore whilst it is acknowledged that interventions could have been missed, comparison with studies identified in other reviews[15,83] suggests a thorough search.

4.6.3 Limitations

The results of the existing search strategy used for the systematic review in Chapter 3 (reported in Section 3.4.3) were utilised to identify interventions for this content analysis. Therefore it is possible that interventions may have been missed. The review addressed different questions and no intervention specific terms were utilised. It was a comprehensive search strategy covering both published and grey literature across eleven sources with citation searches of identified reviews. The search also identified all interventions identified from the reviews discussed in Chapter 1 (Section 1.3), which suggests the search strategy was sufficiently broad to capture interventions as well as literature on the barriers and enablers.

The content analysis used an inclusive coding strategy with the inclusion of assumption-based identification. These assumptions were included to reflect the, often acknowledged, limited descriptions of intervention content and two of the assumptions have been used in previous literature[210] This may result in an overly optimistic inclusion and may not reflect the reality of intervention content. For example, it is arguable that it is possible to deliver Education, which includes giving instructions on how to perform the behaviour, without also providing information on the health consequences of action or inaction. It is therefore possible that using an assumption-based approach could inaccurately identify the presence of behaviour change techniques. In this synthesis it was however possible to identify behaviour change techniques without the inclusion of the assumptions. Whilst the use of the coding assumptions resulted in identification of two of the most frequently identified behaviour change techniques across five of the interventions (*Instructions on how to perform the behaviour* and *Information about health consequences),* it was possible to identify these behaviour change techniques from the intervention description, for example, *Instructions on how to perform the behaviour* could be identified from the following descriptions: "Instructions covering (a) the 15 steps in taking blood sugar reading with a glucometer, (b) identifying symptoms of hypo/hyperglycaemia along with diet and exercise and (c) the classes of diabetic medicines and their side effects"[223]. A further example can be identified in the description of a clinical decision support aid which provides instructions on behaviours to perform in response to provided HbA1c levels of admitted patients[224]. *Information on health consequences* was identifiable in intervention descriptions, for example in the description of the long-term consequences of T2D considered as part of the intervention[93] and in the inclusion of details on the side-effects of antipsychotic medications on health consequences for people with T2D/SMI,[176].

This is a secondary content analysis and as such the components of the intervention identified reflect only what has been reported. It is acknowledged that the reporting of interventions is often poor with limited descriptions therefore what has been identified may not fully reflect the intervention content. Whilst other studies using similar methods have sought additional information on interventions from intervention developers, they report a similar median number of identified behaviour change techniques in each individual intervention[125], as identified in this review. This suggests that identification of behaviour change techniques in this review is largely representative of the interventions. Furthermore, it is not possible from reporting of the interventions to identify whether other intervention functions or behaviour change techniques, even if not explicitly in these terms, were considered but rejected and an underpinning rationale. This has resulted in several considerations for future research but not definitive statements on what should be included. It also underscores the value of a theory and evidence-based approach for clearly defining intervention content.

The domains of the Theoretical Domains Framework identified as important were mapped using barriers and enablers from a diverse range of countries (United Kingdom (*n=11*), North America (*n=8)*, Australia and Canada (*n=2*), Denmark, Sweden, Saudi Arabia, Uganda and China (*n=1*); yet the interventions were carried out in only three countries (UK, USA and Australia). The differences in healthcare contexts may impact the barriers and enablers and affect the resulting analysis i.e., certain domains may be identified to relate to certain healthcare contexts or geographical regions and therefore a sub-set of the identified potential components may be relevant. Whilst this impact is acknowledged, it was felt that an international focus would allow a more robust analysis, and could be used to support more specific analysis at a later date, furthermore such parameters have been utilised in other publications[209,232]

The authors of the mapping matrices, including the Theory and Techniques Tool[144], highlight that the links between domains and behaviour change techniques are not robustly evidenced and as such it is recognised that these links are hypothesised and will need to be tested. Such actions will also support the work being undertaken to draw conclusions as to the effectiveness of the hypothesised links detailed in the Theory and techniques tool[143].

It is not possible, owing not only to heterogeneity of interventions but also to the study methods, to undertake any analysis of effectiveness to ascertain which of the components may be more likely to be effective. Whilst identification of promising behaviour change techniques was made using the reported significant outcomes of each intervention, the substantial heterogeneity in intervention content including both behaviour change techniques and forms of delivery as well as limited number of identified randomised controlled trials reduces the ability to make definitive statements about which behaviour change techniques are most likely to change professional behaviour to improve T2D care for adults with an SMI.

There was considerable heterogeneity in the operationalisation of a very limited number of behaviour change techniques. This was evident through the variable forms of delivery identified. For example, the promising behaviour change technique *Instructions on how to perform a behaviour* had variable intensity of delivery ranging from a one-day session[88,92,93] to multiple interactions[224]. The variability in the delivery format is an important consideration as it may impact the effectiveness of the technique[212]. Future intervention development will need to carefully consider the form (or mode) of delivery to ensure it optimises the likely effectiveness.

Finally, critical appraisal of included studies demonstrated variability in quality across the criteria for each study design. It was also challenging to ascertain whether interventions were delivered as intended. This has implications for the behaviour change techniques identified as promising, as the studies on which this decision is made have this risk of bias. It is therefore necessary to ensure that decisions on inclusion of future behaviour change techniques are made using multiple criteria and not solely identification in these studies.

4.6.4 Future Research

Before any interventions are designed, a more nuanced understanding of specific aspects of T2D care should be considered. T2D care itself comprises multiple care processes carried out by different professionals, additionally care could be provided in different contexts i.e., by the Community Mental Health Team or in an inpatient setting. Analysis in the systematic review (Chapter 3) identified domains which did not meet the importance criteria and were therefore not examined but were particularly relevant to specific care process. For example, the identification of the domain Optimism, and the lack of it felt by professionals, particularly when delivering diet and exercise advice to adults with an SMI and T2D. It is possible that these types of contextual differences will impact on the barriers and enablers and as such may vary the important domains. Therefore, future research could focus on more specific T2D care to understand the potentially nuanced barriers and enablers.

Finally, any future interventions should be designed to not only target the specific barriers and enablers, and thus domains of importance, but also designed to allow testing of the proposed relationships between the behaviour change techniques, form(or mode) of delivery and specific context using rigorous evaluation.

4.6.5 INDEX key considerations

The key INDEX considerations within this chapter were the established processes for decision making, reviewing published evidence, drawing on existing theories, understand context and pay attention to future intervention delivery through the identification of potentially promising intervention content, detailed in Table 22.

Table 22: INDEX key considerations within the content analysis of existing interventions

Key Issue	Included	Evidence
Plan the development	X	Not applicable at this stage
Involve stakeholders	X	Not applicable at this stage
Bring together a team and establish decision making processes	✓	Supervisory team supported independent coding of intervention content
Review published research evidence	✓	Identification of existing interventions
Draw on existing theories	✓	Intervention functions, policy categories[108] and behaviour change techniques[112] used as a framework to code intervention content
Articulate programme theory	X	Not applicable at this stage
Undertake primary data collection	X	Not applicable at this stage
Understand the context	✓	Support consideration of wider context of existing interventions
Pay attention to future implementation of the intervention in the real world	✓	Use of criteria to identify promising behaviour change techniques considered feasibility of implementation in real world.
Design and refine the intervention	X	Not applicable at this stage
End the development phase	X	Not applicable at this stage

4.7 Conclusion

This comprehensive review of interventions aimed at improving the delivery and organisation of T2D care for adults with an SMI highlights diversity within a limited number of interventions. The interventions encompassed a range of approaches, including staff training, care pathway reorganisation, introduction of new staff and programmes, and electronic decision support aids. The content analysis demonstrated that whilst a narrow range of intervention functions, policy categories and behaviour change techniques have been utilised in interventions they are largely congruent with theory, suggesting that the designed interventions are likely to target some of the retrospectively identified barriers and enablers. While a solid theoretical alignment was evident, there remains untapped potential to expand interventions to support consideration of the wide range of domains important to the delivery and organisation of T2D care for adults with an SMI. The identified gaps, both in terms of untargeted domains and under-utilised behaviour change techniques, indicate avenues for more comprehensive intervention strategies. Achieving this aim can be facilitated though the use of a theory and evidence-based approach to intervention development, which can support consideration of both a wide-range of determinants and intervention content.

Notably, four behaviour change techniques emerged as promising candidates for future intervention development, *(1) Instructions on how to perform the behaviour, 2) Information about health consequences, 3) Behavioural practice/rehearsal* and *4) Restructuring the social environment.* Additionally, a focus on the social determinants of health professional behaviour, specifically targeting *Social/professional role and Identity* and *Social influence* demonstrate promise and are currently under-represented in existing intervention. These factors will be prioritised for consideration during later intervention development. There is a need however for cautious extrapolation of these findings, with evidence-driven decisions required when designing future interventions. The identified interventions were limited in their focus on when and what care was provided, this offers an opportunity for further research which has a more specific focus. Finally, there is a need, prior to intervention development, to explore whether there are differences in the barriers and enablers, and thus domains of importance, for different care processes given the complexity of T2D care for adults with an SMI. Overall, the need and potential of a theory-informed and evidence-based intervention to support improvements in T2D care for adults with an SMI has been underscored throughout the four previous chapters. The next three chapters will detail the development of a theory-informed and evidence-based intervention supported by the Behaviour Change Wheel[108].

5 Chapter 5. Stages 1- 3 of the Behaviour Change Wheel

Study 3: Identify, select, and specify target behaviour(s) using outcomes from a Delphi study with service users, carers and health professionals, existing evidence, and expert opinion.

5.1 Prologue

There is an increased prevalence, higher morbidity, reduced quality of life and excess mortality in adults with an SMI and T2D. Previous chapters have highlighted that healthcare service provision is a significant contributing factor. Existing reviews identified that educational interventions showed promise in improving mental health professionals' physical health knowledge, skills, attitudes, and confidence. Nevertheless, a more comprehensive approach that considered a wider range of influencing factors was essential to enhance clinical practice and outcomes. This was underscored by the findings of the systematic review (Study 1) reported in Chapter 3 of the perceived barriers and enablers of provision of T2D care for adults with an SMI. Barriers and enablers were mapped to seven important domains of the Theoretical Domains Framework, *1) Knowledge, 2) Skills, 3) Environmental Context and Resources, 4) Social influence, 5) Goals, 6) Social/professional role and responsibility and 7) Beliefs about capabilities*, highlighting the wide range of factors which influence professional behaviour. A second comprehensive review (Study 2) undertaken and reported in Chapter 4 identified eight interventions which were designed to target improvements in T2D care for adults with an SMI. Retrospective coding identified four intervention functions, three policy categories and nine behaviour change techniques combined across the eight studies. Analysis revealed a high level of theoretical congruence but elucidated that interventions were limited in number and scope. Four promising behaviour change techniques were identified, as well as the potential contribution of social norm interventions, which could be important to future intervention development.

Chapter 2 detailed the considerations of the overall theoretical and methodological considerations of this project. The INDEX guidance provided a framework for intervention development considerations. In *Planning the Development Approach* it was decided that The Behaviour Change Wheel[108] was an appropriate published framework to support intervention development. This theory and evidence-based approach was selected to allow a transparent, replicable development with a focus on theory to explicate potential causal mechanisms. This choice also provided strategy to address overarching issues identified in the literature by ensuring a broad consideration of behavioural determinants and the ability to sufficiently describe the intervention in detail.

The Behaviour Change Wheel, detailed in Chapter 2 (Section 2.4.2), is a 3-stage (8-step) framework intended to support clear identification of the problem, a detailed behavioural analysis and support in selecting those specific intervention components which are considered by experts to be more likely to impact behaviour change[108]. This chapter will detail the completion of steps 1 -3 resulting in the identification, selection, and specification of an appropriate behaviour target.

5.2 Introduction

The first three steps of the Behaviour Change Wheel act as a funnel taking a broad idea and narrowing down to ensure a specific target which will be the focus for intervention development, illustrated in Figure 7.

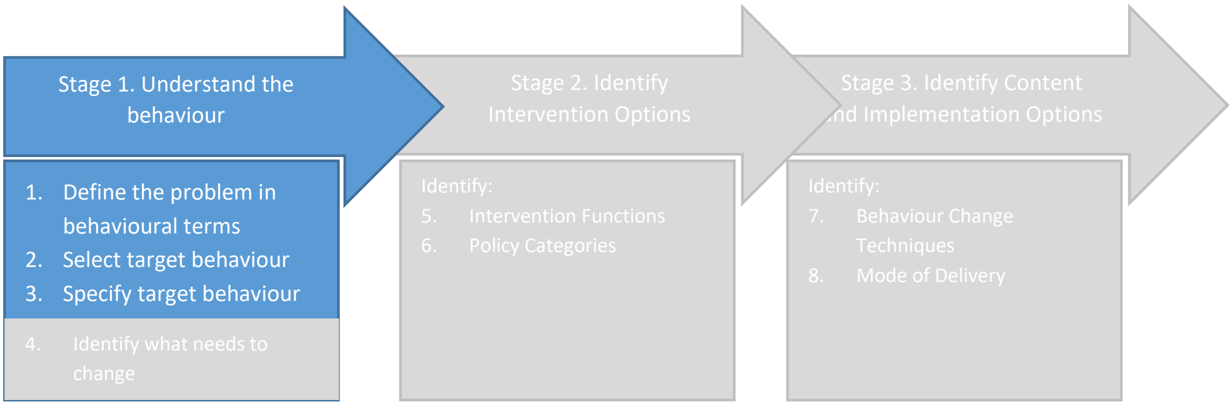


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Figure 7: Stage 1 (Steps 1 -3) of the Behaviour Change Wheel

Although this is the third study of this PhD, it addresses Stage 1 of the Behaviour Change Wheel. Studies one and two were conducted prior to embarking on Stage 1 to support development of an intervention that would not be redundant owing to overlap with existing evidence and/or interventions. INDEX guidance asserts a flexibility in intervention development and recommends reviews of previous research evidence (Section 2.3). Choosing to undertake the systematic review prior to completion of any intervention development enabled the identification of existing interventions. This highlighted the need for interventions with a specific focus on care processes and time of care. This is important given the complexity of both T2D care and the challenges in T2D management owing to the variability in SMI symptomology (discussed in Chapter 1). These findings were used to ask questions of participants focussed on when (time) they would like to receive care. They also reinforced the decision to utilise the Behaviour Change Wheel[108], as this approach supports specification of *when* the target behaviour occurs (the time of T2D care delivery) as well as *what* the specific behaviours are (the specific care processes). The steps required for the first stage are now outlined.

Step 1 of the Behaviour Change Wheel requires a clear definition of what the behaviour is that will be targeted, where does the behaviour occur and who is involved in the behaviour. An often cited example is improving hand hygiene (behaviour), in hospital wards (where) of all hospital nursing staff (who)[108]. Step 2 requires the generation of a long list of candidate behaviours that the intervention could target. The example of hand hygiene could include increasing visibility of senior staff washing hands and increasing the availability of hand washing facilities. It is important in this step that a wide range of behaviours are considered, which are then shortlisted using a systematic method prior to selection. Selection is informed by considering 1) the perceived impact of the prioritised behaviour on the outcome, 2) the likelihood of change, 3) the likelihood of this change negatively or positively affecting other behaviours and 4) the ease of measurement. Finally, Step 3 requires a detailed specification of the target behaviour. This involves identifying who needs to perform the behaviour, what they need to do differently to achieve the desired outcome and when, where, how often and with whom will they do it[108]. The result of these three steps is a clearly specified behaviour target which will be the focus of the developed intervention. These steps can be informed by a variety of sources including original research, existing literature and local knowledge[108]. Step 1 was completed using existing literature described in Chapter 1. Steps 2 and 3 were addressed in Study 3, using a Delphi with relevant stakeholders, discussion with health professionals and supervisory team, as well as existing literature to select and develop an understanding of the target behaviour[108]

5.3 Step 1 Outcome: Define the problem in behavioural terms

Prior to undertaking Study 3 the first step of the Behaviour Change Wheel[108] was completed, which required a definition of the problem in behavioural term. This was kept purposefully broad as it was important to enable participants to suggest ideas for improving T2D care for adults with an SMI without constraint in the Delphi study. As outlined in Chapter 1, there are substantial and increasing inequalities in prevalence, morbidity, and mortality in T2D outcomes in adults with a comorbid SMI, compared to adults diagnosed solely with T2D[39–44,54]. It was proposed on the basis of accumulating evidence that the suboptimal organisation and delivery of physical health care for people with an SMI may be a contributory factor [15,35,40,49,50]. Concurrent management of T2D and SMI care is complex requiring input from a variety of professionals as well as multiple care processes as described in Chapter 1 (Section 1.1.3 and 1.1.4). Finally, it was decided that the focus should be on adults with an SMI and T2D, this is defined as those aged over 18 years of age. This distinction was made as mental health services in the UK are separated by age, with adult mental health services offered from 18 years[233]. Whilst evidence suggests an elevated risk of T2D in SMI populations across all age-groups[1] (i.e., 15-34 years, 35–54 years and 55-74 years), the potential to impact a larger proportion of individuals affected by these conditions (i.e. services for those aged 18 years or over) was selected. Therefore, the problem was defined as follows:

1. ***What behaviour?***

   Delivery of T2D care for adults with an SMI

2. ***Where does the behaviour occur?***

   Primary and secondary care

3. ***Who is involved in the behaviour?***

Multiple health professionals including mental health nurses, care coordinators, diabetologist, diabetes nurse specialists, psychiatrists, and general practitioners.

5.4 Study 3

Steps 2 and 3 of the Behaviour Change Wheel were informed by a remote asynchronous Delphi event, discussion with health professionals and the supervisory team as well as existing literature.

5.4.1 Aim and Objectives

The study aimed to select and specify an appropriate target behaviour, achieved through the following objectives:

1. Complete Step 2 of the Behaviour Change Wheel *(Select target behaviour)*
   1.1. Identify a longlist of potential behaviour targets, related to the delivery and organisation of T2D care for people with an SMI, with service users, carers, and health professionals
   1.2. Use consensus methods to identify the behaviour targets important to stakeholders, creating a short-list of behaviour targets
   1.3. Identify appropriate behaviour target(s)
2. Complete Step 3 of the Behaviour Change Wheel *(Specify target behaviour)*
   2.1. Identify 1) who needs to perform the behaviour, 2) what the person needs to do differently to achieve the desired change, 3) when they will do it, 4) where will they do it, 5) how often will they do it and 6) with whom

5.4.2 Study Design

The Delphi method is a set of procedures for identifying and refining opinions of a group of individuals, or experts[234]. The method systematically combines expert opinion (where the ‘expert’ panel composition is based on the extent and depth of experience and understanding relevant to the topic) in order to reach a group consensus[235]. The Delphi technique involves interactions between panel members, via surveys; the use of an online survey tool to disseminate the surveys, collect and collate data is commonly referred to as an e-Delphi[236]. Using this technique enables remote participation which was important given the restrictions on interactions due to the COVID-19 pandemic at the time of data collection. It also enables a transparent and auditable method aligning with the James Lind Alliance principles[237].

The Delphi method may be seen to reflect philosophical influences of Locke, Kant and Hegel[238]. The original Delphi technique[234] is suggested to be a prime example of Lockean philosophy whereby the “raw data” are the opinions or judgements of the panel and the validity of the judgment of the panel is measured explicitly on the “degree of consensus”[239]. In contrast, the underlying objective of a Kantian Delphi is to solicit diverse alternatives, facilitating a comprehensive exploration of the subject matter. Complex “social problems” are better suited to this type of enquiry where there is no one approach which is likely to bring about change. The exploration of multiple viewpoints is more aligned with a Kantian philosophy whereby the focus is on elicitation, understanding and comparison of different opinions to identify the “best bet” for future endeavour[239]. This approach does not preclude identification of consensus at later stages[239].

To address the aims of this study a heterogeneous panel consisting of service users, carers and health professionals was recruited. A Kantian Delphi is designed to create a structure that accommodates numerous "informed" individuals from varying backgrounds, enabling them to contribute insights and judgments to a problem domain that extends well beyond the expertise of any individual participant group[239]. This compares to a Lockean Delphi which is better suited to an already knowledgeable group that shares a common foundational understanding[239]. Thus, a Kantian Delphi was deemed more appropriate to accommodate the likely diverse opinions of the proposed panellists.

Finally, a Kantian Delphi is not only interested in the feedback from the panel but also sensitive to it. That is to say that focussing on the consensus of the group, or identifying the compromised position, is not the sole aim (as would be in a Lockean Delphi) but in considering the often-diverse viewpoints of the panel[239]. A Kantian Delphi does not preclude arrival at a single focus but acknowledges that identification of the focus can be informed as much by disagreement as agreement, and that informed decision-making can be informed by both[239]. Therefore, a Kantian Delphi was adopted in this study as it accommodates the diverse panel and the potential for different priorities. It also supported recognition of the value of varied backgrounds as well as being sensitive to the potential differences in beliefs, amongst health professionals, which were identified in the systematic review (Chapter 3. Section 3.6)

5.4.3 Asynchronous Participation

The use of asynchronous modes of data collection have become increasingly popular, with the ability to respond at convenient times, increased flexibility and participation from home acknowledged benefits[240]. The anonymity from such methods is also advantageous as it can ameliorate some of the power imbalance when convening a diverse group of stakeholders[241], furthermore preserving the anonymity of the expert panel is a key characteristics of the Delphi method[242]. This is helpful given the identified power imbalance in previous work with a mix of service users, health professionals and policy makers[241]. Additionally, the use of asynchronous collection may confer an advantage in obtaining less censored data; this could be because questions regarding research prioritisation may, although not always, stem from experiences or views of suboptimal care which may be difficult to share openly in synchronous data collection. Equally, given that the systematic review findings (Chapter 3) highlighted intergroup conflict is a barrier to T2D care, convening a multidisciplinary team to identify areas for prioritisation in which the focus may be aligned to such a barrier could be challenging and opportunities to provide data anonymously may be more likely to yield more open responses.

5.4.4 Stakeholder Decision Making – levels of involvement

The involvement of stakeholders was considered in Chapter 2 (Section 2.5), it was concluded that the involvement of stakeholders in research could be optimised and some of the proposed "dark" aspects of co-production addressed with clarity over the level of involvement and clear actualisation. The relevance to this study is now outlined.

It has previously been suggested that in much of health-related research, the needs of patients (or service-users) and health professionals are insufficiently considered when deciding on research priorities, rather the needs of services, industry and academia may take precedence[243]. More recently there has been a shift in the involvement of stakeholders (the collective term used within this project to refer to those proposed to be impacted by the intervention, e.g. service users, carers and health professionals), with their active involvement throughout the lifespan of research considered best practice[241].

It is important that inclusion of stakeholders equates to meaningful involvement. Examination of patient and public involvement and engagement (PPIE) in quality improvement initiatives has identified variable beneficial levels of involvement[244]. It was identified that PPIE was of benefit when considering patient-facing elements of redesign (e.g. advising on and contributing to materials for patients), however there was a risk of tokenism if patients and public (not health professionals) were invited to provide input on the aspects of implementation research of which they have little direct experience (e.g., understanding how health professionals will respond to audit and feedback reports) [245]. A more recent PPIE framework, developed with patients and public, sought to address these challenges and identified activities for patients and public in implementation research with strong, weak and contested support[245]. Similarly, the results suggest that patients and public strongly feel their role in implementation research is to guide research into the care that will impact their lives, however there is weaker support for their involvement in designing and testing interventions where the behaviour itself is the remit of the health professional[245]. Additionally, the involvement of stakeholders in the decision-making process is congruent with recent development of UK standards for public involvement in research, of which one standard outlines the need for public involvement in decision making [246]. It was therefore important to involve service users and carers in the priority setting of this research. Involvement at this stage would support meaningful involvement with decisions about how best to narrow the focus informed by those who would be impacted by the resulting care in the research.

5.4.5 Stakeholder Decision Making – how to involve stakeholders?

Whilst stakeholder involvement in priority setting is of great importance, of equal necessity is the need for tools, guidance and additional research to properly harness the true potential of stakeholder involvement in behaviour change research[241]. The tools and guidance need to be shaped by the specific role of stakeholders within the research, especially given as previously argued (Chapter 2. Section 2.5) that many of the challenges involving stakeholders in research seem linked to the lack of clarity and congruence between expected and actual involvement.

The guidance provided by James Lind Alliance (JLA) *Priority Setting Partnerships*[237] which brings together healthcare professionals and service users to prioritise treatment uncertainties for research can provide tools to support meaningful involvement. The overall aim of the Alliance is to ensure that health research funders are aware of the issues that matter most to the people who need and use the research in their everyday lives[237]. This is achieved by bringing together service users, carers and health professionals on an equal footing and identifying a final list of agreed priorities (often a Top 10*)* in a specific health area. Currently, there are Top 10 priorities for schizophrenia, bipolar and Type 2 diabetes, however there are none for the combination of severe mental illness and Type 2 diabetes. The JLA assert that this process enables a balanced inclusion of perspectives and a transparent and auditable process of priority/research question identification.

Transparent and auditable priority setting can be achieved using consensus methods, as detailed earlier in this chapter (Section 5.4.2 and 5.4.5) Consensus methods have been successfully utilised to identify Type 1 and type 2 diabetes priorities.[247] Notable limitations of this method included uneven contributions, in particular patients contributing less than health professionals and feeling less well prepared for their involvement; and a waning interest in the project as time passed [241]. These factors were considered as part of the study methods, with the use of asynchronous data collection methods (discussed in Section 5.4.3) and through regular email updates with the stakeholders to promote continued engagement.

Finally, the diversity and inclusion in PPIE activities of those with a mental illness, arguably even more so for those with an SMI, are often under represented[248]. This is especially problematic as those with an SMI often have an increased morbidity and mortality and may encounter negative experiences of healthcare services[57,59,60,202]. Meaningful inclusion of individuals with an SMI can support a focus on issues of interest to key stakeholders as well as relevance to policy and practice. In this study the JLA Priority Setting Partnership principles and the positive practical example of stakeholder involvement in diabetes priority setting[247] was used to guide the identification of a target behaviour.

5.4.6 Participants

5.4.6.1 Eligibility

The eligibility criteria, which differed across the members of the online expert panel, are outlined below:

Health professional eligibility:

<u>Inclusion</u>

- Health professionals providing care for people with a diagnosis of SMI and/or T2D
- Aged 18 years or over
- Able and willing to give informed consent
- In a position to implement the ideas (i.e., Team leaders where possible)
- Working in the UK healthcare setting (NHS community, secondary or Primary Care)

Service user eligibility:

<u>Inclusion</u>

- Aged 18 years or over
- Diagnosed with an SMI (schizophrenia, bipolar disorder, or other psychoses) (self-confirmed)
- Diagnosed with T2D (self-confirmed)
- Able to read/write in English

<u>Exclusion</u>

- Unable to access the Internet

Carer eligibility:

Inclusion

- Aged 18 years or over
- Able to read/write in English
- Care for someone who has been diagnosed with T2D and an SMI

Exclusion

- Provide care for someone with a diagnosis other than schizophrenia, bipolar disorder, or other psychoses
- Unable to access the Internet

5.4.6.2 Sample size

The online expert panel consisted of health professionals, service users and carers. It was anticipated that a wide range of health professionals would participate with each member of the multidisciplinary team represented. The team members frequently include the following:

- Mental health nurse
- Diabetologist
- Diabetes nurse specialist
- Psychiatrist
- Mental healthcare coordinator
- General practitioner

With the addition of a team lead and service manager this resulted in a proposed sample of eight health professionals. As service users/carers should have equal opportunities to guide prioritisation within this project, the proposed sample size was *n*=16.

There is no standardised method to calculate a panel size for a Delphi[249]. There is also debate as to the need to provide and adhere to a specified sample size as the Delphi is concerned not with a generalisable sample but on the input of a purposively sampled panel[250]. Therefore, the proposed sample was based on the principle of having a balanced input across the desired panel members (i.e., service users and carers, and health professionals).

5.4.6.3 Recruitment

There were three main pathways for recruitment, one for health professionals and two for service users and carers.

5.4.6.4 Service user/carer recruitment

Service users and carers were recruited through two websites *MQ Transforming Mental Health*[251] and *Call for Participants*[252]. Both websites allow promotion of research studies and are frequently used by several universities across the UK. Both websites publish study details including brief information, ethical approval, time of participation, which institution the research is affiliated with, whether there are any participant payments, details of how to contact the researcher. Participants were asked to contact TD for further information and given the opportunity to discuss the study before deciding whether not to take part and a link to the survey hosted in Qualtrics[253], a secure web-based survey tool, for which City, University of London, has a contract

5.4.6.5 Health professional recruitment

Team leads at East London NHS Foundation Trust (Tower Hamlets) were approached by the Local Collaborator and disseminated information regarding the study. Emails containing brief study information were sent to teams as deemed appropriate by Team Leads. Individuals who were interested in participating contacted TD who responded to any questions and provided an online link to the participant information sheet and access to the consent form and survey which were hosted in Qualtrics survey software[253].

5.4.6.6 Consent

All participants completed an informed consent form prior to participation (Appendix 9). The form was provided within Qualtrics in a series of statements. The statements had to be agreed to prior to participation, if a response to any statement was 'No' the participants were sent to the end of the survey. All participation was remote therefore capacity to consent was self-confirmed by participants. The use of self-confirmed capacity has been utilised in previous research involving service users[200], which was also focussed on attitudes, views and experiences of the participants.

5.4.7 Procedure

Participation was facilitated using Qualtrics. Participants were initially asked a series of demographic questions to allow a sample description to be provided, for example., age, gender, and self-described ethnicity. The questions were tailored to whether the participant was a service user, carer, or health professional, e.g., years since diagnosis for service users, or years since diagnosis of those you care for when framed for carers. Once completed, participants were presented with the first round of the Delphi.

5.4.7.1 Round One: Idea Generation

The first Delphi round required idea generation, with the panel encouraged to provide health professional behaviours that could be a behaviour target for the intervention. The first round remained open for service users and carers for 24-hours. This was closed after this timeframe as the number of recruited participants exceeded the proposed sample. For health professionals the round remained open for 4-weeks enabling the recruitment target to be reached. No reminders were sent for the first round. Once participants began the survey they could return to it as many times as they wished until they submitted. All participants completed the survey within one session.

The questions asked were tailored to the participants. Questions were designed to elicit a behaviour target as a response, and these were informed by 1) the JLA priority setting partnerships questions[254], 2) a previous study which identified priority diabetes behaviour targets for non-SMI populations[247], and 3) the questions proposed for behavioural specificity provided in Step 3 the Behaviour Change Wheel, i.e. who would you like to perform the behaviour? [108]. Information was provided to guide participants to focus on the organisation and delivery of T2D care with examples, as well as clarify that it was not a focus on T2D prevention but on post diagnosis care. The questions were reviewed by the supervisory team as part of preparing materials for ethical approval. These three sources were combined, and individuals were first proposed a series of questions about T2D care, whether as a provider, recipient, or carer of recipient; they were then asked to provide three behaviours that could be targeted. An example of the questions asked of those with a lived experience of T2D and SMI are:

1. What about your diabetes care works well (if anything)?
2. What could be done differently or better to improve your diabetes care?
3. Please tell us about a time when you feel you needed more support for your diabetes from a person who provides your care. What happened? What would have made it better?
4. Who would you like to provide your diabetes care? For example, is there a particular provider or person you would like to provide your care? Would you prefer your care

to be provided by one person or a large team? Would you like to be cared for in one place?

5. Is there anything else you would like to tell us about when you received your diabetes care or wanted to receive care?
6. Please list three behaviours (a specific action by a person) that you think we should focus on to improve diabetes outcomes for people who have a severe mental illness.

Identification of a behaviour target, to an audience not familiar with the terminology may be challenging and therefore an example was provided to support appropriate identification. The definition provided "a specific action by a person" as well as the examples of what a behaviour is and is not, was informed by the work of the Behaviour Change Network (University College London)[255] and was used in previous research to identify behaviour targets[247]. Examples of what a behaviour would be defined as included walking in the park and taking a statin tablet, whereas examples of what a behaviour would not be defined as included losing weight and having the confidence to ride a bike. All questions, for all participants groups, are provided in Appendix 10.

5.4.7.2 Round Two: Idea Ranking

A link to Qualtrics[253] to begin the second round was emailed to all panel members once the proposed sample size was reached for service users, carers and health professionals. The time between completing round one and round two differed between participants. Round one was completed by service users and carers in February 2021, and by health professionals in May 2021. This difference owed to the additional approvals required to recruit health professionals via NHS sites. Round two was completed by all participants in June 2021. Round two remained open for three-weeks with one reminder sent at the end of the second week.

As with round one, once participants began the survey they could return to it as many times as they wished until they submitted. All participants completed the survey within one session.

The data from round one was reported back to participants and the second round focussed on ranking the ideas. The opportunity for the panel to modify their responses considering the feedback from the entire panel is a key distinguishing feature of the Delphi[239]. The panel were advised to consider the following, taken from the Behaviour Change Wheel guidance on behaviour target selection[108], when ranking the ideas:

- How much of an impact the idea will have on improving T2D outcomes for people with an SMI
- How likely it is that the behaviour can be changed
- How likely it is that the idea will result in a trickle effect and have positive or negative impacts on other behaviours
- How easy it will be to measure the behaviour

Using these criteria, the panel were asked to identify and rank their top three target behaviours. In round two the ideas were presented randomly to participants and not grouped by themes.

5.4.7.3 Stopping

Whilst more typically in Lockean Delphi a stopping point is determined based on achievement of consensus[256], this is not the sole objective of a Kantian approach and therefore not appropriate for this Delphi. The number of rounds, and not achievement of consensus, was used to signify the stopping point of the Delphi. Two rounds were chosen as it allowed for participants to consider their originally provided behaviours, as well as those of others, prior to making a final top three ranking. The ability to consider and modify their judgements based upon their reaction to the collective views of the group is a distinguishing feature of the Delphi method[239]. This was achieved by providing participants with the data from round one, in which they were asked to provide their top three ideas and asking them to once again rank their top three ideas in round two. It was also chosen to be sensitive to the challenges of as those who are living with an SMI or caring for a person living with an SMI, as well as participating health professionals, who are under increased pressure owing to the COVID-19 pandemic (as discussed in Chapter 1. Section 1.2), to ensure that participation did not become burdensome nor hamper recruitment.

5.4.8 Analysis

5.4.8.1 Round One: Idea Generation

Whilst it is advised that thematic analysis is used in Delphi studies[257], there is little guidance on how best to utilise the method[258] and there is need for careful consideration given the variations in thematic analysis that exist[259]. In this study, codebook thematic analysis[260–262] was utilised to examine, analyse and combine responses. This combines the more structured approach of coding reliability thematic analysis (e.g., early theme identification and conceptualisation of themes as topic summaries concerned with semantic meaning) with the qualitative values of reflexive thematic analysis[259]. This analysis method acknowledges the role of the researcher within generation of themes and requires reflexivity, whilst combining the structured approach of coding reliability thematic analysis and the answering of pre-existing information needs[259]. This is congruous with the study questions designed to support generating a long list of ideas, thus making Codebook Thematic Analysis a suitable approach.

Familiarisation with data was achieved through reading the responses several times to develop understanding. Initial codes were applied to the data which best summarised the responses from participants. As more codes were identified and familiarisation with data increased the codebook was refined. The codes were systematically identified, applied, and revised; collectively creating themes. The themes focussed on narrowing the ideas generated by collapsing similar ideas to reduce redundancy and overlap, as well as ensure a focus on behaviour. The codebook is provided in Appendix 12. This process resulted in a long list of behaviours (Step 2 of the Behaviour Change Wheel[108]). It was important to retain the language used by the participants when presenting the ideas for ranking in the second round. This decision was made to ensure that the ideas presented for ranking accurately reflected the behaviours generated by participants.

5.4.8.2 Round Two: Ranking

The method for identifying rank order was guided by previous research that had been successful in identifying diabetes priorities for non-SMI populations and created a total score for each idea to support a hierarchical ranking[247]. The total score was calculated using reverse scoring, whereby ideas scored 3 if they were ranked in first place, 2 points in second and 1 point in third. Ideas were then ranked based on their total score to give a hierarchy of prioritisation for the ideas. The percentage of participants who selected the idea in their top three and first place, as well as the percentage of ideas selected for prioritisation, was also calculated. The score for each idea was calculated and detailed in two panels 1) service users and carers and 2) health professional separately as well as in total. This allowed inspection of data to identify areas of agreement and disagreement, or discordance, between service users and carers, and health professionals - a key feature of a Kantian Delphi[239]. A lack of consensus in identification of the top three ideas was explored by comparing the ideas ranked by each panel. Where the idea was present in both panels this was identified as consensus. Where the ideas diverged this would be identified as disagreement between the panels on the most important focus for subsequent research. This process resulted in a short list of behaviours by identifying the ideas which were in the top three for service users and carers, and health professionals. As consensus is not a key feature of a Kantian Delphi, the decision as to which idea should be the focus for subsequent research was made based on inspection of the top three ideas for each panel, the identified areas of consensus and disagreement as well as exploration of existing research which may already be focussed on the top ranked ideas. The final decision was discussed and decided by TD and the supervisory team.

As highlighted earlier in this chapter (Section 5.4.2), consensus is not the sole aim of a Kantian Delphi, although it can be used. Therefore, it was judged that to support selection of a final behaviour, consensus would be reviewed alongside inspection of discordance between the ranked ideas by each panel. The ideas were assessed to establish whether they reached a 60% level of consensus - i.e., 60% of the panel ranked the idea in their top three. Although lower than a more commonly selected 70% level[263], this consensus level is utilised in Health Sciences[256] and reflects the idea that consensus is influenced by panel heterogeneity as was the case in this study, as well as the reduced emphasis on the need to identify consensus in a Kantian Delphi[239].

5.4.8.3 Reflexivity

As highlighted earlier in the chapter (Section 5.4.8.1) whilst thematic analysis specifically is recommended in qualitative Delphi studies[257], it is acknowledged that there is relatively little written about how best to engage with this analysis in Delphi research[258]. Given this, it is not unsurprising that reflexivity receives limited discussion in the Delphi literature. The choice to utilise codebook thematic analysis was therefore used to guide this choice and given that researcher reflexivity plays a pivotal role in codebook thematic analysis, it was undertaken in this study to reflect on the potential impact that my position of the researcher may have the choices and outcomes of this research.

5.4.9 Ethical Approval

Ethical approval for the study was sought and approved by the City, University of London, School of Health Sciences Research Ethics Committee (REF: ETH2021-0292) (Appendix 13). Recruitment of healthcare professionals was also approved by the Health Research Authority (REF: 20/HRA/6187) (Appendix 14) with East London NHS Foundation Trust (Tower Hamlets) providing confirmation of capacity and capability (Appendix 15).

5.5 Results

5.5.1 Participant Characteristics

Recruitment methods preclude a clear statement of the number of individuals approached or exposed to the study. It is however possible to identify that all service users and carers were recruited through Call for Participants, there were 110 study page views. Furthermore, emails were disseminated to all members of the community mental health teams in East London Foundation Trust (ELFT) which employs 6,500 permanent staff[264], although these are not all clinical, and may not be indicative of the number of individuals who were exposed to the study. In total, 21 individuals participated in round 1 and 18 in round 2. Reasons for non-participation are unknown as participants were free to withdraw without giving reason.

The panel in round one consisted of four service users with of SMI/T2D, nine carers for adults with SMI/T2D and eight healthcare professionals who provide care to adults with either T2D or SMI. Full details are provided in Table 23. Thirteen participants were female. Bipolar disorder (*n*=5, 22%) was the most common diagnoses for those participating, with either personal lived experience or experience as a carer. Length of time since diagnosis averaged 6.8 years for SMI and 6.3 years for T2D. Carers most frequently identified caring for a parent *(n=4, 36%)* or child *(n=4, 36%)*. Mental Health Nurses (n=3, 33%) or Mental Health Liaison Nurses (*n=2, 22%*) most frequently participated. Other participant roles included a General Practitioner, Assistant General Manager of Adult Mental Health Services, and Mental Health Care Coordinator. Three of the participants noted multiple mental health roles of relevance in their past experiences. Most health professionals (*n=6, 66%*) had more than 5 years' experience in their current role as well as overall in their professional career, with one participant having more than 15 years' experience.

Survey two was completed by all four service users (100% retention), eight carers (89% retention) and five health professionals (56% retention) from round one. An additional health professional participated ranked ideas in round two, who had not provided ideas in round one. The overall retention rate for survey two (considering only those who participated in survey one) was 81%, the general characteristics remained similar.

Table 23: Participant characteristics for round one and two of the Delphi Study 3

SERVICE USER		
	Round One (*n*=4)	**Round Two (*n*=4)**
Age	31.5 years (average) 29-39 (range)	
Gender	M 4 (100)	
Ethnicity	British South Asian 1(25) Caribbean 1(25) Black British 2(50)	
SMI diagnosis	Bipolar 1(25) Schizophrenia 1(25) Schizoaffective Disorder 2(50)	
CARER		
	Round one (n=9)	**Round two (n=8)**
Age	27.7 years (average) 20-42 (range)	27.1 years (average) 20-42 (range)
Gender	M 3 (33) F 6 (66)	M 2 (25) F 6 (75)
Ethnicity	Black American 1(11) White 3(33) Asian Pakistani 1(11) Black British 2(22) White & Black African 1(11) Black Caribbean 1(11)	Black American 1(12.5) White 2(25) Asian Pakistani 1(12.5) Black British 2(25) White & Black African 1(12.5) Black Caribbean 1(12.5)
Care For	Partner 1(9) Parent 4(36) Grandmother 1(9) Aunt 1(9) Multiple (Partner, Child, Parent 1(12.5)	Partner 2 (25) Parent 3(37.5) Grandmother 1(12.5) Aunt 1(12.5) Multiple (Partner, Child, Parent 1(12.5)
SMI Diagnosis (of those they provide care for)	Not Specified – severe mental illness 1(11) Bipolar 4(44) Schizophrenia 2(22) Psychosis 1(11) Schizoaffective Disorder1 (11%)	Not Specified – severe mental illness 1(12.5) Bipolar 3(37.5) Schizophrenia 2(25) Psychosis 1(12.5) Schizoaffective Disorder1 (12.5)
HEALTH PROFESSIONAL		
	Round one (*n*=8)	**Round two (*n*=6)**
Age	51 years (average) 27-60 (range)	56 years (average) 48-60 (range)
Gender	M 1 (12.5) F 7 (87.5)	M 2 (33) F 4 (66)
Ethnicity	Pakistani British 1(12.5) African 1 (12.5) British Black African 2(25)	British Black African 2(22) White 3(33) Asian 1(11)

	White 3(37.5) Mixed 1(12.5)	Mixed 1(11)
Role	Mental Health Nurse 3(37.5) Mental Health Nurse (Liaison) 2 (25) Care coordinator 1 (12.5) Assistant General Manager Adult Mental Health Services/Mental health nurse 1(12.5) General Practitioner 1 (12.5)	Mental Health Nurse 3(50) Diabetes Nurse Specialist 1(16) Assistant General Manager Adult Mental Health Services/Mental health nurse 1(16) General Practitioner 1 (16)
Years of service	1-5 years 3 (37.5) >5 years 4 (50) >30 years 1 (17)	1-5 years 2 (33) >5 years 3 (50) >30 years 1 (17)

5.5.2 Round 1: Idea Generation

Completion of the first survey resulted in 111 ideas, of which 69 ideas were focussed on health professional behaviours. The remaining 42 ideas were either focussed on service-user behaviours (*n*=20) e.g., “eat healthily”; or were insufficiently specified (*n*=22) i.e., “improve care generally”, or targeting of a potential determinant of behaviour such as knowledge or stigma, rather than specifying which behaviour these are likely to affect.

The 69 behaviours that related directly to health professionals were examined and ideas consolidated where there were similarities in responses. An example of this is the combination of the responses 1) “Support from the family” and “The family members of the patients should know as much as possible about the knowledge of diabetes so as to help the patients better implement the treatment plan of diabetes” were combined into “Provide consultations which engage family members to support diabetes management”. This process resulted in 29 health professional behaviours which were sent to participants for ranking in round 2. The 29 ideas were linked to nine themes; personalised care contained the most ideas (*n*=6) with three themes that contained only one idea (1) Appointments, 2) Dietary advice and

3) Wellbeing. Table 24 contains a list of all themes and associated ideas and Appendix 16 contains the full list of ideas, themes and resulting refinement for the second round.

Table 24: Table listed the identified themes and associated narrowed list of ideas which were taken forward for ranking in Phase 2.

Theme	**Behaviour**	**Contributed by *n***
Appointments	Regularly schedule and monitor physical health	11
Care process	Regularly assess cholesterol, blood pressure and medication	3
	Ensure discharge of individuals is not related to frustrations around poor engagement	1
	Ensure foot care is regularly and closely monitored	1
Collaborative Care	Proactive service which initiates meetings between all professionals involved in care	2
	Create a treatment plan collaboratively with the diabetes and mental health teams to ensure a focus on both	1
	Improve liaison between mental health care team and diabetes nurses	1
	Improve liaison/communication between all members of the care team (i.e., physical, and mental health professionals)	1
	Set goals for the individual as a whole care team (i.e., physical, and mental health professionals)	1
Dietary Advice	Provide guidance on distraction techniques to focus on eating	1
Relationships	Focus on the interaction between service user and healthcare professional e.g., to improve the interaction to ensure it is friendly, not disregarding fears and communication	9
	Provide consultations which engage family members to support diabetes management	3
	Healthcare professionals talk positively to service users	1
	Conduct consultations which provide one on one information giving	1
Self-management provision	Offer self-management education programmes and support	4
	Offer weight management education and support	1
	Offer lifestyle modification education and support	2
	Provide consultations which empower the service user and make them feel confident in diabetes management	2
	Provide consultations which promote self-care and self-management focussing on the daily life of the individual	2

Personalised care	Set individual goals relevant to the service user	3
	Ensure information provided in consultations is easy to understand and appropriate for the individual	1
	Offer mental health support to target comfort eating	1
	Provide a guided, personalised, exercises programme	1
	Provide individualised healthy eating plans which cover foods which should eaten less frequently.	1
Provision of care at different times	Use a proactive approach to care focussing on difficult times such as mental health breakdown	7
	Focus on the time of diagnosis as time to provide care	7
	Offer more intensive support at critical times of diabetes management - e.g., when continuous uncontrolled high blood sugar	1
	Provide additional support when physical health (diabetes) affects mental health	1
Wellbeing	Offer advice and guidance on emotional wellbeing	1

5.5.3 Round 2: Ranking

In total, 24 (83%) of the ideas were selected in the top three ranking by at least one participant, with 15 (52%) different ideas prioritised as the number one idea. Service users and carers selected 19 of the 29 ideas (66%) within their top three. The top three ideas and the number of panel members who selected the idea are presented in Table 25.

Table 25:Top Three Prioritised Ideas Based on Total Score by Service Users and Carers (n=12)

Theme	Idea	Total Score	First Place n(%)	Top Three *n(%)*
Collaborative Care	Create a treatment plan collaboratively with the diabetes and mental health teams to ensure a focus on both	9	2 (17)	4 (33)
Provision of care at different times	Use a proactive approach to diabetes care focussing on difficult times such as mental health breakdown	8	1 (8)	4 (33)
Personalised care	Provide individualised healthy eating plans which cover foods which should be eaten less frequently	8	1 (8)	4 (33)

Health professionals identified fewer ideas (n=15, 42%) with four ideas jointly prioritised in third position, presented in Table 26 based on total score. The ranking of all ideas can be found in Appendix 17.

Table 26: Prioritised Ideas Based on Total Score by Health Professionals (n=6)

Theme	Idea	Total Score	First Place *n*(%)	Top Three *n*(%)
Collaborative Care	Improve liaison between mental health care team and diabetes nurse	6	2 (33)	2(33)
Collaborative Care	Create a treatment plan collaboratively with the diabetes	4	0 (0)	2 (33)

	and mental health teams to ensure a focus on both			
Provision of care at different times	Focus on the time of diagnosis of diabetes to provide more intensive support	3	1 (17)	1 (17)
Personalised care	Offer lifestyle modification education and support	3	1 (17)	1 (17)
Personalised care	Set individual goals relevant to the service user	3	1 (17)	1 (17)
Self-management provision	Provide consultations which promote self-care and self-management focussing on the daily life of the individual	3	1 (17)	1 (17)

There was only one idea “Create a treatment plan collaboratively with the diabetes and mental health team to ensure a focus on both” which was ranked in the top three by both service users and carers, and health professionals. The remaining eight ideas in the top three ranking position differed between service users and carers, or health professionals. Figure 8 illustrates the ideas and the total scores, comparing these across service users and carers, and health professionals.

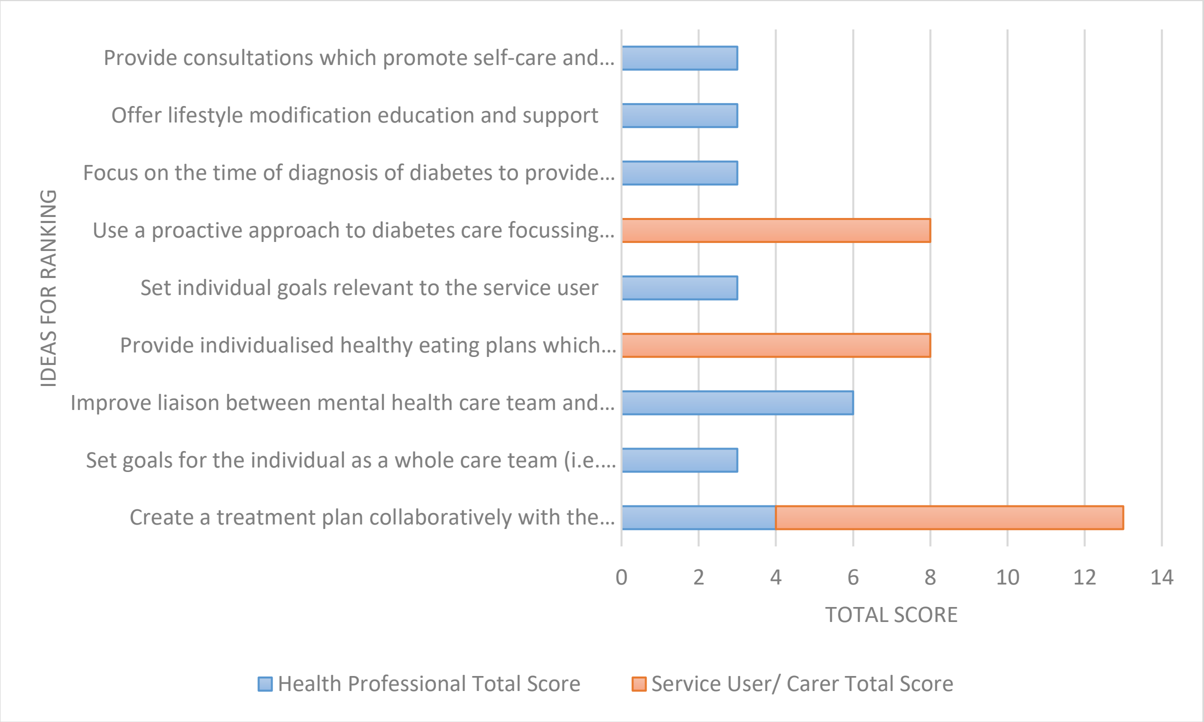


Figure 8: Graph showing the top ranked ideas and the total scores obtained, by service users and carers, and Health Professionals

The completion of the second round of the Delphi resulted in a short list of behaviours. As consensus was not achieved for behaviour selection, as proposed the top ranked ideas were reviewed using the target behaviour prioritisation guidance in the Behaviour Change Wheel[108] alongside review of discordance in ranking as is appropriate for a Kantian Delphi[239].

5.6 Step 2 Select the target behaviour

Table 27 outlines the outcomes of the prioritisation assessment as well as evidence of discordance between the health professional panel and the service user and carer panel. Following discussion with the supervisory team, eight of the nine ideas were identified as being unacceptable (using terminology from the Behaviour Change Wheel[108]), as they were targets of current research thus offering limited potential to add value and improve T2D care at this time . A brief discussion of these assessments is provided after the table.

Table 27: Prioritisation assessment of nine shortlisted behaviours including prioritisation criteria as provided by the Behaviour Change Wheel and evidence of discordance

Potential target behaviours relevant to improving T2D care for adults with an SMI	**Impact of behaviour change**	**Likelihood of changing behaviour**	**Spillover score**	**Measurement score**	**Discordance**	**Outcome**
Theme 1: Collaborative care						
Create a treatment plan collaboratively with the diabetes and mental health teams to ensure a focus on both	Not acceptable	N/A	N/A	N/A	No	Not acceptable
Set goals for the individual as a whole care team (i.e., physical, and mental health professionals	Not acceptable	N/A	N/A	N/A	Yes	Not acceptable
Improve liaison between mental health care team and diabetes nurse	Not acceptable	N/A	N/A	N/A	Yes	Not acceptable
Theme 2: Personalised care						
Provide individualised health eating plans which cover foods which should be eaten less frequently	Not acceptable	N/A	N/A	N/A	Yes	Not acceptable
Set individual goals relevant to the service user	Not acceptable	N/A	N/A	N/A	Yes	Not acceptable
Theme 3: Self-management provision						
Offer lifestyle modification education and support	Not acceptable	N/A	N/A	N/A	Yes	Not acceptable
Provide consultations which promote self-care and self-management focussing on the daily life of the individual	Not acceptable	N/A	N/A	N/A	Yes	Not acceptable
Theme 4: Timing of care						
Use a proactive approach to diabetes care focussing on difficult times such as mental health breakdown	Very promising	Very promising	Very promising	Promising	Yes	Very promising
Focus on the time of diagnosis of diabetes to provide more intensive support	Not acceptable	N/A	N/A	N/A	Yes	Not acceptable

5.6.1 Theme 1. Collaborative care

Collaborative treatment planning between both mental health and diabetes care teams was prioritised by both service users and health professionals. Both the service user and carer panel, and health professional panel ranked “Create a treatment plan collaboratively with the diabetes and mental health teams to ensure a focus on both” in the top three. The ability to “improve the liaison between the mental health care team and diabetes nurse” and “Set goals for the individual as a whole care team (i.e., physical and mental health professionals)” was however only selected by health professionals highlighting discordant ideas. Across all three ideas, the impact of behaviour change was rated as unacceptable as there is already considerable research being undertaken to target collaborative care[86,265,266] and as such there is limited scope to add to this important field which would enable improvements in T2D care for adults with an SMI.

5.6.2 Theme 2: Personalised care and Theme 3: Self-management provision

The themes of personalised care and self-management provision were considered concurrently. Similarly, all ideas were rated as unacceptable for the criteria of impact of behaviour change, as all these ideas are being targeted by current research. Currently, the suitability of structured diabetes self-management education programmes for those with SMI is currently being researched as part of the National Institute for Health Research funded DIAMONDS project[267,268]. DIAMONDS has developed a structured self-management education programme tailored to address the barriers faced by adults when managing these comorbid conditions[267,268]. There is a focus on the creation of individualised goals and modified lifestyle advice[267] which thus also addresses the priorities within the personalised care theme. Therefore, as there is research currently being conducted which tackles the ideas ranked within the two themes, this makes their selection unacceptable given the likely limited scope for adding to improvements in the T2D care of adults with an SMI..

5.6.3 Theme 4: Timing of care

Providing T2D care at differing times was identified by both panels. Service users and carers selected the importance of a proactive approach to T2D management during challenging times for a person with an SMI. Whereas health professionals identified the time of T2D diagnosis as a time for more intensive support.

The DIAMONDS research programme[267,268] has focussed on the development of a structured self-management education programme for individuals with T2D and an SMI. Whilst the proposed timing of delivery of this education programme is not evident in the literature, currently self-management education is offered at the point of diagnosis of T2D (or at least within 12-months) [32]. It is therefore assumed that this education programme will be offered at a similar time, thus this research will address the idea "Focus on the time of diagnosis of diabetes to provide more intensive support", creating limited opportunity to add to the improvements in T2D care for adults with an SMI.

The idea selected by service users and carers (Use a proactive approach to diabetes care focussing on difficult times such as mental health breakdown) has been identified in previous literature. Findings from service user experiences describe the need for more intensive support for T2D when service users' mental health deteriorates[57,59,60,64]. The importance of T2D care for services users during a mental health relapse is further underscored by the findings of the current study, despite not being selected by any of the health professionals. Findings from the systematic review of the barriers and enablers of delivery and organisation of T2D care for adults with an SMI[269] (Chapter 3) found that increased severity of SMI symptoms was likely to act as a barrier to the provision of T2D care. Whilst service users (and carers) are clear that there is a need for more intensive T2D support during exacerbations of SMI symptomology, health professionals are less likely to provide this support. There appears to be limited literature exploring how best to provide physical health support, including T2D support, at times of mental health relapse. Furthermore, as outlined in Chapter 1 (Section 1.1.4), in the UK, current provision of T2D care for adults with an SMI should follow standard NICE guidance for diabetes (NG28)[32]. The results of this study support previous suggestions[45] that there is a need for additional support outside that which is currently mandated in NICE guidance(NG28)[32].

In summary, the importance of this idea to service users and carers, alongside limited prior literature, highlights that research exploring how, by whom, and when additional T2D support could be provided during mental health deterioration, has the potential for meaningful impact. Therefore, the idea "A proactive approach to diabetes care focussing on difficult times such as mental health breakdown" was the selected target behaviour.

5.6.4 Step 3 Outcome: Specify the target behaviour

The third step of the Behaviour Change Wheel requires consideration of the following questions: 1) who needs to perform the behaviour, 2) what the person needs to do differently to achieve the desired change, 3) when they will do it, 4) where will they do it, 5) how often will they do it and 6) with whom will they do it.

Specification of the target behaviour was informed by multiple sources including discussion with the supervisory team, input from two health professionals (one with mental health experience and a second with diabetes care experiences), data from the Delphi study and existing literature. The specification is discussed below with a summary provided in Table 28 at the end of the section.

The language used by participants was retained for the second round of ranking. The term "breakdown" required further consideration and following discussion with the supervisory team and review of the literature[57,59,60,202], it was identified that relapse, but not crisis, was the appropriate time for this intervention (***When***). The difference between these terms was used to distinguish between when an individual was experiencing an increase in their mental health symptoms suggesting a deterioration, but was not experiencing a crisis e.g., they were not at risk of immediate harm, suicidal or requiring detainment under the Mental Health Act (1983). A RAG (Red, Amber, Green) rating of risk is often applied[270], with a crisis existing in *red*, therefore any intervention to support T2D would be carried out in *amber* and/or *green*. This focus helped to identify that an intervention would be useful when provided by a mental health professional (***Who***) in a community setting (***Where***) (as this would not target those at risk of harm requiring hospitalisation or requiring a section 2 of the Mental Health Act, i.e., compulsory admission[271]) and would be advantageous if delivered at each relapse episode (***How often***). Beyond the attention on T2D care during a relapse specifically predicating a focus on mental health professionals in a community setting; this choice is supported by existing literature. For example, community mental health nurses have more face-to-face contact with individuals with an SMI[272] , mental health nurses are willing to provide increased physical health support[83,273] and service users' have expressed a preference for T2D support from mental health professionals, particularly mental health nurses[57]. Furthermore, the changing landscape of mental health services, with a renewed focus on community care and support to live well in communities[78] creates an opportunity to explore and embed T2D care for adults who are experiencing a relapse of their SMI (**With Whom**), provided by community mental health nurses(***Who***).

It was important to identify specific behaviours (***What***) that would be appropriate and feasible during a relapse. Across NICE guidelines on management of schizophrenia and other psychoses[3], bipolar disorder[9] and T2D[32], there is no specific reference to ongoing management of T2D during a relapse of an SMI. The Clinical Knowledge Summary on managing a relapse of an established psychotic disorder requires assessment of risk of harm to self or others[274]. Alongside this it is advised that management is carried out according to the care plan (or equivalent) and advance statement of the service user[274]. The advance statement is written and signed by the service user is well and sets out how they wish to be treated if they become ill in the future[274]. Selection of specific behaviours therefore could not be informed by current care guidance and would therefore constitute new behaviours being carried out.

As the target selected was focussed on provision of T2D care ("Use a proactive approach to **diabetes care** focussing on difficult times such as mental health breakdown"), the guidelines on management of T2D[32] provided a list of possible care behaviours to be carried out during relapse of SMI. The Behaviour Change Wheel[108] guidance advises intervening intensely on only a few behaviours in the first instance. As highlighted in chapter 1 (Section 1.1.3) T2D care comprises multiple care behaviours thus it was necessary to identify a subset of this management that could be delivered during relapse of SMI. Using existing evidence, the results of the Delphi, and in collaboration with two health professionals (a mental health professional and diabetes specialist nurse) three specific target behaviours were identified which would constitute a "light-touch" proactive approach to T2D care potentially deliverable during relapse. These were 1) HbA1c monitoring, 2) referral to other services, and 3) provision lifestyle advice.

HbA1c monitoring was identified as a proactive approach by the health professionals as it provides detailed information on glycaemic control (over 10–12-weeks[275]) during periods of relapsing SMI symptomology. Furthermore, it does not require fasting, which is potentially challenging for individuals with an SMI[275], more so arguably owing to links between comfort eating as a coping strategy[27]and SMI relapse. Whilst HbA1c monitoring was identified as a suitable behaviour target, critically there is the need to interpret HbA1c values and ensure timely referral to relevant medical colleagues, e.g., GPs or secondary care diabetes teams. For this reason, onwards referral was selected as the second target behaviour. This target behaviour was selected as discussion with the health professionals identified that the wider care team (i.e., those outside of the mental health team – particularly the secondary care diabetes team) may not be aware of the relapse being experienced and therefore the potential risk to T2D stability. Finally, the third behaviour - the provision of lifestyle advice, was selected as service users and carers identified in this Delphi study that the challenge of dietary management is an area for improvement. Although this idea was not specifically linked to provision during relapse, existing literature (discussed in Chapter 1. Section 1.2) highlighted the challenges of dietary management and emotional eating as a coping strategy particularly in the face of relapse related stressors which are often overwhelming[55,57,73,202,276]. The NICE guidance for management of T2D in adults[56] outlines that dietary advice for those with T2D should be the same as the general population (e.g., eating high-fibre, low-glycaemic-index sources of carbohydrates, eating oily fish etc.). Collaboration with the two health professionals identified that dietary advice would not be discussed alone but in conjunction with other lifestyle advice (e.g., exercise, alcohol intake and smoking), confirmed by NICE guidance[56]. These provide a core set of advice guidelines which are delivered in conjunction and reflect the reality of T2D care provision, thus lifestyle provision was selected as the third target behaviour. These three specific behaviours reflect a pragmatic set of behaviours that could be enacted by mental health professionals during relapse to provide a framework of ongoing T2D support for individuals with an SMI. A summary of the specified target behaviour is provided in Table 28.

Table 28: Idea Specification

Questions	***Specification***	***Decision support source***
Who needs to perform the behaviour?	Community mental health nurses	Delphi outcome Existing literature
What does the person need to do perform the behaviour?	1) HbA1c monitoring including blood taking and inspecting HbA1c values 2) Provision of lifestyle advice to support T2D stability (diet, exercise, alcohol, and smoking) 3) Referral to other services as required (I.e., GP or secondary diabetes care team	Discussion with mental health professional and diabetes nurse specialist Existing literature Delphi outcome
When do they need to do it?	During a SMI relapse	Delphi outcome Existing literature Supervisory team discussion
Where will they do it?	In a community mental health care setting	Delphi outcome Existing literature
How often will they do it?	Every time a service user experiences a relapse	Delphi outcome Existing literature
With whom will they do it?	Service user (recipient) and other professionals (e.g., GP or diabetes secondary care team) for referral.	Discussion with mental health professional and diabetes nurse specialist Existing literature Delphi outcome

5.6.5 Strengths and limitations

This study explored the priorities of service users, carers, and health professionals to support identification of a target behaviour to improve T2D care for adults with an SMI. The inclusion of service users and carers in setting the priority for this research is a strength of this study. Their inclusion led to the identification of the target behaviour as a gap in the wishes of service users and carers for additional T2D support during relapse was not identified by health professionals. Without the involvement of service users and carers this important area of research would not have been identified. The involvement of a range of stakeholders in the setting of research priorities is beneficial as it can minimise the chances of research options being overlooked[277]. As this project is intended to design an intervention, the involvement of service users, carers, and health professionals in establishing the intervention focus supports a crucial link between the needs of those that will implement the intervention and those that will benefit. This is suggested to increase the overall credibility as well as potentially having a greater impact on health and health equity[278,279], a fundamental tenet of this project. Finally, the adoption of a Kantian Delphi enabled the involvement of a diverse range of participants as well as synthesis of a wide range of ideas to meet the aims of the project.

The sample was designed to be representative of key health professional roles and disciplines, as well as service users and carers. This was widely achieved with participants having experience of a range of SMI diagnoses either personally or within a carer role capacity. Health professionals were recruited with experience of primary and secondary care, and management positions, additionally over half the health professionals had more than five years' experience and one participant over 15 thus bringing considerable knowledge and experience to the panel. Whilst care was taken to purposively sample health professionals to ensure that a cross-section of those involved in care of people with T2D and/or SMI were included the health professional sample predominantly comprises professionals working in a mental health setting. It may be that priorities would be different if the sample were different and thus identifying priorities for different teams (e.g., in diabetes secondary care teams or primary care providers, e.g., GPs), or in other aspects of care delivery e.g., supported housing for adults with an SMI, could be a beneficial focus for future research priority setting. Fortuitously, there is currently a shift in the provision of primary care for T2D[280] and cardiovascular risk for adults with an SMI[281] through the development of UCL Partners' Proactive Care frameworks. These frameworks are focussed on large scale prioritisation of clinical activity stratified by patient risk with the aim of reducing GP workload and improving personalised care[282], thus closely aligned with priorities identified in this study.

Although information was provided to participants on how to identify a behaviour (Section 5.4.7.1) the top prioritised ideas can be described as broad overall behavioural targets. Online, asynchronous, data collection has many benefits as previously outlined; however, without the guidance offered when meeting with stakeholders face-to-face, the ability to ensure ideas are sufficiently operationalised to be classified as a behaviour were challenging. This may however be equally as impacted by the language of the Behaviour Change Wheel[108] which may not be suitable for those without prior knowledge of this field. Whilst care was taken to provide examples from existing studies to clarify terminology[255] the considerations suggested when ranking behaviours, e.g., *"How likely it is that the idea will result in a trickle effect and have positive and negative impacts on other behaviours"* may have been challenging to interpret. The use of a synchronous data collection would have provided opportunities for clarity which were not possible with an asynchronous approach. The use of an asynchronous method of data collection was chosen to both address issues of recruitment from time-pressured stakeholders as well as power imbalances from previous similar research[241]. In particular the use of a synchronous method could have resulted in an outcome with a greater level of agreement between participants owing to the perception that health professionals would be the more dominant members of the group. The power imbalance between health professionals and patients (or service users) has been highlighted in previous research[241] but is also the central tenet of much of the literature on shared-decision making. Reviews have demonstrated that there is a powerful influence of long-standing normative beliefs about the roles of patients (service users) and health professionals with patients (service users) being passive[283]. It is asserted that these attitudes exist outside of the shared-decision making encounter and reflect a wider social structure which places health professionals in a position of power. This imbalance may result in a compromised position being reached, which relegates the opinions of service users and carers to a lesser status. The use of a separate synchronous approach for each panel could have been utilised which would potentially address this issue, however challenges around time-constraints would not have been addressed. Future data collection using asynchronous methods could utilise messaging technology (e.g. WhatsApp or other online chat forums) to offer feedback to participants and opportunities for them to seek clarity during asynchronous data collection

Utilisation of a Kantian Delphi resulted in the decision to use the number of rounds completed rather than achievement of consensus (defined using standard measures such as agreement of >70% panel) as the parameter for ending the Delphi. It is acknowledged that Delphi studies can serve to identify whether a consensus exists and/or whether there are divergent opinions on a topic area[284], which is important information. The lack of consensus in this Delphi is congruent with the type of Delphi selected i.e. is designed to handle divergence in opinions by reporting on the information available after the selected number of rounds. The lack of consensus serves as an indication that there is a wide range of avenues that those impacted consider important to target to improve T2D care for people with an SMI. This outcome is also synergistic with the need to generate a wide range of ideas for further action when identifying research priorities with stakeholders. Eight, of the nine, identified ideas are subject to previous extensive research or current research (e.g. the DIAMONDS study[267,268]), as discussed in Section 5.6. As such the chosen approach allowed for identification of a novel area of research which was not under investigation.

Whilst the overall retention rate is acceptable for this study (81% participants completed round two), the dropout rate was larger for health professionals (38% for health professionals, 0% for service users and 11% for carers). Whilst this did not affect the ranking nor the selection of the target behaviour thus not affecting the outcomes of this study, it does perhaps highlight the considerable demands placed on health professionals during the COVID-19 pandemic which made ongoing participation challenging.

5.6.6 Reflexive Statement

As detailed in the methods (Section. 5.4.8.3) reflexivity is central to codebook thematic analysis. This method was selected to analyse and organise the initial round of data to create a long list of ideas for ranking by participants in round two. I am an individual without T2D nor an SMI therefore I lack experience both personally in managing these complex conditions but also as a non-clinical student, I also have no experience of supporting management of these conditions. This therefore impacted my decision to ensure the central involvement of those with these experiences in this study. I was also aware of the relatively limited involvement in service users with an SMI and carers in the setting of research priorities as discussed earlier in this chapter (Section 5.4.4 and 5.4.5). This informed the decision to utilise a Delphi method, as a key component is the anonymity of respondents which can address power imbalance, particularly important in a health provider/service user panel. Studying what is termed the "unfamiliar", i.e. when you have no personal experience of the topic being researched, can provide an empowering position for participants as they are positioned as the expert[285], which is of particular importance in marginalised or otherwise disadvantaged populations.[286]. This decision is also congruous with the central involvement of stakeholders throughout the research guided by the INDEX key consideration of *involvement of stakeholders* (Chapter 2. Section 2.5) Whilst this is undoubtedly a strength of this study, my lack of direct experience in combination with my desire to ensure my project aligned to the priorities of service users and carers, potentially more so than that of the professionals, may have impacted the selection of the target behaviour in absence of an objective consensus level being met. Although consensus is not the primary aim of the Kantian underpinned Delphi, it is important to acknowledge my role in the selection of the target behaviour owing to the aforementioned sensitivities.

5.6.7 INDEX key considerations

The active involvement of stakeholders within this chapter and the completion of steps 1,2 3 of the Behaviour Change Wheel offered opportunities for additional key considerations of INDEX guidance including planning development, involving stakeholder and undertake primary data collection. This is reflected in the detail provided in Table 29

Table 29: INDEX key considerations within the completion of steps 1 -3 of the Behaviour Change Wheel[108], including the Delphi data collection from Study 3

Key Issue	Included	Evidence
Plan the development	✓	Completion of steps 1, 2 and 3 of the Behaviour Change Wheel[108] support the development of the intervention
Involve stakeholders	✓	Service users, carers and health professionals recruited
Bring together a team and establish decision making processes	✓	Supervisory team supported search strategy, review of studies for inclusion, and assessment of quality of evidence

Review published research evidence	✓	Published existing evidence used to complement results of the Delphi and support decision making
Draw on existing theories	X	Theory not explicitly utilised in this study
Articulate programme theory	X	Not applicable at this stage
Undertake primary data collection	✓	Delphi
Understand the context	✓	Inherent in the involvement of stakeholder
Pay attention to future implementation of the intervention in the real world	✓	Inherent in the involvement of stakeholder
Design and refine the intervention	X	Not applicable at this stage
End the development phase	X	Not applicable at this stage

5.7 Conclusion

This chapter details the completion of step 1 (Define the problem in behavioural terms), step 2 (Select a target behaviour) and step 3 (Specify the target behaviour) of the Behaviour Change Wheel[108]. A Delphi, guided by Kantian principles, was undertaken with 21 participants, comprising service users, carers, and health professionals, to identify a behaviour(s) that could be targeted to improve T2D care for adults with an SMI. A diverse range of ideas were proposed and ranked leading to the identification of nine ideas across three themes, 1) collaborative care, 2) personalised care and 3) provision of care at critical timepoints.

Although there were commonalties in the themes, the underpinning ranked ideas differed across the panel groups. Only one ranked idea was selected by both service users and carers, and health professionals. The ideas underpinning collaborative care and personalised care are both being actively researched, however targeted T2D support during a mental health relapse, highly ranked by service users and carers, remains largely unexplored within existing intervention literature, and presents an opportunity to make impactful change. Specification of the target behaviour was informed by existing evidence, NICE guidelines, supervisory team discussion and discussion with health professionals. A specific focus on HbA1c monitoring, referral to appropriate services and the provision of lifestyle advice were identified as target behaviours to be delivered during SMI relapse by mental health nurses. The next chapter will detail the completion of the fourth step of the Behaviour Change Wheel; an in-depth behavioural analysis exploring mental health professionals’ perceived barriers and enablers of delivering these target behaviours during SMI relapse.

6 Chapter 6. Stage 4 of the Behaviour Change Wheel: Behavioural analysis

Study 4: What are the perceived barriers and enablers of a "light touch" T2D care package consisting of HbA1c monitoring, lifestyle advice and referral to appropriate services, delivered by mental health nurses during an SMI relapse?

6.1 Prologue

Involvement of service users, carers and health professionals helped to identify that an intervention supporting proactive T2D care during times of difficulty, specified as during an SMI relapse has potential for adding value to current care. Further elaboration using existing evidence and discussion with health professionals knowledgeable and experienced in mental health and diabetes care identified three specific target behaviours - 1) HbA1c monitoring, 2) provision of lifestyle advice to support T2D stability and 3) referral to appropriate services, could be a "light-touch" proactive approach to T2D care during SMI relapse. This is proposed to be in addition to existing NICE guidance[3,9,32], which currently does not specify monitoring of T2D during relapse. It is proposed to be delivered by mental health nurses in the community during every SMI relapse episode. This chapter will focus on the completion of the fourth step of the Behaviour Change Wheel[108], a behavioural analysis, conducted using an interview study with mental health professionals who have experience of working in a community setting and supporting adults with an SMI. The interviews focus on identification of potential barriers and enablers of the of the three target behaviours. The analysis was both inductive (codebook thematic analysis) and deductive (framework analysis) using the Theoretical Domains Framework to build a detailed picture of the barriers and enablers of these target behaviours during relapse, as well as identify any contextual moderators of the proposed intervention.

The identified important domains of the Theoretical Domains Framework will become the focus of intervention development as part of this PhD detailed in Chapter 7.

6.2 Introduction

The fourth study was an interview study conducted to complete the fourth step of the Behaviour Change Wheel (Figure 9).

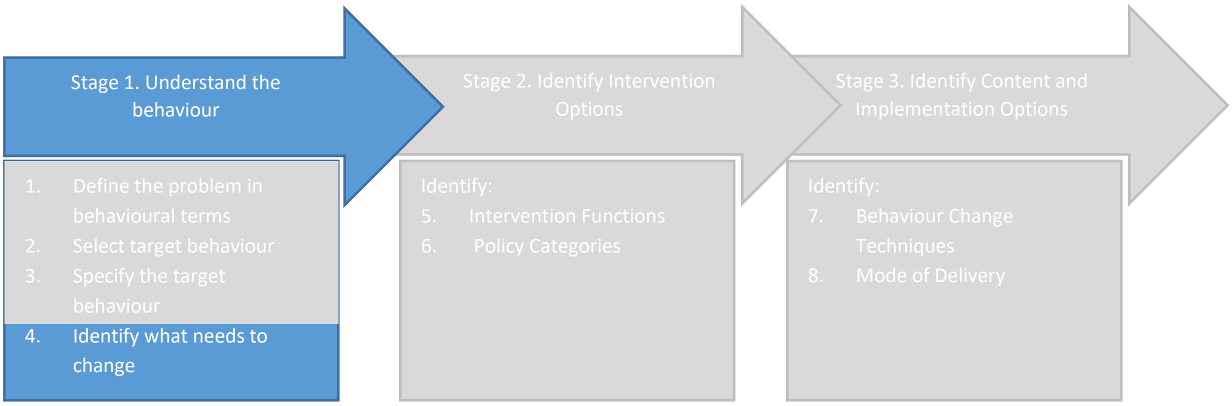


Figure 9: Steps of the Behaviour Change Wheel completed in Study 4

The fourth step in the Behaviour Change Wheel is designed to support an understanding of what needs to change in the environment and/or individual in order to achieve the desired outcome[108]. This important step is often over-looked in intervention design, with the Behaviour Change Wheel authors suggesting that a more accurate analysis will likely result in an intervention which will change behaviour in the desired direction[108].

6.2.1 Aim and Objectives

Study 4 aimed to identify the barriers and enablers of the three proposed target behaviours, as perceived by mental health professionals. This was achieved through the following objectives:

1. Identify mental health professionals' perceived barriers to and enablers of 1) HbA1c monitoring, 2) providing lifestyle advice and 3) referral to external services, whist supporting an individual through relapse of their SMI
2. Extract barriers and enablers and map these onto the 14 domains of the Theoretical Domains Framework
3. Assess the relative importance of each domain in relation to the three target behaviours to identify domains to be targeted by the subsequent intervention
4. Analyse any data not related to the target behaviours to identify any potential contextual moderators of the subsequent intervention

6.3 Method

6.3.1 Study Design

The study design was qualitative semi-structured interviews. Interviews are an appropriate method for identifying barriers and enablers of behaviour[109]. They are of particular relevance when intended for use in supporting intervention development where richer data can support better insight into the needed content of theory-informed interventions[109]. As highlighted in Chapter 5 (Section. 5.6.3) there is limited literature specifically focussing on health professionals' perceptions and experiences of providing T2D care during relapse of a service users' SMI, thus making interviews a suitable method choice. Furthermore, knowledge of relationships between domains of the Theoretical Domains Framework may serve to better inform more effective behaviour change interventions[206] and this is best obtained through in-depth exploration provided by interviews, further supporting selection of interviews. Finally, the utility of interview studies for understanding barriers and enablers to be targeted in subsequent intervention development has been demonstrated in a range of existing literature, e.g.,[287–289], underscoring the suitability of this method. In summary, the exploratory nature of the aims of this study supports the use of an interview study to allow a more detailed analysis and understanding of T2D care during SMI relapse.

6.3.2 Eligibility

- Mental health professional (defined as any mental health professional who has delivered information, guidance, screening, or treatment to adults with SMI and T2D) with experience of providing care for people with a diagnosis of SMI
- Experience of working in a community setting in the UK
- Aged 18 years or over
- Able and willing to give informed consent

6.3.3 Recruitment

Previous introductions to known personnel within ELFT (Tower Hamlets) were utilised, this included Senior Operational Leads for the Community Mental Health Teams, the Primary Care Lead and Quality Improvement Lead. Additionally, contact was made with research champions within the Trust and previous participants. Details of the study were emailed by TD, with individuals asked to forward on the email to those who would be appropriate and to contact TD for further information and/or to participate.

Additional recruitment was carried out using snowball sampling whereby those that participated were asked to put TD in touch with other colleagues who would be happy to hear more about the study and consider participation.

Finally, national organisations such as Royal Colleges and appropriate charities (MQ Transforming Mental Health and Diabetes UK) were approached and asked to promote the study through their usual procedures. This included their digital platforms containing links to the study and social media promotion.

6.3.4 Procedure

All participants were sent the participant information sheet (PIS) (Appendix 18) when they contacted TD. They were offered the opportunity to ask questions and asked to send back the informed consent when all questions, if asked, were answered satisfactorily. Participants provided consent to confirm that they understood the information provided in the PIS and that participation was voluntary, that they had sufficient time and opportunity to ask questions, that they could withdraw at any time, that anonymised quotes could be published in peer-review journals, conference papers and completed thesis and finally to participate in the study.

Recruited and consented participants were interviewed by TD remotely utilising Microsoft Teams with which City, University of London has a license agreement. All audio files were sent for transcription to Essential Secretary using their secure AMS file transfer portal. Analysis of transcripts was undertaken in NVivo 12 and Microsoft Excel.

6.3.5 Interview Schedule

The semi-structured interview schedule (Appendix 19) was influenced by pre-existing interview schedules[157], suggestions for optimising the use of the Theoretical Domains Framework within qualitative research[206] and expertise within the supervisory team. Rather than focussing on asking questions related to each separate domain of the Theoretical Domains Framework , questions focussed on eliciting opinions or experiences of T2D care which could be coded deductively using the Theoretical Domains Framework. This approach has been successfully utilised in existing literature(e.g.,[290]) and linked to data coded outside of the Theoretical Domains Framework[206], which can be used to understand wider contextual moderators of the target behaviours. Whilst there is the potential to overlook some of the domains of the Theoretical Domains Framework by not asking questions specifically about the domains, the interview schedule did ask questions about barriers and enablers with follow up prompts related to the domains of the Theoretical Domains Framework. Furthermore, the high level of researcher (TD) familiarity with the framework supported the prompts and follow-up questions. This flexibility is advantageous when the enquiry is exploratative[206]. It can support formation of an unconstrained theoretical understanding and support an understanding of context by allowing participants to openly discuss their perceptions and experiencesl[206]. Understanding context is a key consideration of the INDEX guidance as discussed in Chapter 2 (Section. 2.9), which is often overlooked[98]. Having an interview schedule which was sensitive to developing an understanding of wider contextual moderators[206] outside of the target behaviours, was critical.

To support this process an opened ended question format which followed the principle of "funnelling" [291] was used. This is typical of qualitative work whereby interviews are broad and less structured before becoming more focussed[291]. This enabled an in-depth exploration of experiences of the participant followed by a more nuanced focus on what might be of benefit for intervention development by offering the opportunity for participants to discuss what is important to them with a free-flowing conversation rather than constraining with a prescriptive interview schedule. This also supported experiences and opinions of participants to be foregrounded, which was important given that management of T2D during relapse, from a health professional perspective, is a relatively novel topic.

6.3.6 Analysis

Data analysis was both inductive and deductive, with inductive analysis guided by a codebook thematic analysis[260–262] and deductive analysis following a framework analysis[292] using the Theoretical Domains Framework. The use of the two methods allows for optimum analysis of all data obtained through "funnelled" questioning, which prioritised experiences and opinions over more direct theoretical questioning. Such approaches to analysis allow for factors outside of the Theoretical Domains Framework to be identified, ensuring that context and detail gained from an inductive approach are not 'lost' within a solely deductive approach[206]. This can be of particular importance for research, such as this, which is exploratory in its investigation of influences that affect behaviour[206]. Guidance on the use of the Theoretical Domains Framework also advocates for inductive approaches to analysis, with researchers advised to follow the established method of analysis selection[109]. Furthermore, framework analysis is categorised as a type of (codebook) thematic analysis[292,293], making a combined analysis using these methods suitably complementary.

Both analysis methods have been described as having theoretical flexibility (they are not atheoretical), therefore a clear statement of the theoretical and epistemological position of the research is important[294]. A critical realist position was adopted as it allows for interpretation beyond which is divulged by the participant to identify factors which drive behaviour[295]. This position allows for creation of latent codes and themes which discuss factors underpinning the delivery of the target behaviours. This, arguably, allows development of understanding, which is not directly divulged, or perceived, by participants. The Theoretical Domains Framework was utilised as a framework for analysing data which specifically discussed the three target behaviours provision during relapse. Data which was outside of the three target behaviours during SMI relapse (to identify potential contextual moderators) were analysed using codebook thematic analysis only. Its suitability and rationale for use has been discussed extensively in previous chapters. In order to support identification of contextual moderators data not specifically related to this timepoint was analysed inductively, this focus on the data meant that rather than adopt a theoretical commitment, the epistemological position and question shape the themes[295].

Codebook thematic analysis sits between coding reliability thematic analysis and reflexive thematic analysis, this has been described as a continuum from *small q* qualitative research (or positivist) to *large Q qualitative research* (non-positivist, reflexive)[296]. Codebook thematic analysis is philosophically aligned to a framework analysis[296], in that it is theoretically and epistemologically flexible requiring a clear statement of positionality, and is suited to studies with pre-existing information needs[259]. This flexibility is therefore suitable for the critical realist position adopted in this project. A critical realist approach allows interpretation beyond which is divulged by the participant to identify factors which drive behaviour[295]. A critical realist approach is congruous with the use of the Behaviour Change Wheel[108] as a fundamental tenet is the understanding of the underlying processes (understood in this PhD to be the constructs which underpin the Theoretical Domains Framework), which may not be directly identifiable by participants. Although participants may not be fully aware of these factors, these identified determinants of behaviour are "real". Furthermore, codebook thematic analysis is appropriate for research which requires actionable outcomes, in this case the development of an intervention, and is interested in how personal experiences are located in wider socio-cultural contexts[259], here exploring how wider issues may impact the delivery and outcomes (contextual moderators) of the resulting intervention. To support identification of potential contextual moderators' inductive analysis was undertaken on data not specifically related to the target behaviour. Whilst the methods for each analysis are described separately for clarity, there was overlap as demonstrated in Figure 10.

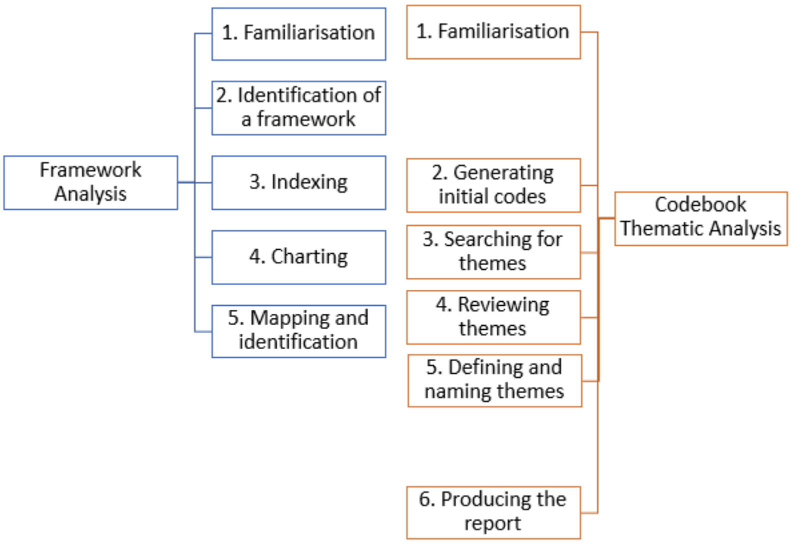


Figure 10: Combining the stages of framework and codebook thematic analysis

6.3.6.1 Deductive Framework Analysis

Familiarisation was supported in multiple ways including re-reading the transcripts whilst listening to the audio file, which also doubled as an accuracy checking process, an independent coding exercise (for deductive coding only discussed in section 6.3.6.3), as well as regularly returning to the transcripts throughout the codebook thematic analysis to support revision of codes and themes. Transcripts were read line by line with codes assigned to the data. Data units consisted of sentences or sections of utterances depending on the flow of conversation. Codes were initially descriptive, summarising a key idea or statement by the participant and stayed true to the overt statement(s) of the participants. The initial descriptive codes were rearranged and sorted in nodes under each Theoretical Domains Framework domain heading as part of charting the data. Where data represented more than one domain, multiple Theoretical Domains Framework codes were assigned. The descriptive coding of the interviews was fluid with the charting of domains. This fluidity owed to familiarity with the Theoretical Domains Framework which meant that when assigning descriptive codes, the domain(s) the data best represented were often within mind and simultaneously coded, e.g., data which described a sense of responsibility for managing mental health during a relapse but not providing dietary advice was descriptively coded as "responsibility for mental but not physical health" and simultaneously coded to the domain *Social/professional role and identity*. Any data not related to barriers or enablers of the three key behaviours was stored separately under a node "not related to the target behaviours" for later codebook thematic analysis. Codes were reviewed under each domain and were grouped together to create a summary of the findings, labelled belief statements, detailing the barriers and enablers. A deductive codebook (Appendix 20) was initially produced but it was acknowledged that this was created for T2D care and not specific to the target behaviours in this study. As familiarity with the data increased examples of the data which supported identification of each domain was included and/or refined. The resulting codebook for deductive analysis included the domains, examples of the codes and illustrative quotes.

6.3.6.2 Identifying Theoretical Domains Framework domains of importance

Identification of Theoretical Domains Framework domain importance, i.e. domains thought to represent the barriers and enablers which influence more strongly the target behaviours, was derived through three sources, 1) frequency of belief statement (the number of participants who contribute to the belief statement), 2) expressed importance of the belief and 3) discordant beliefs, i.e. conflicting positions between beliefs. The three criteria applied were informed by previous literature[109,161,209], and were also used in the systematic review[269], reported in Chapter 3 (Section. 3.4.10). Domains were documented as being of high importance if any of the belief statements met all three criteria across the target behaviours, of moderate importance if they met two or more criteria and of low importance if they met only one. A Venn diagram was used to illustrate the identified moderately and highly important domains for each target behaviour.

The selection of these three criteria were also re-examined for appropriateness considering the theoretical and epistemological position underpinning this qualitative study, which is briefly outlined. Frequency is a positivist notion, and it is accepted that the number of times something is said, or the number of people who said it, is not necessarily congruous with something being important, and so this method was not the sole criteria chosen nor was it the leading criteria. Conversely, the criteria of expressed importance and discord, are understood in part through my interpretation of the participant experience, thus are more aligned to interpretivist research and a critical realist position. Consideration of factors judged to be important required reflection, when using this analysis to identify domains of importance. It also enabled themes to be discussed and presented in a balanced manner by considering conflicting viewpoints. Thus, the adoption of these three methods for identifying domain importance was assessed as congruous with the adopted epistemological position of this research.

6.3.6.3 Independent coding for deductive analysis

Independent coding checks were undertaken for the deductive coding, a process that has been used in other qualitative research using the Theoretical Domains Framework [161,297]. The purpose of this exercise was two-fold: it helped to support replicability in the allocation of data to domains, as well as facilitating reflexive consideration about the interpretation of data through active discussion between TD and KM. A 10% sample of the data was selected at random, equating to one full manuscript, and independently coded by KM. Disagreements in coding were reconciled through discussion between TD and KM, with the option for an additional supervisor with knowledge and experience of the Theoretical Domains Framework (HM) to support decisions if needed. The overall inter-coder percentage agreement was calculated and discussions continued until all domains reached >=60%[109]. The final belief statements were then reviewed by KM. As is appropriate for codebook thematic analysis no independent coding was undertaken for the inductive analysis as this method acknowledges the subjectivity of the researcher in analysis and consensus and inter-coder reliability are not measures of quality[298].

6.3.6.4 Inductive Codebook Thematic Analysis

Inductive analysis was utilised to create both the belief statements within the Theoretical Domains Framework domains as well as code data which did not relate to the target behaviours. The creation of the belief statements is detailed earlier in this chapter (Section. 6.3.6.1). Data which did not relate directly to the target behaviours but provided information about the experience and opinions of participants was coded separately as "not related to the target behaviour". This data were analysed and included as whilst the themes were not related to the target behaviours, and thus coding them as such would not be relevant[206], it provided some important context relating to the perceived responsibility of mental health professionals.

The inductive codebook thematic analysis was undertaken concurrently with the deductive analysis (as demonstrated in Figure 10) and began with data familiarisation and coding. By reading the codes several times, a deeper meaning was created and drawing together several codes helped to identify wider contextual issues of interest. Codes were initially descriptive, however with further familiarisation with the data and codes, further interpretative codes were added. This helped to shape the narrative of the analysis. The descriptive codes summarised what participants were saying, whereas the interpretative codes utilised my subjectivity to illustrate less directly evident patterns and meanings. Codes were reviewed and mapped for their ability to tell a cohesive narrative of participant experience whilst exploring the wider issues of T2D care for people with an SMI that may impact intervention development or provide information on contextual moderators for intervention delivery. Through an iterative process, codes were added and refined as themes were developed and understood. These processes involved rereading each transcript several times to identify whether any codes had been missed and whether the codes appropriately reflected interpretation of the data. This process was supported through the creation of the inductive codebook (Appendix 21). The codebook was used to document the process of analysis and was not used as a tool for measuring reliability[299], as it would typically be utilised in coding reliability thematic analysis. This iterative process was carried out multiple times with revisions to codes which reflected a deeper interpretation of the data, aiming to go beyond semantic descriptions to create latent understanding. As with previous steps, the definition and naming of themes was iterative and fluid with ideas conceptualised multiple times through engagement with the data. Using the node feature in NVivo, data were assigned to codes and grouped together under a theme. This process allowed revision of themes and codes, if upon reflection they were better served elsewhere. Analysis and subsequent writing were an active part of analysis with themes and codes flexible, and adjusted, with deepening engagement with the data. The decision to stop coding was pragmatic, as is appropriate for codebook thematic analysis[299], reflecting a decision that sufficient information was extracted to have an interpretation of the data outside of the target behaviours, and to begin the next steps of intervention development. This decision also marked completion of the codebook.

6.3.7 Sample and data saturation

A sample size range was initially proposed of 10-30 participants. This was based on the anticipated number of professionals who worked within a community mental health team (detailed in Study 3. Section 5.4.6) and allowing for recruitment of individuals with team management or senior management experience. Sampling a range of professionals with varied experience and perspectives was important to support triangulation through different data sources (i.e., perspectives of professionals with different experiences)[300].

The approach for analysis of the data is both inductive using a framework analysis and an inductive analysis using codebook thematic analysis. Demonstration, and appropriateness, of achieving saturation in qualitative analysis is much debated and both types of analysis offer options for achieving data saturation.

For theoretical analysis, such as using the Theoretical Domains Framework deductively, there are suggested processes for determining data saturation and the final sample size[301]. Specification *a priori* of an initial sample for analysis, i.e. 10 interviews, and a proposed *stopping criterion,* again specified *a priori*, detailing the number of additional interviews, suggested to be 3, required for no “new themes or ideas to emerge”[301] (Page 8.). This criterion is likened to the use of 0.05 significance in quantitative studies, but it is acknowledged that such parallels and use may not sit comfortably with all epistemologies[301].

The inductive analysis is guided by codebook thematic analysis and the concept of saturation requires consideration regarding the *type* of thematic analysis (i.e., coding reliability, codebook, or reflexive) [302]. The use of data saturation as a concept is less contested in codebook thematic analysis, than within reflexive thematic analysis[302]. Reflexive analysis sits within the interpretivist camp, situating the researcher central to the production of the analysis. Thus, reaching saturation is argued to be redundant as the knowledge and researcher's immersion in the data will continue to evolve with new information and thus the "end point", i.e., saturation, is an ever-moving goal post. Codebook thematic analysis however sits between positivism and interpretivism, thus depending on the positionality of the research the employment of data saturation may be less incongruent if more closely aligned to positivism, or post positivism[302]. Saturation in codebook thematic analysis can be argued to be achieved when the codebook stabilises (i.e. no new codes are identified) [303]. Unlike saturation for theoretical analysis, there are no *a priori* assumptions on the numbers of interviews, however it has been suggested that 53% of all codes and 75% of high prevalence codes can be identified in the first interview and code level saturation (i.e., codebook stability) reached in nine or fewer interviews[303]. Framework analysis is categorised as a type of codebook thematic analysis[262,292], thus data saturation can be demonstrated through values aligned to codebook thematic analysis. In summary, as a critical realist position was adopted which sits between positivism and constructivism, achieving data saturation, and thus the sample size determination was determined by codebook stability and thus likely to be achieved in nine or fewer interviews.

6.3.8 Reflexivity

Whilst reflexivity is a defining feature of qualitative research[304], and qualitative methods are advocated for use in understanding barriers and enablers of behaviours (e.g.,[108,109]) as well as in practical examples (e.g.,[160,297,305,306]), there is limited attention to reflexivity in these examples. Reflexivity focuses on the explicit and transparent effect of the researcher on the process and resulting analysis, its application however can vary depending on the underpinning theory and methodology[304]. Given the limited attention to reflexivity in literature related to identifying barriers and enablers of behaviour, a focus on reflexivitity guidance underpinned by the selected methods was utilised. As detailed in Study 3 (Chapter 5. Section 5.4.8.3) researcher reflexivity is a critical aspect of codebook thematic analysis as it shares a qualiative philospophy and values with reflexive thematic analysis, including recognising the researcher's subjectivity and contextualised knowledge[296]. Subjectivity is considered a resource within this conceptualisation[307] with an emphasis on the subjectivity of the researcher in the enagegement with theory, data and interpretation[296]; furthermore it supports a critical realist analysis. It is also compatiable with framework analysis, an example of a deductive codebook thematic analysis, whereby the Theoretical Domains Framework is an exisiting explanatory framework through which the data is coded and understood[296]. A reflection on my role within this study and its impact was undertaken and detailed in the discussion section of this chapter.

6.3.9 Ethical Approval

Ethical approval was provided by the School of Health Sciences, City University Ethics Committee (REF: ETH2223-0133 – 18th August 2022) (Appendix 22), Health Research Authority (REF: SCDS01 – 8th September 2022) (Appendix 23) and the ELFT Research and Development Department (Noclor) (REF: SCDS01 – 15th September 2022) (Appendix 24)).

6.4 Results

6.4.1 Participant Characteristics

Ten semi-structured interviews with health professionals were undertaken between 13/09/2022 and 08/12/2022, with interview duration ranging from 10 to 54 minutes and the median interview length of 33 minutes. Owing to recruitment methods it is not possible to identify how many people were approached, however three potential participants did ask for additional information but chose not to participate. In each case, stress and workload constraints were cited as the reason for non-participation.

Over half of the participants (*n*=6, 60%) were female and white British (*n*=7, 70%). The participants had substantial clinical experience, with half of the participants (n=5, 50%) having more than 20 years' experience with two of those having worked for more than 30 years supporting individuals with an SMI. Current and previous roles held by participants were varied but were predominantly mental health nurses (n=5, 50%). Previous roles included working as nurses in crisis support teams, in early intervention in psychosis teams, and on acute inpatient wards. Four participants also had experience of managing teams and/or services who provided support to individuals with an SMI. One participant had participated in the Delphi study. Full details are provided in Table 30.

Table 30: Study 4 Participant Characteristics

Participants (*n*=10)	
Gender	Female 6(60) Male 4(40)
Age	46 (31-58)
Ethnicity	White British 7(70) Asian British 2(20) Black 1(10)
Roles	Community mental health nurse 2(20)

	Assistant General Manager Adult Mental Health Services/Mental health nurse 1(10) Community mental health and learning disability nurse 1(10) Community support worker 1(10) Care coordinator 1(10) Physical health coordinator 1(10) Advanced nurse practitioner 1(10) Clinical practice lead in patient services 1(10)
Length of time as a health professional	>5 years: 1(10) 5-10 years 4(40) 20+ years: 4(40) >30 years: 1(10)

Participants were recruited from different geographical locations with the majority working in London (n=4, 40) or across the north-east of England (n=4,40).

6.4.2 Deductive Analysis: Framework Analysis

6.4.2.1 Assessment of importance

Deductive analysis using the Theoretical Domains Framework resulted in 48 belief statements identified across 13 domains, no data was identified representing the domain *reinforcement*. Three domains (*Social, professional role and identity, Skills,* and *Social influence)* met the criteria for high importance. Five domains (*Knowledge, Beliefs about consequences, Goals, Memory, Attention and Decision Processes and Environmental Context and Resources)* met the criteria for moderate importance. The five remaining domains (*Beliefs about consequences, Emotion, Optimism, Behavioural regulation, and Intentions)* were all identified, but did not meet any of the importance criteria. There were 28 belief statements, which were identified within the highly and moderately important domains. These belief statements, assessments of importance and sample quotes are provided in Table 31. The analysis of the domains of low importance are provided in Appendix 25.

The domains *Knowledge, Social/professional role and identity, and Environmental Context and Resources* were identified as important to all three target behaviours. Seven of the domains identified as of high or moderate importance were linked to the delivery of lifestyle advice. Five domains were identified as linked to HbA1c monitoring and four to referrals. The interplay between domains and target behaviours is illustrated in Figure 11.

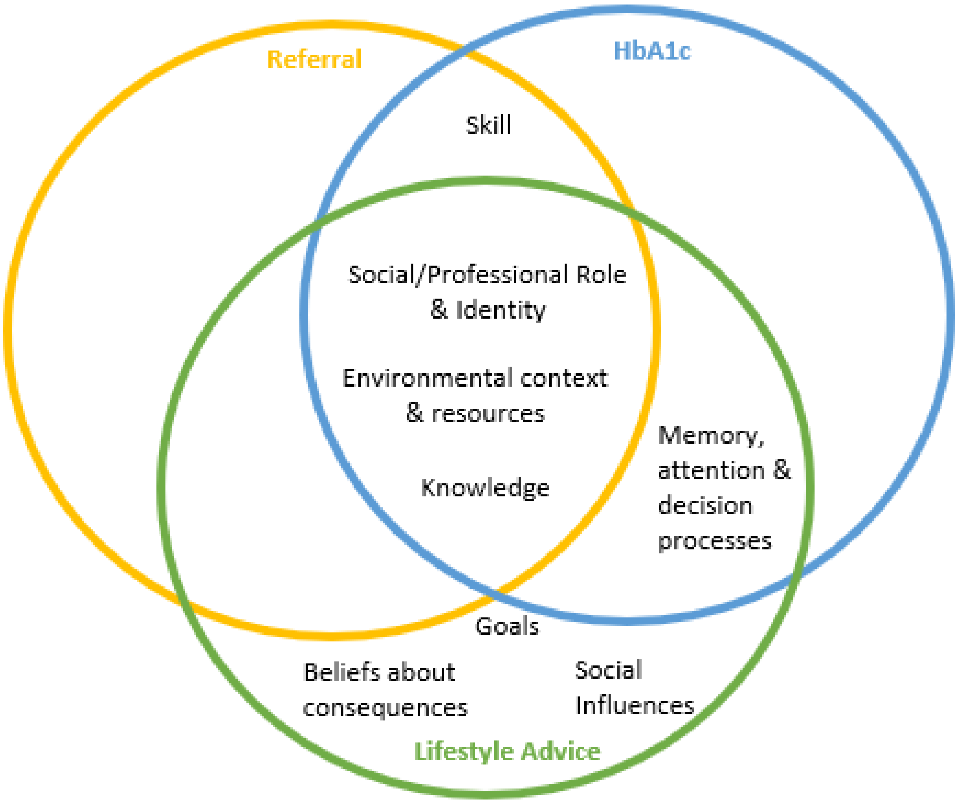


Figure 11: Venn diagram illustrating highly and moderately important domains of the Theoretical Domains Framework across the three target behaviours

Table 31: Table detailing the belief statements, assessments of importance and sample quotes of the domains of high and moderate relative importance for the delivery of the three target behaviours

Target Behaviour 1: HbA1c Monitoring						
Domain	**Belief Statement**	**Frequency**		**Discordant Belief**	**Expressed importance**	**Sample quote**
		Barrier	Enabler			
Knowledge	Mental health professionals do not have knowledge of optimal blood glucose levels	3	0			P004: But you do actually have to have quite a lot of understanding of blood sugars and monitoring to be able to manage it. TD: Yeah, yeah, you do. P004: And, I don't. (*Participant 003)*
Skills	Mental health professionals believe that their skills in relationship building, and rapport are important for supporting management of T2D during relapse including taking bloods for HbA1c monitoring	0	3		✓	TD: So, it is about having, would you say then that things that make it easier then, having the right skills, building relationships, is that, do you know what I mean, the person that you're supporting to achieve that with them? 008: Definitely, and I think that is really important, in terms of why we would be doing it, because we built up the relationship with the person. (*Participant 008*)

	Mental health professionals do/do not have appropriate phlebotomy skills as well as opportunities to practise this skill	1	2	✓		Especially the bloods, taking the blood can be very challenging for some people, because I've been in care for about 11 to 12 years now that I've been doing care, so I'm used to it, so for somebody coming new, [yes] they may find the blood challenging. (*Participant 006*)
Social/professional role and identity	Mental health professionals believe their role during relapse is to manage the mental health of the individuals and not intervene in T2D care inclusive of monitoring of HbA1c which is the responsibility of GPs	5	0	✓	✓	TD: Now two specific parts of type II diabetes that I'm just going to ask you about. One is about taking some bloods to do HBA1C blood glucose measurements, and the other one is at the time of relapse and you're seeing a service user, (a) would you take bloods? P001: No. TD: Not at all. How do you think people would feel, or how would you have felt being asked to take a diabetes specific blood at that time point to see how the person was doing? P001: But none of us are trained to do that. It's specific training, and none of us would be trained to do that. So that would just not be in the scope of our role at all…………..Because we just don't have the clinics, we don't have the infrastructure to do that, and we're not trained to do that. That would be primary care's responsibility (*Participant 001*) *Also coded as Skill as having the skill training and Environmental Context and Resources as a lack of training resource.*

Memory, Attention and Decision Processes	Mental health professionals must decide, during relapse, what is the best time to take bloods and provide general lifestyle advice	3	0		✓	If they don't have capacity, then they're most likely be detained and put into hospital, but a lot of the times, is, if they're relapsing, but they're willing to engage, but they don't want you to take their blood, because they don't believe, you're putting a chip in my body or you're putting chemicals in my blood stream, anything like that. You could gradually get them back on medication, and then we can gradually look at your physical health. (*Participant 007*)
Environmental Context and Resources	Relapse and psychosis symptoms can increase suspicion and make blood taking for blood glucose monitoring difficult	3	0			P005: So, if they're relapsing in their mental health it can often be quite difficult to engage them, even in care with their mental health. (cont.) TD: Okay, right, right. P005: Because if someone is paranoid and doesn't want to see their care coordinator they might think that we're looking at putting them in hospital or something like that, it's very difficult. They're unlikely to want to come into physical health monitoring clinic and have the bloods taken at that point and it's a lot more important to just get them taking their medication. (*Participant 005)*
	Mental health professionals believe that T2D specific training (resource) is limited	5	0			To some extent. I think we have got some training during our nursing, X(first name) … what is her name. X(first name) one of the lead [unclear 0:10:24] at X (University name).

						INT: Okay. RES: Did a diabetes lecture which was very useful. I don’t think we get enough since … to pass on the nursing, on the mental health nursing [unclear 0:10:34] personally. So, that’s one thing. I think we … we had an away day yesterday, and I did say that … I did say that we need more … we do need more training around diabetes. (*Participant 010*)
	Mental health professionals do/do not have access to integrated IT systems which are believed to be important for blood monitoring, referrals and liaison with GPs and other services	2	1			It’s been integrated, into the system, fairly recently, previously, it was only certain clinicians that would have access to the Web ICE (clinical results system), because I think we had to pay a fee, so, when I was, the [unclear 00:19:31] practitioner, I had access, to that system. But it was a completely separate system, so, you’d have two log-ons. But now it’s integrated, you can just pull that straight through PARIS, which makes life a whole lot easier. (*Participant 008*)

Target Behaviour 2: Lifestyle advice						
Domain	Belief Statements	Frequency		Discordant Beliefs	Expressed Importance	Sample quote
		Barrier	Enabler			
Knowledge	Mental health professionals believe they have knowledge of lifestyle advice generally but less so more specialised knowledge of T2D specific advice	3	0		✓	I think, I was just going to, I think having the Diabetic Nurse is really important, wherever that information comes from, in terms of the dietetics, and thinking about what might be helpful, what might be the options, I think with food? Because actually, when somebody is relapsing, the motivation is often very low, the self-care is very poor, so, it's maybe thinking about what is going to be easier? I suppose, we can do that to a point, but having that specialist support from a Diabetic Nurse, somebody with special training, would be really helpful, to support that person to really just think about what is going to be easiest, until their mental health improves? (*Participant 008*) (Also coded as *Social Influence* and *Environmental context and resource*)
Social/	Mental health professionals believe their role during relapse is to manage the mental health of	5	0	✓		So, we tread this fine line between wanting people to get better and my priority obviously is if someone is really unwell, violent towards themselves most commonly or violent towards other people, just being really

professional role and identity	the individuals. and not intervene in physical health					disinhibited, you want to treat that before you treat anything else. (*Participant 003*)
	Mental health professionals feel responsible for health promotion generally, but this is not related to T2D	3	0	✓		I think because we are trained to always consider health promotion, and that's early on in your training. So health promotion is always an important part of your care, but it wouldn't be targeted to type II diabetes. It would just be a generic thing. Lifestyle, healthy diet, exercise, substance misuse, getting out and about, socialising, it would be all part of health promotion. Meaningful activities, you'd always consider that, but it wouldn't be related to type 2 diabetes. (*Participant 001*)
Beliefs about consequences	Mental health professionals believe that the (perceived) outcome of lifestyle advice affects their provision. This can be manifest as avoidance owing to a) not wishing to put additional pressure on the individual (exercise), b) inability to positively impact dietary choices owing to unmodifiable provision (from parents/food banks), c) the fact that improvement is not immediate, or d) the ability of the service user to understand the information.	4	0			P001: And this is very specific stuff, but for some people it would be, what do you need to do to get back to the point where you're getting some exercise again? Whereas for others you just wouldn't raise it, because there'd be no point. TD: You'd know the person you were working with. P001: It would be an impossible goal at that point. To raise it would be just futile, and it would put them under pressure. So you have to pick your moment of saying, when do you think you're going to get back to cycling, swimming, walking? (*Participant 001*)

						(This was also coded as Goals but the perception of pressure was a consequence which created a barrier to provision)
	Mental health professionals believe that providing T2D care (at the wrong time) during relapse has the potential for harmful consequences for service users. Examples include putting too much pressure on them for exercise, disengaging with service, putting themselves at risk	3	0		✓	P007: You could gradually get them back on medication, and then we can gradually look at your physical health. TD: Yes, that makes sense. P007: So, in those situations, it’s more, the risk of harm to themselves and others, is if their mental health isn’t treated. (*Participant 007*)
Goals	Mental health professionals know lifestyle advice should be discussed but during relapse the priority is a "back to basics" lifestyle discussion focussed on mental wellness rather than being T2D specific for T2D management	5	0		✓	I would say it’s (lifestyle advice) more often more generic and, of course, we don’t want to separate physical health and mental health but, by default, in mental health that’s our own goal (*Participant 004*) (*Also coded as social/professional role and identity*)

Memory, attention, and decision process	Mental health professionals have to decide, during relapse, how and when is the best time to provide exercise advice, take bloods and provide general lifestyle advice	3	0		✓	TD: How important is it to continue to give lifestyle advice and support people with their lifestyle, so support them management of diabetes? P009: Yeah. So, it's definitely ... It's got to be a gentle approach. It's really important that the ongoing teaching, if you like, or coaching – not teaching, coaching – about healthy lifestyle choices and the impact that behaviours such as overeating, not eating the right things, not taking the prescribed medication, all of those things ... So, yeah, not bombarding and overwhelming people, but a gentle coaching approach is definitely ... And very person-centred. Not one way is going to work for all patients, for all individuals with severe mental illness during a relapse. (*Participant 009*)
	Mental health professionals have to frequently consider multiple issues when teasing out what they should focus on including lifestyle advice, monitoring of T2D, mental health maintenance, other challenges	4	0			So, then you say to someone, if they're like, you're going to get more hungry, you're going to eat more comforting food, but you really need to keep up, keep up your exercise. Somebody has just come out of hospital who is now struggling with weight gain and also has just come to terms with the fact they've had a severe break in their mental illness they're not going to be out on the job every day. So, then you get stuck in this vicious cycle of they get bigger, we need them to take their medication, they don't like taking the mediation, that means. And, then it all just gets in this big, old ball of teasing out what is important. (*Participant 003*)

Social Influence	Mental health professionals believe that having access to others supports care including colleagues in diabetes services, or diabetic nurses within the service, as well as family and friends is important for providing guidance in action when an individual is experiencing a relapse of their SMI (general and diet specific)	2	4	✓	✓	P009: And if we needed any more input ... Potentially, it might need some help from the ... We had a good relationship with the diabetes nurses at the hospital. So, we could ring them up and ask for some advice and things like that. So, that was in the plan, the contact number for them and ... TD: Ah, brilliant, and was that ... P009: So, just ... TD: Go on, go on, sorry. P009: No, I was just going to say, it's just really important that we had those lines of communication, just to ring up for some ... We could ring for any patient, really, that we had concerns with about diabetes, yeah. (*Participant 009)*
	The perceived priorities of service users drive the focus of care including lifestyle advice	2	0			Yes, well the thing is that a lot of our clients will have difficulties with their social situations, they have difficulties with money, housing, relationships, substance abuse, all of that kind of thing can often seem more important to the client themselves at the time, than talking about whether or not they had a healthy breakfast or whether they've played sport that week you know, if they haven't got anywhere safe to live, obviously that's the bigger priority at the time isn't it? (Participant 005)
Environmental Context	Mental health professionals believe that beyond initial training at university, T2D specific training (resource) is limited	5	0			And I feel because of their limited resources, what happens is staff members are not adequately trained to the level that they need to be, to provide this sort of holistic care. *(Participant 002*)

and Resources	Relapse intensity, specifically timeframe, can affect provision of lifestyle advice	1	0			TD: Earlier you were saying about the individual that you were working with and supporting. Some would be maybe a slow burn from relapse, some would be 48 hours. Would your approach differ depending on whether that person was a 48 hour, your knowledge of that person, would that impact how likely you'd be to give that information (lifestyle), talk through that information, or would it be always?....... P001: You'd probably miss all that. TD: It's maybe not as important at that point. P001: No, you'd probably miss all that. You'd be wanting to nip the mental illness in the bud, and you'd probably miss all that. (Participant 001)
	Mental health professionals believe having access to other professionals to provide care is important to lifestyle delivery	0	3		✓	I think, I was just going to, I think having the Diabetic Nurse is really important, wherever that information comes from, in terms of the dietetics, and thinking about what might be helpful, what might be the options, (Participant 008)
	Innovative methods to engage service users in exercise can be prohibited by cost implications	1	0			So, although the services are improving, it is trying to be a little bit more innovative in the way you engage these people and exercising, because one of the things I was wanting to look at, was, especially for the Clozapine, was getting those steppers, those, them step, having a bit of a competition, making it a bit of fun. Exercise, you know, come on, win a prize, do a raffle or

						anything to get people involved. But there is a cost implication in getting these, they’re not dear, but again, you’re limited. (Participant 007)
Target Behaviour 3: Referral						
Domain	**Belief Statements**	**Frequency**		**Discordant Beliefs**	**Expressed Importance**	**Sample quote**
		Barrier	**Enabler**			
Knowledge	Mental health professionals have awareness of external service agencies appropriate for referral	0	5			P006: With the community, it depends, because the majority, some of these patients they are independent, some of them have a Care Coordinator yes [right. Yes] so these are the things we always discuss with the Care Coordinator that this has, [right] taking place for this person so can they support this patient for him to start engaging with X (Named referral service). TD: Yes, I’ve got you. P006: And then on my own hand here I do my own referral to X (Named referral service). (*Participant 006*)

	Mental health professionals are knowledgeable about the process of referral	0	2			Yes, so, we have Care Coordinators within Mental Health Services and the Care Coordinators literally these days, coordinate care. So, within our team, we have psychological team, and we have Physical Health team as well. So, if somebody was to deteriorate in their mental health, they, and their physical health was compromised, they would then, we would liaise with the Physical Health team, get them booked in, think about the frequency of physical health monitoring, and we would report any concerns to the GP, in relation to the diabetes. (Participant 008)
Skills	Mental health professionals believe that their skills in relationship building/rapport are important for supporting management of T2D during relapse including engagement with other services offered as part of intervention referrals	0	3			there are a lot of really good literature, in regards to improvements, we've got a long way to go and one of the interesting things is tackling that, of all these wonderful services, but supporting someone getting to those services, is the challenge. So, it is really difficult in regards to building that connection and that relationship in getting somebody. So, you can do all the monitoring, but it's not necessarily, it's how you do the monitoring and getting these people, because they are the most unmanaged people and you may meet people and not even know, when they're really well and they're managing with their lives, the best they can and dealing through life. (*Participant 007*)
Social/professional role and identity	Mental health professionals are clear on the responsibility of others regarding T2D care and where they feel the boundaries are for provision.	0	6		✓	Then the GP didn't re-prescribe it. So, I just basically umbrella it and come into the GP and say please can you re-prescribe it and then they do. So, I have to have understanding of what's going on for them. I don't leave them completely on their own because sometimes, especially with language barriers or they don't understand how the system works, but I'm more of an

						overseer, but with the interventions physical health it needs to come through the GP. (*Participant 003*)
Environmental Context and Resources	Mental health professionals believe that the workload of staff (across multiple departments and services e.g. GP/Occupational therapy) hinders ability to provide T2D care, whether that be for relationship building for referral purposes, self-protection of staff when separating out mental and physical health demands.	3	0			But if you look at the more generic community mental health teams, their caseloads are north of 45, you know, they haven't got that time. It becomes perhaps a lower priority, rightly or wrongly. And I think it's absolutely natural, for those individual teams' sanity, to separate it out a bit and go, "You know what, that's a physical health thing, we can't deal with that, because I've got five people with psychiatric crisis waiting to speak to me." (*Participant 004*)
	Mental health professionals do/do not have access to integrated IT systems which are believed to be important for blood monitoring, referrals and liaison with GPs and other services	**2**	**1**			We are working on maybe sending the GP a report automatically every time someone comes in, which would be ideal but at the moment it can't be automated so we would have to be sitting and writing letters which we don't really have the time for at the moment. I mean, it would be great if we were just all on the same computer system and they could see, wouldn't that be lovely? (Participant 005)

Within the important domains, 24 of the belief statements met the criteria of frequency. Many of the statements were informed by at least three participants, with two statements in the domains S*ocial/professional role and identity*, and *Social influences*, having the greatest number of participants (n=6, 60%) informing a belief. Those beliefs which did not meet frequency criteria but were identified within domains of high or moderate importance were included in the analysis.

Discordance was identified in two domains, *Social/professional role and identity*, and *Social influence*. Discordance in the belief surrounding levels of responsibility for T2D care (*Social/professional role and responsibility)* were identified with some participants clearly articulating that it is not their responsibility and that their focus would be mental health whereas for others their responsibility would be the well-being of the whole individual inclusive of mental and physical health. Likewise, a divergence in perceptions of responsibility for HbA1c monitoring emerged, as some strongly rejected the idea of mental health professionals being involved in such monitoring, while others argued that the specialised skills of mental health professionals make them the most suitable candidates for this task. Discord was also identified in the potential influence of others on care (*Social influence)* with divergence in experiences of family and friends positively or negatively supporting lifestyle care.

Expressed importance was identified in all domains. The significance of mental health professionals’ skills in establishing and maintaining relationships with service users was emphasised as “very important”, justifying their suitability for providing the target behaviours care during relapses. The strong opposition to any questions regarding the involvement of mental health professionals in HbA1c monitoring particularly underscored the importance placed on both their skills (*Skills)* and the perceived boundaries of their professional role, for some participants (*Social/professional role and identity).* The importance of ensuring the safety of service users during a relapse is crucial and impacted decisions made surrounding when, what and how to provide lifestyle advice and HbA1c monitoring (*Memory, attention, and decision process*) and the prioritisation of mental health during relapse (*Goals*). Concerns regarding the adverse effects of T2D lifestyle advice were notably troubling due to their potential to strain the relationship with service users and lead to potentially harmful consequence (Beliefs about consequences). Additionally, the availability of other staff members, referred to as a resource (*Environment, context, and resources*), their knowledge in comparison to that of mental health professionals regarding T2D (*Knowledge*), and the relationship between members of the wider care team (*Social influence)* were important enablers of lifestyle provision. The outcomes of the assessment of domain importance, as well as summary of the relevance as per Behaviour Change Wheel worksheet 4a[108] are summarised in Table 32. A discussion of the domains of high and moderate importance are provided in sections 6.4.2.1 to 6.4.2.7.

Table 32: Outcome of the assessments of domain importance and a summary of domain relevance

Domain	HbA1c	Lifestyle Advice	Referral	Importance	Relevance of domain
Social/professional role and identity	Frequency Expressed Importance Discord	Frequency Discord	Frequency Expressed Importance	High	Perceptions of professional responsibility important as both a barrier to HbA1c and lifestyle provision during relapse but enabler of referrals
Social influences	Not identified	Frequency Expressed Importance Discord	Not identified	High	The benefits of collaborative work with peers for providing T2D care is an enabler of care, however the perceived benefit of family and friends is variable. Not relevant to HbA1c monitoring nor referral.
Skill	Frequency Expressed Importance	Not identified	Frequency	High	Skills in relationship building and rapport are important for both HbA1c monitoring and building relationships with others in the multidisciplinary team to support referrals. Skills related to phlebotomy training and opportunities to practise this skill are variable acting as both a barrier and enabler. Skill was not relevant to lifestyle advice.
Knowledge	Frequency	Frequency Expressed Importance	Frequency	Moderate	A lack of knowledge of optimum HbAc1 levels hampers monitoring. Whilst knowledgeable about general healthy lifestyles perceptions of suboptimal T2D specific advice act as a barrier, particularly in comparison to others in the

					multidisciplinary team. Knowledge of referral procedures as well as available services is an enabler of referrals
Environmental Context and Resources	Frequency	Frequency Expressed importance	Frequency	Moderate	The severity of symptoms during relapse can act as a barrier to HbA1c monitoring, specifically blood taking. Improvements in IT system integration can act as an enabler to care. Having access to other professionals who act as a resource for information is an important enabler of lifestyle advice. Insufficient training in T2D care is a barrier to both HbA1c monitoring and lifestyle advice. The increased workload of all staff across the multidisciplinary team can hinder referrals
Memory, attention, and decision processes	Frequency Expressed Importance	Frequency Expressed Importance	Not identified	Moderate	Deciding, what, when and how to monitor HbA1c and provide lifestyle advice is an important barrier, particularly concerning maintain relationships and ongoing safety of service users. It was not relevant to referrals
Beliefs about consequences	Not identified	Frequency Expressed Importance	Not identified	Moderate	Concerns about the perceived negative outcomes of lifestyle advice create an important barrier to provision during relapse. This was not relevant to HbA1c monitoring nor referrals
Goals	Identified but didn't meet any criteria	Frequency Expressed Importance	Not identified	Moderate	The goal during a relapse is a "back to basics" lifestyle advice and not concerned with ongoing management of T2D acts as an important barrier. Goals did meet any

					criteria for important in HbA1c monitoring, although it was identified. It was not relevant to referrals
Beliefs about capabilities	Not identified	Identified but didn't meet any criteria	Not identified	Low	Low relevance to lifestyle advice, not relevant to HbA1c monitoring nor referrals
Optimism	Not identified	Identified but didn't meet any criteria	Not identified	Low	Low relevance to lifestyle advice, not relevant to HbA1c monitoring nor referrals
Intentions	Not identified	Identified but didn't meet any criteria	Not identified	Low	Low relevance to lifestyle advice, not relevant to HbA1c monitoring nor referrals
Emotion	Identified but didn't meet any criteria	Not identified	Not identified	Low	Low relevance to HbA1c monitoring, not relevant to lifestyle advice nor referrals
Behavioural regulation	Not identified	Identified but didn't meet any criteria	Not identified	Low	Low relevance to lifestyle advice, not relevant to HbA1c monitoring nor referrals
Reinforcement	Not identified	Not identified	Not identified	N/A	Not relevant to the target behaviours

6.4.2.2 Knowledge

Overall, participants felt confident in their knowledge of the interaction between T2D and relapse. Participants discussed a level of knowledge they perceived to be appropriate for general lifestyle advice but that they felt would not be specific to T2D. Participants described variable knowledge about optimal HbA1c levels, with some participants aware and some less certain. Participants that were knowledgeable about optimal levels tended to be those who had worked in multiple roles and settings, suggesting that their knowledge was not related to the role of a mental health nurse but developed more generally. Participants had knowledge about the relevant professionals, teams and services for referrals that included the GP, diabetes team and additional third sector services including those for dietary and alcohol advice. These were often providers specific to the geographic locations of participants.

6.4.2.3 Social/Professional role and identity

Participants were very clear about their professional responsibility and role, and its perceived parameters, this differed across roles and services. This was particularly relevant for HbA1c monitoring with some participants, predominantly mental health nurses, indicating that this was not their role during relapse. These participants made clear links to training provided for their roles, noting that they were not specifically trained to take blood. Alongside this it was described that reviewing the results of HbA1c monitoring would not be within the scope of their role. This differed however when participants discussed the role of nurses in services outside of community mental health teams, such as the Early Intervention in Psychosis service, where it was noted that a nurses' role would include HbA1c monitoring as they were "expected to be with them [service users] all the way" (P004). The mental health nurse who worked currently as the physical health lead did feel it was their responsibility to take bloods but not to ensure any action regarding review of the outcome of the blood taking including review of the results. It was evident however, across all services and experiences, that participants felt that their primary professional responsibility during relapse was to support the mental health of the service user with this taking precedence over the target T2D behaviours. Overall, there was a perceived responsibility for the general health of service users with T2D seen as the responsibility of other professionals, predominantly GPs. Finally, positively, the importance of role clarity was highlighted as an enabler of referrals with clear professional roles and responsibilities enabling appropriate and timely referrals, which would avoid longer term complications for servicer users.

6.4.2.4 Environmental Context and Resources

Having access to staff, discussed as a resource, who have specialist knowledge and clinical experience of physical health care and particularly for T2D care was highlighted as an enabler of the proposed target behaviours. The importance of access to this expertise was reinforced by some participants who felt that beyond their initial university training they had not received sufficient training to enable effective lifestyle advice and HbA1c monitoring. Participants frequently discussed how the severity of relapse would likely impact the provision of the target behaviours. Symptoms experienced during relapse of an SMI, such as abnormal thoughts, beliefs, and perceptions, were highlighted as particularly challenging in the monitoring of blood glucose, involving uncertainty and suspicion surrounding the process of taking the blood. The ability to take bloods sensitively and appropriately is discussed in the *Skill domain (see below).* Similarly, providing lifestyle advice when service users were experiencing a relapse would likely be impeded by sensitivity to risk of harm (either to self or others) during relapse. Participants discussed an increased workload, highlighting how this would act as a barrier in terms of both provision of lifestyle advice, and HbA1c monitoring;

but they also acknowledged that the workload of other professionals was also increased which made referral discussions more challenging, which would be applicable to this target behaviour. Finally, integrated IT systems were discussed as both an enabler (where IT systems were integrated and accessible to all staff) supporting information sharing between providers, important for both referrals and Hba1c monitoring, and a barrier when the systems did not "speak" to one another.

6.4.2.5 Skills

Skills in relationship building were discussed as an enabler and this supports the view that this type of care (i.e., proactive management of T2D during relapse) would be best provided by those within mental health services, i.e., mental health nurses. In particular, the relationship and ability to build rapport with service users was highlighted as an enabler to carrying out HbA1c monitoring, particularly being sensitive to the challenges of taking bloods whilst an individual was experiencing a relapse (as discussed in *Environmental context, and resources).* Furthermore, the ability of mental health professionals to build and maintain a relationship with service users could also support onward engagement with the services to which individuals are referred. Phlebotomy skills and engagement with developing this skill were discussed as an enabler to HbA1C monitoring. It was noted however that a lack of training in this skill was a barrier, which was exacerbated by phlebotomy skills not seen as related to a mental health role (as discussed *social/professional role and identity*). Experience, and length of time in a professional capacity, was discussed as an enabler of HbA1c monitoring enabling a development of both phlebotomy skills and relationship building which are necessary for HbA1c monitoring during a relapse.

6.4.2.6 Memory, attention, and decision processes

Health professionals discussed the challenges of deciding when it would be best to intervene with T2D when a service user was experiencing a mental health relapse. Identifying appropriate timing for lifestyle advice and HbA1c monitoring were perceived as challenging in the context of a relapse. For example, participant 003 highlighted that the symptoms of relapse would impact capacity and ability to understand information of service users and thus deciding when to provide lifestyle advice would likely pose a challenge to ensure that information provided could be acted upon by service users. A further example provided included how relapse symptoms such as abnormal thoughts, beliefs, and perceptions were perceived as potentially producing a situation where “you might lose the trust [with the service user]” (P007) who “might be suspicious, they might feel as though you are trying to put something in them, rather than taking something out” (P007), thus making HbA1c monitoring (specifically taking blood taking) challenging. Additionally, deciding when to undertake the target behaviours of lifestyle advice and HbA1c monitoring would need to be balanced and considered alongside the potential for risk to the relationship between mental health professional and service user. Compromising the relationship would need to be avoided at all costs, particularly during relapse where the risk of disengagement from the team could result in harm to the individual or the need for hospitalisation either voluntarily or through compulsory admission under section 2 of the Mental Health Act[274], which should be avoided wherever possible. This proposed challenge in decision making and the focus on proactive care of T2D during SMI relapse was considered by some participants in the context of how management of SMI relapse would often require an increase in medication that could negatively impact T2D. Thus, deciding how best to approach provision of the T2D care behaviours, specifically lifestyle advice and HbA1c monitoring, during relapse was described as a “dilemma”(P004) considering this context.

6.4.2.7 Beliefs about consequences

There was a perception that giving lifestyle advice could create a pressured environment for service users, which could act as barrier. This manifested as a careful consideration about when best to provide such advice to avoid this being futile or promoting irritation or annoyance (linked to *Memory, Attention and Decision Processes*). Inability to positively impact dietary choices owing to food provision being outside of the control of service users, e.g., via food banks or parents, was interpreted as a barrier to providing lifestyle advice. The involvement of parents or food banks were arguably more likely when an individual was experiencing a relapse. Furthermore, the perceived difficulty a service user may face in understanding, retaining, and acting on lifestyle advice during relapse meant that delivery could be less likely.

Barriers were also discussed regarding the perceived consequences of providing lifestyle advice at the “wrong” time during a relapse resulting in potentially harmful consequences for the service user, again linked to *Memory, attention, and decision processes*. The perceived negative consequences included the belief that service users would feel pressure from lifestyle advice resulting in an adverse impact on the relationship between service user and health professional with the potential for the service user to disengage from services if pushed too hard putting them at additional risk during a relapse.

Additionally, there was an empathetic understanding of the comfort provided by food during relapse, further reinforcing barriers to the target behaviours (specifically lifestyle advice).

6.4.2.8 Goals

During relapse, the priority goal was often described in terms of either ensuring the safety of the service user (as described in *beliefs about consequences)* or restarting/dose adjusting medication to address the relapse. The focus on getting service users to take their medication again was “a lot more important” than care delivery focussed on physical health. During relapse, lifestyle advice was discussed in relation to mental well-being. This manifested as either asking about dietary input for the purpose of understanding its use as a coping strategy. It was also described as a *“back to basics”* lifestyle advice to improve general mental well-being, rather than any advice which was specific to the management of T2D, or to inform their care plan e.g., identifying that increased alcohol consumption was a sign of relapse. This was underpinned by professional goals with the acknowledgement that whilst holistic care was aspirational it was not always possible - “of course, we don’t want to separate physical health and mental health but by default in mental health that’s our own goal” (P009)

6.4.2.9 Social influence

Professionals identified that family and friends can often provide additional information that can support provision of appropriate lifestyle advice, particularly discussed in relation to dietary and exercise advice. There was consideration of the involvement of the service user in development of their care planning, both prior to relapse and in updating care plans after relapse. It was also noted by several participants that the involvement of other staff with appropriate expertise and experience such as other mental health professionals and/or diabetes specialists would be beneficial in enabling the T2D target behaviours during relapse This demonstrates that other members of the multidisciplinary team can ensure that mental health professionals are delivering appropriate T2D advice and support during relapse.

6.4.3 Inductive Analysis (Thematic Analysis) of data not related to the target behaviours – identifying potential contextual moderators of subsequent intervention development

Analysis of the data that was not directly related to the target behaviours during relapse identified one theme *T2D is serious but it's never my problem.* This was identified as enduring outside of relapse, though likely to be impactful on the provision of the target behaviours during relapse, thus warranting further elaboration. It also provided additional information on the potential contextual moderators of the intervention. Table 33 provides a summary of the themes and the respective codes.

Table 33: Summary of identified themes and codes

Theme	Codes
T2D is serious but it's never my problem	Awareness Causation Empowerment of service users Physical health generally Contracts Disconnection

During relapse the acute nature of the challenges faced in the mental health of service users was brought to the fore, this served to bring into focus the perceived boundaries and roles and responsibilities, and goals, of mental health professionals. Analysis of data also highlighted that beyond this timepoint the responsibility for T2D management is discharged to others, whether health professionals or service users. Participants were unequivocal in their perceived understanding of the harmful impacts of T2D in combination with an SMI for service users, demonstrated by participant 004.

> *And then sometimes, you know, if you think about it the other way around, if you're not looking after your diabetes, that can have a huge impact on your mental health. (Participant 004)*

Although holistic care was acknowledged to be aspirational, this was discussed more generally in relation to provision of generalised physical health care and not management of a specific condition such as T2D. For example, whilst there was an awareness of the negative side-effects of medications used to manage SMI, responsibility for monitoring the physiological changes caused by the medication, specifically Clozapine, was the remit of mental health professionals.

> *A lot of the people that we have, that particularly with diabetes, are probably taking a medication, called Clozapine. Now with Clozapine, we have to do very regular physical health monitoring, because of the nature of the side effects. (Participant 008)*

In contrast, any treatment for a resulting long-term condition i.e., obesity/T2D treatment (and thus the overarching responsibility) would be with other professionals.

> *I’m just trying to think, [mumbling to himself] yes, so, a couple I’ve had experience with, where they’ve and that’s through, there was a lady on lithium, and with lithium, again, it’s indicative of how often you monitor these people. So, lithium, it is three months, so, they have a blood test every three months. So, if they’ve got a diagnosis of diabetes and generally, we have that test done, the lithium test, however, if there are indications of, if they complain of the symptoms of diabetes, then we would look into that. The other thing with mental health is that, although*

> *we monitor it, we don't manage it, that's the General Practitioner, and they have Specialist Diabetes Nurses. (Participant 007)*

This separation is likely to be compounded by wider organisational structures that contribute to this division through division of finance and contracts:

> *But the way contracts would work with my manager's head on, the way that services were divided up and contracted, the contractual obligation for physical healthcare was with the GP. (Participant 001)*

It may also be exacerbated through a general sense of disconnection between mental and physical health within mental health service:

> *TD: What helps you to think that way? What do you think has made it so that, is it that you've thought, hang on a minute, it could be their physical health? Is it your training? What has helped you to think in that way?*
>
> *P007: I think a lot of it with me, is my experiences within delivering care mainly. Where, I've always been interested in that connection between mental health and physical health, hence, doing my first year as a General Nurse and then in my second and third year, in mental health. I've always felt that there was a massive disconnect in regards to physical healthcare, within mental health services. (Participant 007)*

Beyond the proposed responsibility sitting with other health professionals, there is also a perceived responsibility lying with the service user. Whether this be through the responsibility for engaging with referrals described by Participant 001:

> *TD: And when you say signpost people, would you follow up on the referral to the GP or signposting, or would it be very much the service user would sort that?*
>
> *P001: You know what, I wouldn't even know whether the service user had done that or not in my time. I just wouldn't know.*

> *TD: It would be down to them.*
>
> *P001: Yeah.*

or discussions of the importance of empowering service users (or building their self-worth) which suggests responsibility for management is with the service user, as illustrated by Participant 007.

> *A lot of that is based round their lifestyles, their diet, so, there is a big push on healthy lifestyles, but again, it is like turning up to your GP for a physical health appointment and you're not with Mental Health Services, you know.*
>
> *A lot of people have got used to not having that push, they've lost that sense of self-worth and a lot of the work involved is building that self-worth up, in regards to getting them engage in activities, but there is a lot, if you mention exercise. (Participant 007)*

The ability to self-manage T2D is necessary for service users with the need for ongoing management on a day-to-day basis. Relapse however poses a challenge for self-management; thus, the shifting of responsibility (i.e., asking mental health professionals to take on responsibility for T2D care during relapse) may create a barrier to care during this critical timepoint.

6.5 Discussion

An inductive and deductive analysis of data from ten interviews identified eight Theoretical Domains Framework domains, *1) Social/professional role and identity, 2) Environmental Context and Resources, 3) Knowledge, 4) Memory, Attention and Decision Processes, 5) Skill, 6) Goals, 7) Beliefs about consequences* and 8) *Social influence* to be of high or moderate relative importance to one or more of the three specific target behaviours of T2D management during relapse (HbA1c measurement, lifestyle advice and referral). Of these, three domains, *1) Social/professional role and identity, 2) Environmental Context and Resources, 3) Knowledge* were judged to be important barriers/enablers to all three of the target behaviours. Social*, professional role and identity* was identified as a central scaffold for the barriers and enablers of the target behaviours, interacting with multiple domains, as well as enduring beyond the critical time of relapse. It was therefore conceptualised as a contextual moderator of intervention effectiveness.

Provision of T2D care is complex, requiring input from several teams and the coordination of related care processes, so teasing out barriers and enablers of specific care processes, their provision at key timepoints and for specific professionals is an important aspect of appropriate behavioural analysis[108]. The domain *Social and professional role/identity* was identified as important across all three target behaviours in this study. This may result from the focus on target behaviours which are not currently mandated in the management of relapse in those with an established psychotic disorder[274]. Thus the assertion by participants, who are mental health professionals, that this is not part of their role is appropriate given the parameters of care during relapse[274]. The systematic review (reported in Chapter 3) as well as inductive analysis of data outside of the target behaviours suggests however that is more likely that a sense of professional responsibility for T2D care is not felt by mental health professionals, even when not considering care specifically during SMI relapse. As suggested in the systematic review (Chapter 3. Section 3.6), and reinforced by the findings of this study, any future intervention will need to ensure that there is clarity around the parameters of professional role and responsibilities. This can be achieved in this intervention, and its subsequent design, through clear guidelines that state provision of the target behaviours during relapse.

The relationship between service user and mental health professional was also a central issue spanning across domains and was of utmost importance during relapse. It was perceived to be both a barrier and enabler to the target behaviours; with protection of the relationship built with service users seen to be of paramount importance particularly during relapse, and concern focused on any behaviours deemed to jeopardise the relationship. Any future intervention needs to ensure that the therapeutic relationship is safeguarded during relapse, particularly as mental health nursing relies on a positive therapeutic relationship[308]. An optimal therapeutic relationship creates a safe space with the nurses a catalyst for the service user's recovery[308], which is perhaps why lifestyle advice in particular was discussed as a threat to this safe space. This finding may provide some answer as to why although service users and carers are clear in their wish for more intensive T2D support during a relapse, particularly dietary advice, as evidenced by the selection and ranking of this idea in the first study (Chapter 5) as well as wider literature[58–60,202] (see Chapter 1. Section 1.2), support during relapse is challenging for mental health professionals and has not been the focus of past literature.

Previous literature has identified that service users find management of their T2D challenging and look to health professionals for guidance in decision making, particularly relating to dietary advice[60]. Without such support individuals can feel either incapable of management or alone, with a lack of support and awareness of the challenges of daily management of both conditions another form of stress[60]. Previous literature has highlighted that caution is needed for service users who feel solely responsible for their conditions(s)[309], which can result from a narrow focus on only one condition[60]. Thus, supporting mental health professionals to provide dual care offers an opportunity to better support adults managing T2D/SMI. This may be challenged however by systemic issues such as the division of roles and responsibilities, buy in from senior management and contracts which keep care separate. Such a division can create a barrier to physical care provision and this study has found that whilst there is clarity of roles and responsibilities this may not be ideal for those with comorbid T2D and SMI. Previous research has demonstrated that whilst community based mental health staff are willing to engage in changes to their roles to accommodate additional physical health care, there is a need to ensure that the new roles have clarity and that there is a clear rationale provided for such changes[310]. Thus, as demonstrated in this study, it is not a lack of clarity in professional roles and responsibility, but an appreciation of moving boundaries concerning T2D care provision and the need for clarity around what this will entail and why that is necessary. This is however impacted by the perceived challenges of deciding when to provide lifestyle advice during relapse, highlighted by the domain *Memory, attention, and decision process.* Participants in this study suggested that this is a particular difficulty and thus subsequent intervention development will need to be sensitive to supporting mental health professionals in the provision of this advice.

Insufficient health professional knowledge has been suggested to be a barrier to provision of T2D care for individuals with an SMI in previous literature[60], which is corroborated by this study. Whilst knowledgeable about the interaction between relapse and T2D, including service users' ability to self-manage their conditions, a lack of knowledge of T2D lifestyle advice was a barrier to provision. This knowledge gap has been documented for many years and yet appears to be a continuing barrier to provision. This is exacerbated by systemic issues related to the siloed provision of care. Exploring health professional perspectives about the management of other physical health conditions, e.g. cancer[311], cardiovascular disease[312,313] for individuals with an SMI highlights some similarities in both barriers (e.g. organisational structure, workload, perceived responsibility) and enablers (e.g. health professional and service user relationship[313]). It is possible that these findings are indicative of wider systemic issues of care delivery for individuals who experience multimorbidity spanning their mental and physical health. This is further enhanced through identification in the inductive codebook analysis of the organisational constraints such as finance and contracts, as well as disparate training of mental and physical health professionals. This study contributes to the preceding literature and supports suggestions[60] that there is a training need which is not just increasing knowledge and skills in management of conditions separately but training in how to manage both conditions simultaneously. Relapse is arguably a timepoint which offers the opportunity to begin a focus on holistic care, by incorporating a proactive approach to T2D at this critical time.

Previous literature has demonstrated that there is some uncertainty about the extent to which the clinical observations taken in a physical health check are useful in guiding care[310]. The authors questioned whether the basic checks are sufficient to support service users.[310] It has also found that there are acknowledged difficulties in the practice of bringing overarching ideas of integrating physical and mental health care to fruition[310]. A more targeted approach, focussing on specific care processes at a specific timepoint, as proposed in this research, may offer an opportunity to bring about practicable change. Additionally, whilst mental health nurses are perceived to be competent in the integration of mental and physical health by service users and other professionals[273], owing to educational background and therapeutic relationship with service users[273] this study suggests that these can sometimes create barriers to their providing lifestyle advice.

The same three methods for identifying domains of importance were used in the systematic review[269] (Chapter 3) and this study. There was congruence in six domains identified as important in this study and those that were identified in the review *1) Social/professional role and identity, 2) Environmental Context and Resources, 3) Knowledge, 4) Skill, 5) Goals, and 6*) *Social influence*. The two domains *Memory, Attention and Decision Processes* and *Beliefs about consequences* which did not meet the criteria for importance in the systematic review but were important in this study highlight the importance of a nuanced understanding of the barriers and enablers of care. These domains particularly underscored the concerns surrounding providing T2D care during relapse and the potential for compromising the safety of service users which is heightened during relapse. Differences in the outcomes between the systematic review and this study were particularly prevalent in the assessment of discordant beliefs. All six domains of importance identified in the systematic review met the criteria for discordance, however only two were identified in this study, 1) *Social/professional role and identity* and 2) S*ocial influence* and were particularly related to differences in perceived responsibility for the mental well-being of service users as opposed to providing holistic care, and the perceived positive and negative impact of family on T2D care. Expressed importance was considerably more identifiable than discord which may reflect the focus on mental health professionals rather than a more inclusive sample employed in the systematic review, potentially accounting for this difference. The final difference of note is the absence of the domain *Reinforcement* which was identified in the systematic review but not in this study. The domain in the systematic review was identified predominantly in studies of mixed samples (i.e. including mental and health professionals[157,158,181,184]), and those which employed the Theoretical Domains Framework to design the interview schedule[157] or survey[158]. Predominantly the domains identified reinforcement or fear of discipline as the concerns attributed to this domain; neither or which were identified in this study. The absence of this may owe to the lack of use of the Theoretical Domains Framework to design the interview schedule and therefore the lack of questions explicitly asking about reinforcement. It may also however be indicative of a domain that is important to those who work predominantly in physical health (e.g., diabetologists) or are more generalist (e.g., General Practitioner). Finally, the absence may also be reflective of the important domains of the chosen target behaviours, as it has been identified that *Reinforcement* was significantly associated with referral for retinopathy screening and not other T2D related behaviours such as weight management diet and nutrition advice and HbA1c monitoring and target setting[158].

These findings should also be considered in relation to the utilisation of importance criteria to identify domains of greater importance. As highlighted previously (see Section 3.5.1) it has not yet been established whether identifying domains of importance leads to more effective interventions[161,162,314] . Furthermore, there is no clear guidance on which methods are optimal for identifying domains of importance. Given that this study was interested in the identification of barriers and enablers of three target behaviours constituting a “light touch” package of care, the three domains identified across all target behaviours, 1) *Social/professional role and identity, 2) knowledge and 3) environmental context and resources* are arguably the “most important” to this package of care. This can be considered in later feasibility work. For example, if the resulting intervention (identified in the subsequent chapter – see Section 7.4) is deemed unfeasible to deliver, it offers the opportunity to further reduce the intervention strategies to target the domains important across the three target behaviours. Finally, the use of the same criteria for identifying domains of importance across the studies in this PhD enabled comparison of the domains of the importance for T2D care more generally (as identified in Chapter 3 – Section 3.5.5) and for the three target behaviours of this study (described in Section 6.4.2). This has been briefly discussed above but will be elaborated on in the general discussion in Chapter 8 (Section 8.2.1).

6.6 Strengths and limitations

This is the first known study to explore the barriers and enablers of T2D care for adults who are experiencing a relapse of their SMI. This is a focus which is significant to service users and carers, as evidenced through Study 3 (Chapter 5) and previous literature[57–60,202]. It therefore makes an important contribution to the literature surrounding T2D care for adults with an SMI as well as addressing an issue of importance to service users and carers. A heterogenous sample enabled exploration of experiences and opinions from different perspectives to support a comprehensive understanding. Participants collectively had extensive experience with several spanning multiple decades across a wide range of roles covering management. These insights help to provide an inclusive understanding of the barriers and enablers of T2D care during relapse, for example the contextual information regarding contracts would likely not have been possible without the insight of those in management positions. Furthermore, the geographic spread of participants provides confidence that the findings are not specific to a particular Trust but indicative of wider care. This is useful given the acknowledgement of differences in outcomes for SMI and physical health across different geographic regions[1]. It was possible to achieve codebook stability, with the majority of codes identified in the early interviews, which is supported by previous research in codebook analysis[303]. Finally, the analysis enabled identification of domains of the Theoretical Domains Framework which are highly and moderately important and can be targeted in further research in this project to support the overall aim of intervention development to improve T2D care for adults with an SMI.

A broader interview schedule was utilised that did not focus directly on the domains of the Theoretical Domains Framework resulted in the identification of thirteen domains. This suggests that the framework is sufficiently broad to capture a range of determinants without a focussed interview schedule. This method enabled an understanding of the relationships between domains, which can sometimes be absent from studies that employ a purely deductive approach to interview schedule design and subsequent analysis[206], supporting its selection. The relationships identified highlight the interrelated nature of determinants but particularly the central role of professional identity (*Social/professional role and identity).*

There are limitations of this study which are acknowledged. Whilst codebook stability was achieved, and the recruited sample fits within parameters for this type of study, it could be argued that the sample is relatively small. Recruitment of additional participants may have provided a greater level of detail which may impact the domains of the Theoretical Domains Framework and the subsequent assessment of importance. This limitation could therefore have implications for later intervention design. It is however thought to be a relatively low risk as the domains identified as either highly or moderately important are largely congruent with those identified in the systematic review[269]. The systematic review (Chapter 3) was comprehensive consisting of 28 studies with 2,243 participants, thus there is reason to be confident in the identification of these domains as important regardless of the number of participants recruited.

Recruitment was particularly challenging for the study. Ten participants were recruited, with a further three who agreed to participate but withdrew prior to the interview. These challenges were likely a result of multiple factors including being a PhD researcher with no direct experience of either T2D or SMI, nor as a mental health professional, potentially impacting recruitment. A second factor is staff shortages (which is also a barrier to the provision of T2D for people with an SMI by mental health professionals): all participants discussed how staff levels were challenging and that recruitment of new staff was a long-winded process. Two of the three potential participants who withdrew prior to interview cited high workload (with one of the potential participants going on to be signed off sick with work related stress) as the reason for their inability to participate. Whilst participating in research, which is outside of the scope of their role, is not akin to providing health care it is worth noting the impact of staff shortages on the participants and the barriers to both recruitment and care giving. A final issue which is of note regarding challenging recruitment is the potential that discussing T2D care was not seen as a remit of their mental health role (an identified barrier in the study) and therefore individuals perhaps felt this was not a study that was relevant to them. The barrier to care provision, was again a barrier to recruitment. This was evident when liaising with Trusts to recruit individuals to the study as team leads would often single out staff within emails to staff teams who were "physical health leads"; once again this could be interpreted as the reality of care provision being siloed to care teams or even individuals within teams. Staff rarely have sufficient time to participate in research, nor do they feel that this is their "responsibility" i.e., T2D is not what "I do". These factors reinforce what is identified within the study. Equally, it may mean that the findings of the study, on which interventions will be developed are perhaps skewed to those who have an interest in the cross-section of T2D and severe mental illness. This may mean that the resulting intervention will also need to factor in the possibility that additional work to engage those who do not feel it is their responsibility, or who do not have an interest in this cross-section, will be needed before engaging with the intervention.

Recruitment challenges can also be considered in relation to the wider context of care provision within the NHS. The effects of staffing shortfalls, recruitment challenges and managing the effects of COVID on morale may limit inclinations to take on care deemed “outside of the scope” of perceived professional role. Participant 004 highlighted this when outlining that community mental health teams can have an excess caseload of 45 with at any given time five service users experiencing crisis. Such workload demands may drive a need to self-protect for their “sanity”(*P004*) by eschewing additional work or responsibility.

Whilst there were difficulties in the recruitment of participants, and the role of saturation is contested (see Section 6.3.7 for discussion), it was felt that the codebook was stable with the completion of the 10 interviews. This was evident through the lack of new codes from later interviews (interviews 9 and 10). This is congruent with previous literature which identified nine or fewer interviews for codebook stability[303].

The sample consisted only of mental health professionals. This was deliberate as the focus was on care provided during relapse, which is provided by mental health teams - thus understanding their perceived barriers and enablers was central to meeting the aims of this study and the overall project i.e., designing an intervention to target these professionals. However, it would be beneficial to understand the perspectives of other professionals who make up the wider care team such as general practitioners, who were largely identified as those responsible for T2D care. This provides opportunities for further theory-driven work to understand the interactional nature of T2D care during relapse, as well as more broadly considering the central importance of *Social/professional role and identity*.

6.7 Reflexive Statement

It is important to acknowledge the active role my own experiences play in making sense of other's experiences. I have worked in the NHS for over a decade supporting the implementation of interventions, within a research capacity, predominantly working as a Clinical Trial Manager. This has provided me with considerable knowledge of delivery of interventions within the NHS context, particularly regarding both the practicalities of implementation and the parameters available. I have also spent time working alongside clinicians providing care and am therefore acutely aware of the challenges faced working in the NHS context. These experiences mean my interpretation was infused with an appreciation for the challenges faced when care is provided by multiple teams as well the stretched nature of service provision. As such my analysis was sensistive to the challenges that individuals face working within the wider care system. This appreciation may be reflected in the identified barriers of care, and the prevalence of domains such as *Environmental Context and Resources*. Furthermore, the completion of the systematic review prior to this study may have senstised me to identify particular domains, for example the centrality of *Social/professional role and identity* was potentially influenced by the prominence of this domain in the review as well as the understanding of the lack of interventions incorporating social norms identified in the content analysis of exisiting interventions. Both my professional experience and personal beliefs are likely influential in the perceptions of expressed importance and resulting identification of important domains. As subjectivity is considered a resource within this conceptualisation[307], the potential influence of my professional experience and understanding of the literature is not a limitation of this work. It is however important to acknowledge how these experiences have shaped analysis ensuring transparency, a key component of reflexivity[286], as well as a core assumption of reflexive thematic analysis[293], reflecting the big Q of the utilised codebook thematic analysis in this study.

6.8 Step 4 Outcome: Identify what needs to change

Completion of study four has supported identification of eight highly or moderately important domains to provision of the target behaviours for adults who are experiencing a relapse of their SMI. These domains are: *1) Social/professional role and identity, 2) Environmental Context and Resources, 3) Knowledge, 4) Memory, attention, and decision process, 5) Skill, 6) Goals, 7) Beliefs about consequences, and 8) Social influence*. These domains will be taken forwards and targeted in the next study, through identification of appropriate intervention content which is believed by experts to be more likely to result in behaviour underpinned by these determinants. This completes step 4 of the Behaviour Change Wheel[108].

6.9 INDEX key considerations

Key considerations were broadly similar within this chapter to those of previous chapters, however the utilisation of the Theoretical Domains Framework and independent coding of the deductive analysis warranted consideration of existing theory and decision-making processes, detailed in Table 34.

Table 34: INDEX key considerations in the qualitative exploration of the barriers and enablers of the target behaviours, completing step 4 of the Behaviour Change Wheel[108]

Key Issue	Included	Evidence
Plan the development	✓	Completion of steps 4 of the Behaviour Change Wheel[108] support the development of the intervention
Involve stakeholders	✓	Health professionals recruited
Bring together a team and establish decision making processes	✓	Independent coding of deductive analysis

Review published research evidence	✓	Published existing evidence used to aid discussion of findings of the interview study
Draw on existing theories	✓	Theoretical Domains Framework[91] used to examine collected data
Articulate programme theory	X	Not applicable at this stage
Undertake primary data collection	✓	Interviews conducted
Understand the context	✓	Inherent in the involvement of stakeholders as well as inductive analysis and considerations
Pay attention to future implementation of the intervention in the real world	✓	Inherent in the involvement of stakeholders and understanding of context
Design and refine the intervention	X	Not applicable at this stage
End the development phase	X	Not applicable at this stage

6.10 Conclusion

The analysis of data from ten interviews using an inductive and deductive approach identified eight important domains within the Theoretical Domains Framework important to three specific target behaviours of T2D support during relapse. It was established that *social, professional role and identity* was of particular relevance, enduring beyond relapse and influenced by wider structural issues including finances, contracts and the siloed training of health professionals.

During relapse, health professionals prioritise the mental well-being of individuals, while perceiving the responsibility for managing T2D to lie with other health professionals or the service users themselves. The therapeutic relationship between service users and health professionals is a central issue influencing the target behaviours, perceived to act both as a barrier and an enabler. The provision of lifestyle advice was identified as a potential threat to the therapeutic relationship, highlighting the need for sensitivity in intervention development to preserve this crucial relationship. The findings also align with previous literature that emphasises the difficulties of integrating physical and mental health care, ambiguity surrounding the effectiveness of physical health checks, and the need for more targeted approaches to bring about practical changes. Recruitment challenges were attributed to factors such as limited direct experience of T2D, an SMI and as a practitioner in the mental health field, staff shortages, high workloads, and the perception that T2D care is not within the role of those who are the target of the intervention, e.g., mental health nurses.

Finally, this chapter has outlined the completion of step 4 of the Behaviour Change Wheel. The next chapter will outline the processes undertaken to design an intervention, combining the findings of this study, existing evidence, and input from health professionals to complete steps 5-8 of the Behaviour Change Wheel.

7 Chapter 7. Stages 5-8 of the Behaviour Change Wheel

Study 5: Identify identification of intervention options, content and implementation options using mapping exercises, expert opinion, existing literature, and a Delphi study with mental health professionals

7.1 Prologue

The previous chapter explored the barriers and enablers of three behaviours relating to T2D care - 1. HbA1C monitoring, 2. lifestyle advice and 3. appropriate referrals. Overall, the findings of the previous chapter contribute to understanding the barriers and enablers of T2D support during relapse, emphasising the importance of the domain *Social/professional role and identity*, the therapeutic relationship, and the challenges of providing whole person care. The findings underscored the complexities of care provision, the impact of systemic issues, and provide opportunities for interventions to improve T2D care for individuals with an SMI. A deductive framework analysis identified eight important theoretical domains with varying degrees of applicability to the three target behaviours. These were *1) Knowledge, 2) Skills, 3) Social/ professional role and identity, 4) Beliefs about consequences, 5) Goals, 6) Memory, attention, and decision processes, 7) Social influences and 8) Environmental, context and resources.* These provide a focus for the completion of the remaining four steps of the Behaviour Change Wheel[108]. This chapter will outline methods and results of the final stages of intervention development using the Behaviour Change Wheel[108], finishing with a draft intervention proposal and programme theory suitable for further feasibility testing in post-doctoral work.

7.2 Introduction

This chapter focusses on Stages 2 and 3 (Steps 5 – 8) of the Behaviour Change Wheel (Figure 12).

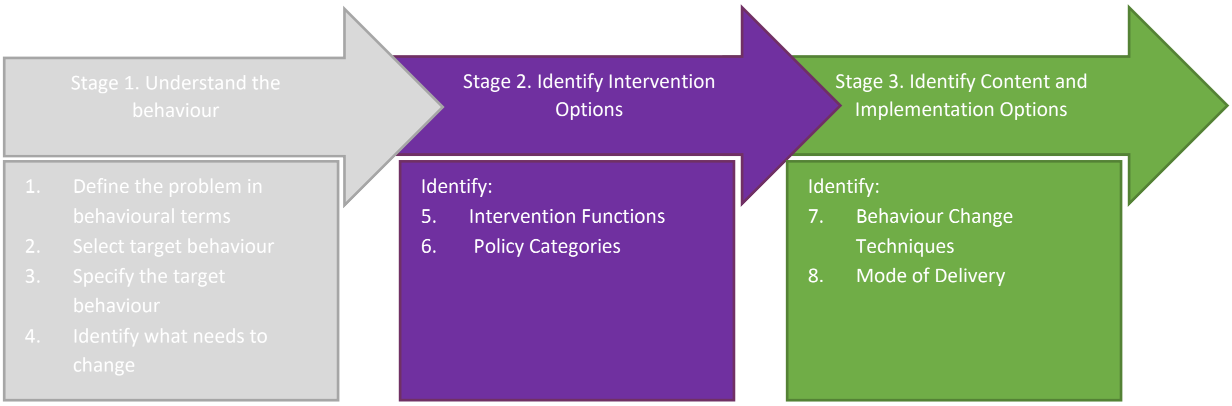


Figure 12: Steps of the BCW completed as part of Phase Three

Stage 2 of the Behaviour Change Wheel recommends identification of appropriate intervention functions and policy categories. Numerous behaviour change frameworks have been developed, varying in comprehensiveness, coherence, and theoretical foundations. A systematic review of these frameworks identified 19 frameworks consisting of nine intervention functions and seven policy categories, as described in Chapter 2 – 2.4.2. To consider interventions effectively, it is essential to explore the full range of available intervention functions and policy categories.

Stage 3 of the Behaviour Change Wheel supports identification of intervention content and mode of delivery. Behaviour change techniques are defined as replicable components of interventions that aim to modify the processes that regulate behaviour[143]. They are designed to either enhance factors that facilitate behaviour or alleviate barriers that hinder behaviour. An example of a behaviour change technique is setting or agreeing upon a behaviour-based goal. Experts identified and classified a taxonomy of 93 behaviour change techniques[90]. Whilst a more comprehensive Behaviour Change Technique Ontology has subsequently been developed[113], this study utilised the Behaviour Change Techniques Taxonomy V1[90], as the updated ontology was published after completion of this study.

Mode of delivery play a crucial role in intervention effectiveness and should be considered during intervention development[108]. The mode of delivery can influence engagement, adherence, understanding of content, and implementation[108,212]; moderating intervention effectiveness[89]. It has however been frequently under-reported and given limited attention[114,212]. Acknowledgment of the importance of mode of delivery has been central to the development of a Mode of Delivery Ontology[114]. This can be used for describing the mode of delivery of interventions in a consistent and coherent manner, improving implementation of effective interventions[114].

The final study in this project focussed on identification of appropriate intervention functions, policy categories, behaviour change techniques and mode of delivery in collaboration with health professionals.

7.2.1 Aim and Objectives

The aim of *Study 5* was to co-design an intervention, supported by the Behaviour Change Wheel targeting delivery of HbA1c monitoring, appropriate referrals and lifestyle advice to individuals experiencing a relapse of their SMI. This was achieved through the following objectives:

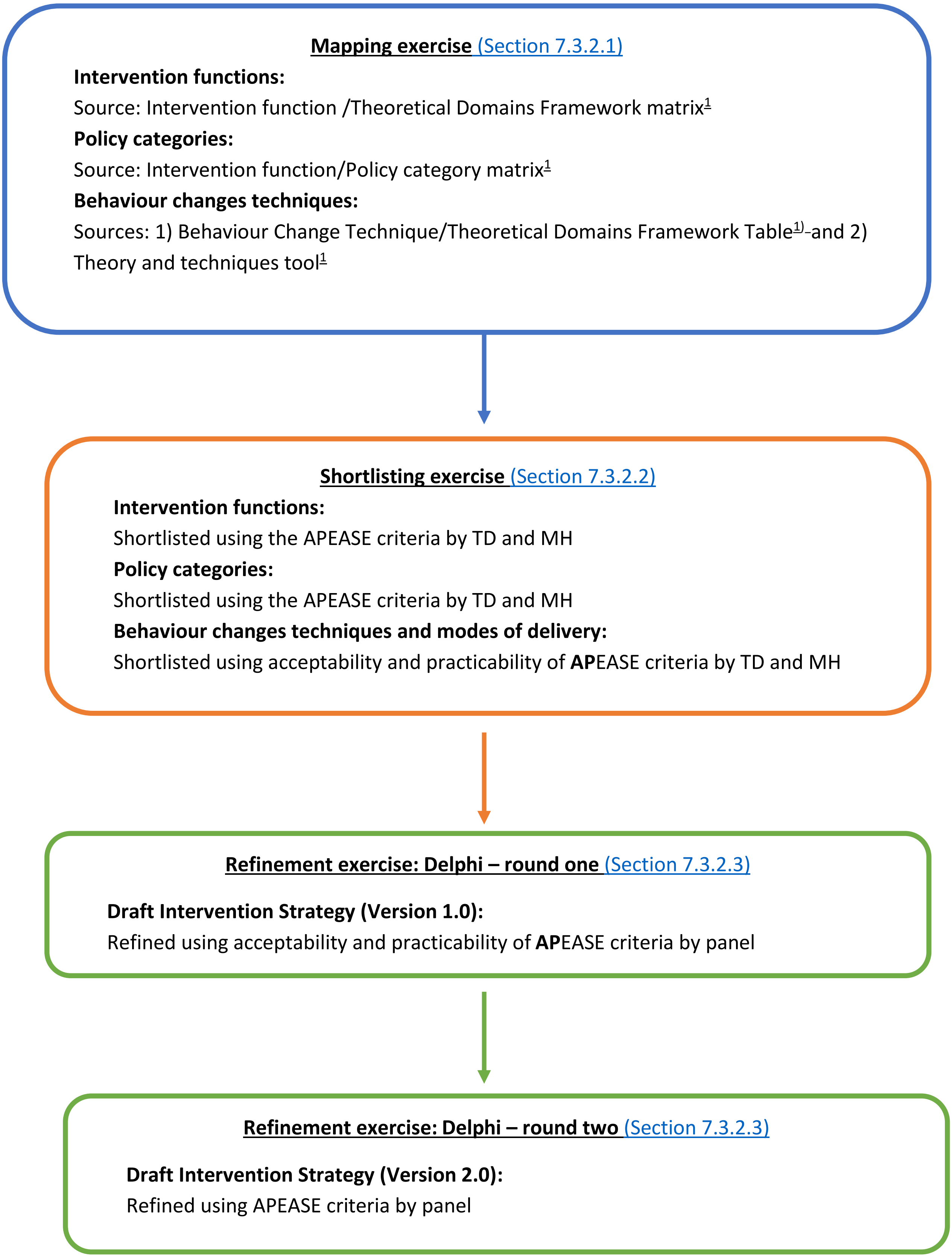
- Produce a list of candidate intervention functions and policy categories using the Behaviour Change Wheel[108]
- Produce, and refine, a list of candidate behaviour change techniques

- Created applications of the selected behaviour change techniques considering the mode of delivery
- Select intervention functions, policy categories and behaviour change techniques using the APEASE criteria
- Design a proposed intervention package in collaboration with health professionals
- Produce a logic model to demonstrate the intervention inputs, activities, outputs, and short, intermediate and long-term outcomes

7.3 Method

7.3.1 Procedure

The aims and objectives were achieved in three stages, 1) mapping exercise, 2) shortlisting and 3) refinement using a Delphi with a panel of health professionals. This process is illustrated in Figure 13 with subsequent sections providing additional detail.



Mapping exercise (Section 7.3.2.1)

Intervention functions:

Source: Intervention function /Theoretical Domains Framework matrix[1]

Policy categories:

Source: Intervention function/Policy category matrix[1]

Behaviour changes techniques:

Sources: 1) Behaviour Change Technique/Theoretical Domains Framework Table[1)] and 2) Theory and techniques tool[1]

Shortlisting exercise (Section 7.3.2.2)

Intervention functions:

Shortlisted using the APEASE criteria by TD and MH

Policy categories:

Shortlisted using the APEASE criteria by TD and MH

Behaviour changes techniques and modes of delivery:

Shortlisted using acceptability and practicability of **AP**EASE criteria by TD and MH

Refinement exercise: Delphi – round one (Section 7.3.2.3)

Draft Intervention Strategy (Version 1.0):

Refined using acceptability and practicability of **AP**EASE criteria by panel

Refinement exercise: Delphi – round two (Section 7.3.2.3)

Draft Intervention Strategy (Version 2.0):

Refined using APEASE criteria by panel

Figure 13: Actions taken to complete steps 5 -8 of the Behaviour Change Wheel[108]

7.3.1.1 Mapping Exercises

The first phase was a mapping exercise undertaken by TD using the important domains (determinants) detailed in Chapter 6 (Section 6.4.2.1) to identify intervention functions, policy categories and behaviour change techniques believed by experts to be effective in changing behaviour underpinned by the determinants.

The mapping matrices provided in the Behaviour Change Wheel[108] were used to identify candidate intervention functions and policy categories. The Intervention function/Theoretical domains Framework matrix illustrates links between intervention functions and domains of the Theoretical Domains Framework that experts identified in a consensus exercise[108]. For example, the domain *Social/professional role and identity* is linked to the intervention functions *education, persuasion,* and *modelling*. This link means that the use of these intervention functions is considered most likely for changing behaviours where *Social/professional role and identity* is a determinant of performing those behaviours. The intervention functions/policy category matrix highlights policy categories believed by experts to support the identified intervention functions[108]. For example, the intervention function *Education* is mapped to the policy categories *Communication/marketing, Guidelines, Regulation, Legislation* and *Service provision*.

Behaviour change techniques were identified through two sources 1) the Theoretical Domains Framework/Behaviour change technique mapping matrix in the Behaviour Change Wheel[91], and 2) the Theory and Techniques Tool[214]. It was originally proposed that the Theoretical Domains Framework/Behaviour Change Technique matrix[91] would be the source of technique identification as this is suggested in the Behaviour Change Wheel[91], however with the subsequent publishing of the Theory and Techniques Tool[214] both sources were examined.

Whilst the Theory and Techniques Tool[214] provides the most recent data on the hypothesised links between the Theoretical Domains Framework and behaviour change techniques and therefore could have been utilised alone, the mapping matrix provided in the Behaviour Change Wheel[91] was still inspected. This decision was taken as there are identified behaviour change techniques that currently have an absence of data to inform a hypothesized link in The Theory and Techniques Tool[214] but are believed by experts to be more likely to bring about change in behaviour, for example *Action planning* is mapped to the domain *Goals* in the mapping matrix provided in the Behaviour Change Wheel[91] however in the Theory and Techniques Tool[214] it is documented as having an absent link. An absence should not be mistaken for the lack of relationship; instead, it presents an opportunity to investigate whether a link does indeed exist. An exclusive reliance on using techniques within the Theory and Techniques Tool[214] that have hypothesised links may result in a missed opportunity to build evidence for other techniques which as yet are uncertain. Using the Theoretical Domains Framework/Behaviour Change Technique matrix[91] alongside the Theory and Techniques Tool[214] provided a pragmatic choice in identifying candidate techniques which do not yet have an accumulated evidence base.

The hypothesised links between the Theoretical Domains Framework domains and behaviour change techniques is documented as either evidence of a link or non-link, absence of evidence or inconclusive evidence[143,214]. Behaviour change techniques identified through the Theoretical Domains Framework/Behaviour Change Technique matrix[91] which the Theory and techniques tool[315] listed as having evidence of a non-link were excluded. All other evidence levels, e.g., links, inconclusive links of absence of evidence, were included for shortlisting.

7.3.1.2 Shortlisting Exercises

Phase two was a shortlisting exercise to reduce the number of candidate intervention functions, policy categories and behaviour change techniques identified by the mapping exercises. Shortlisting was intended to reduce the burden on Delphi participants by reducing the number of intervention functions, policy categories and behaviour change techniques presented for consideration.

The mapped intervention functions, and policy categories were reviewed by TD and MH and shortlisted using the APEASE criteria. The APEASE criteria considers six criteria for designing interventions, including selection of intervention functions. The criteria are *Acceptability, Practicability, Effectiveness and cost-effectiveness, Acceptability, Side-effects/safety,* and *Equity.* The descriptions of each of these criteria are provided in Table 35.

Table 35: Description of APEASE criteria (Adapted from the Behaviour Change Wheel[108] P. 20)

Criteria	Description
Acceptability	Affordable if within an acceptable budget it can be delivered to, or access by, all those for whom it would be relevant or of benefit
Practicability	Refers to the extent that it can be delivered as designed through the means intended to the target population
Effectiveness and cost-effectiveness	Effectiveness refers to the effect size in relation to the desired objectives in a real-world context. Cost-effectiveness refers to the ratio of effect to cost
Acceptability	Acceptability refers to the extent to which an intervention is judged to be appropriate by relevant stakeholders.
Side-effects/safety	Unwanted side-effects or unintended consequences need to be considered when deciding whether to proceed
Equity	The extent to which the item may reduce or increase the disparities between sectors of society

Judgements made were based on previous literature (e.g. the Behaviour Change Wheel guidance examples[108] and other described intervention development studies[314,316]). Additionally, consideration was made by the researcher (TD) who has 10 years' of personal experience of research delivery within the NHS (See Chapter 6. Section 6.7 for more discussion), as well supervisory team member (MH). MH has considerable experience of providing health professional training and education and using this as well as participant feedback[317], was able to reflect on the value of this approach in general as well as consider specific (interactive workshop) methods that would be particularly suitable as well as feasible. This also supported identification of *Persuasion*, with the importance of particular communication styles and approaches noted from previous research[317]. This research, plus experience of informal previous feedback from participants and colleagues (at conferences, discussions, and presentations) indicated the value of having the support of a champion embedded in the team to reinforce and promote ongoing professional development. This supported identification of *Environmental restructuring, Modelling, and Enablement.* Finally, the decision to include a T2D relapse champion and shortlist appropriate intervention functions was informed by consideration of broad Public health England and MIND directions on the value of champions in this and related areas, as well as local innovations e.g. King's Health Partners[318]. Shortlisting of policy categories was undertaken, however it was noted that access to "policy levers" was limited, with this constraint leading to this step sometimes being omitted in other research[319] as supported by the Behaviour Change Wheel authors[108]. It was decided that these would be considered with suggestions made for possible policy categories to be considered in later work and those available included where appropriate within this project. The shortlisted intervention functions and policy categories were used to suggest applications of all mapped behaviour change techniques prior to shortlisting.

Behaviour change technique applications were created to target the belief statements from Study 4 (Section 6.4.2.1). Creation of the applications was informed by existing literature[112,314,320], which included plain English descriptions and examples provided as part of the Behaviour Change Wheel literature[112], descriptions of interventions developed within the NHS context using similar methods[314] and the *Cards for Change*[320]. Application creation was also informed by consideration of the mode of delivery. The Mode of Delivery Ontology[114] was inspected and used to guide descriptions. For example, the technique *Social reward* was proposed to be delivered via a synchronous mode of delivery (BCIO:011060) as the interaction between the T2D relapse champion (who would provide the social reward) and the intervention participant (mental health professional) was proposed to take place during a daily meeting or huddle. Given the frequency of the meeting this met the criteria for synchronous mode of delivery (BCIO:011060) as the interaction would be "occurring at the same time or ***very close*** in time"[114]. Finally, identifying practical applications for two behaviour change techniques, 1) *Social support (Practical)* and 2) *Adding objects to the environment,* required additional clinical knowledge, and therefore were posed as a question rather than an application.

Two members of the research team (TD and MH) independently shortlisted the identified behaviour change techniques. The initial assessment was undertaken by TD with a secondary review of the assessments undertaken by MH, who has a significant experience and understanding of the NHS context and the mental health professional role. The techniques were assessed using two of the six APEASE criteria, acceptability, and feasibility. These two criteria were utilised as a short-hand version of the APEASE criteria as they allow pragmatic assessment of the usefulness of the behaviour change techniques within the NHS context. This process has been successfully utilised by other developers to refine the included list of behaviour change techniques[314,321]. The decision was also informed by the acknowledgement that the application of the full APEASE criteria prior to the finalised version of the behaviour change techniques was challenging. For example, the technique "*Adding objects to the environment*" required clinical knowledge to create an initial application therefore as an application wasn't created, the acceptability and feasibility of the technique was assessed using the plain English descriptions and examples provided as part of the Behaviour Change Wheel literature[112]. Without sufficient detail it would not have been possible to realistically assess the other criteria, for example the side-effect of the technique, therefore the two criteria which could be broadly assessed prior to this knowledge were utilised. Judgements were documented by TD as either "Yes", "No" or "Unsure" regarding the practicability and acceptability of each technique. This was used to assess whether the technique should be taken forwards for consideration by participants in the Delphi in the opinion of TD. MH reviewed the assessments by TD and provided a judgement as to whether he believed the technique should be taken forwards for consideration in the Delphi. Those with a "Yes" response by both MH and TD were taken forwards to the Delphi panel. Those techniques documented as "No" by both TD and MH were not taken forwards to the panel. For the remaining techniques an inclusive approach was taken, whereby if either MH or TD responded Yes to the technique it was taken forwards to the Delphi study.

7.3.1.3 Refinement: Delphi Study

7.3.1.3.1 Study Design

As with Study 3, an asynchronous Delphi method was utilised which is discussed in detail in Chapter 5 (Sections 5.3.2 and 5.3.3).

Unlike the underpinning Kantian philosophy, which is adopted in Study 3, a Lockean philosophy underpinned this study, see Chapter 5 (Section 5.4.2) for discussion of the philosophy underpinning Delphi studies. A Lockean philosophy was selected as unlike Study 3 which had a heterogenous sample including service users, carers, and health professionals where disagreement could be as informative as agreement, the focus of this study was to reach a consensus on which intervention functions, policy categories, behaviour change techniques and modes of delivery should be included within the final proposed intervention strategy. Lockean Delphi is best suited to working on well-structured problems, with answers to these problems not adversely impacted by reaching a compromise position, which is typical in consensus exercises[239]. Furthermore, a strength of a Lockean approach lies in the ability to include rich sources of experiential data[239] and apply a pragmatic approach to using this data to reach consensus. This is appropriate for this study as selecting intervention content is well structured and reaching a compromise to select which content to include is pragmatic with the outcomes able to be assessed and changed through further intervention refinement.

7.3.1.3.2 Participants

7.3.1.3.2.1 Eligibility

Eligibility criteria, listed below, were broad to enable a wide range of participants with varied experiences.

- Any mental health professional with experience of providing care for people with a diagnosis of an SMI
- Experience of working in the UK NHS healthcare setting
- Aged 18 years or over
- Able and willing to give informed consent

7.3.1.3.2.2 Sample size

As discussed in the sample selection for Study 3 (Chapter 5. Section 5.4.6.2) there is no standardised method to calculate a panel size for a Delphi[249]. There is also debate as to the need to provide and adhere to a specified sample size as the Delphi is concerned not with a generalisable sample but on the input of a purposively sampled panel[250]. It was proposed that the recruitment sample would consist of eight participants to reflect the range of potential roles within a community mental health team, as previously detailed in Chapter 5 (Section 5.4.6) . Purposive sampling to identify participants with management experience would also be advantageous to ensure sensitivity to later implementation of the intervention in the wider context. The recommendation of eight participants is also congruous with sample sizes of 6-20 participants when designing interventions with stakeholders, which is suggested to be appropriate to enable participants to express their perspectives whilst also fostering diversity[322].

7.3.1.3.2.3 Recruitment

Participants were recruited through multiple sources including approved platforms including *Call for Participants* and the research directory on *Diabetes UK*. Both websites allow promotion of research studies and are frequently used by several universities across the UK. Both websites publish study details including brief information, ethical approval, time of participation, which institution the research is affiliated with, whether there are any participant payments, and details of how to contact the researcher. Participants were asked to contact TD for further information and given the opportunity to discuss the study before deciding whether not to take part and a link to the survey hosted in Qualtrics[253].

Additionally, emails were sent to participants recruited through Phase 1 as well as additional emails sent by team leads within ELFT (Tower Hamlets). All participants were also asked to forward on study details to anyone they felt would be eligible and interested in participating.

7.3.1.3.2.4 Consent

Participants were emailed the participant information sheet (Appendix 26) and a link to Qualtrics which contained the informed consent form (Appendix 26). This consent form was presented to them in Qualtrics as a series of statements. To proceed with their participation, participants had to agree to each of these statements. If they answered 'No' to any statement, they were directed to the end of the survey.

By providing their consent, participants affirmed their understanding of the information presented in the Participant Information Sheet. They also acknowledged that they had been given ample time and opportunities to ask questions. Participation in the study was stated as voluntary, with participants having the option to withdraw themselves and their data at any point. Furthermore, participants consented to the usage of anonymised direct quotes, which might be included in peer-reviewed journals, conference papers, and the completed thesis. Lastly, participants expressed their willingness to actively engage in the study.

7.3.1.3.3 Round One: Application ideas generation

Participants were provided with a draft Strategy Information Package (Version 1.0, Dec 22; Appendix 27), which contained a list of all candidate behaviour change techniques, a definition of the techniques taken from published literature[112] examples of the barriers and enablers the techniques would be used to target, and the proposed technique application. It was stressed to participants that at this stage the proposed application was just a proposal and given to provide examples with the need for the participants to shape and take forwards the intervention package. This information was provided as it was anticipated that the participants would have limited knowledge of behaviour change theory and language and thus practical examples would support their engagement. Participants were asked to review the proposed applications and were asked two questions, 1) Do you think this is feasible? And 2) Do you think this is acceptable?; with the response options of “Yes” and “No”. Guidance was provided advising participants to reflect on these questions considering themselves and colleagues. There was space available for them to add comments and provide alternative suggestions of how the behaviour change technique could be delivered. It was challenging to identify potential applications for two behaviour change techniques, 1) *Social support (Practical)* and 2) *Add object to the environment*. Therefore, these two were posed as questions to the participants asking for them to consider the descriptions and provide any suggestions for operationalisation given their extensive knowledge of the clinical environment.

The link to the survey remained open for four months with two emails sent during this time to try to increase recruitment. Once participants began the survey they could return to it as many times as they wished until they submitted. All participants completed the survey within one session.

7.3.1.3.4 Round Two: Selecting behaviour change techniques

Responses to round one were used to make amendments to the Strategy Information Pack (Version 1.0 December 2022; Appendix 27). This included removing or amending behaviour change techniques and resulted in an updated Strategy Information Pack (Version 2.0 May

2023; Appendix 28). The updated Strategy Information Pack and a link to Qualtrics[253] to begin the second round was emailed to all panel members. The second round enabled participants to appraise the responses to the applications from round one as the updated Strategy Information Pack (Version 2.0 May 2023; Appendix 28) was a summary of the responses obtained in the first round.

The participants were asked to consider the application of each Behaviour Change Technique provided in Strategy Information Pack (Version 2.0 May 2023) and asked to judge the extent to which they agreed with six statements. The six statements were devised using the APEASE criteria (*Affordability, Practicability, Effectiveness and Cost-effectiveness, Acceptability, Side-effects,* and *Equity) and posed as:*

1. *This is likely to be affordable when delivered at scale in the NHS setting (Affordability)*
2. *This is practicable at scale within the NHS with appropriate materials and human resources (Practicability)*
3. *This is both likely to be effective and provides good value for money (Effectiveness and Cost-effectiveness)*
4. *This is acceptable to professionals working in an NHS setting (Acceptability)*
5. *This will not have unintended adverse outcomes (Side-effects)*
6. *This will help to reach the intended audience (health professionals) and will not disadvantage others (Equity)*

Participants were provided with a 5-point Likert-type scale to respond to these statements; 1: Strongly disagree, 2: Disagree, 3: Neutral, 4: Agree and 5: Strongly Agree. They also had an option for Unable to answer.

The link to the survey remained open for one-month with one email reminder sent to participants after two-weeks. Once participants began the survey they could return to it as many times as they wished until they submitted. As with previous rounds all participants completed the survey within one session.

7.3.2 Analysis

7.3.2.1 Round One: Behaviour change technique applications – idea generation

All responses were entered into Microsoft Excel. The overall frequency of Yes/No responses regarding the feasibility and acceptability of each behaviour change technique were calculated, which enabled an understanding of which applications were broadly acceptable and/or feasible to the panel. The responses for alternative suggestions, suggested applications of the techniques *Social support (practical*) and *Adding objects to the environment*, and any other comments were summarised to provide an overview of the general suggestions by the panel. Applications were amended where the technique was not feasible and or acceptable to >70% of the panel **and** an alternative was suggested.

7.3.2.2 Round Two: Selecting behaviour change techniques

All responses were analysed in Microsoft Excel. Consensus on behaviour change techniques to include in the intervention were made based on an agreement level of ≥70% of the recruited panel providing an overall APEASE score of 4 or 5 (4= Agree and 5 = Strongly Agree). The overall score for each technique was calculated using the mode score of each APEASE criteria, for example where a technique scored 4 across all six criteria, the calculated overall mode score was 4. All techniques met the consensus criteria thus further rounds of the Delphi were not required.

The frequency of responses on the Likert-type scale for each of the six APEASE criteria were calculated and presented individually to provide a detailed understanding of the intervention strategies.

7.3.3 Design Process (Logic Model)

TD utilised the feedback from participants to formalise the design of the intervention, this included bringing together all the elements of the intervention on which the participants commented and using the highly rated ideas to produce a final first draft design of the intervention. An initial intervention logic model was created to visually demonstrate the inputs, activities, outputs, and short, medium and long-term outcomes. The logic model is designed to be fluid, undergoing revisions in proposed post-doctoral work, serving to clarify goals and identify conceptual gaps, support development of evaluation measures in the form of a data plan for further work involving the intervention and act as a basis for supporting efficient assessment of the applicability and generalisability of an intervention to other contexts[323].

7.3.4 Ethical Approval

Ethical approval for the study was sought and approved in the original application by City, University of London, School of Health Sciences Research Ethics Committee (REF: ETH2021-0292) (Appendix 13). Recruitment of healthcare professionals was also approved by the Health Research Authority (REF: 20/HRA/6187) (Appendix 14) with ELFT (Tower Hamlets) providing confirmation of capacity and capability (Appendix 15).

7.4 Results

Figure 14 illustrates the mapping, shortlisting, and refining of the content of the intervention through each stage resulting in the final proposed intervention strategy. All stages are discussed below the figure.

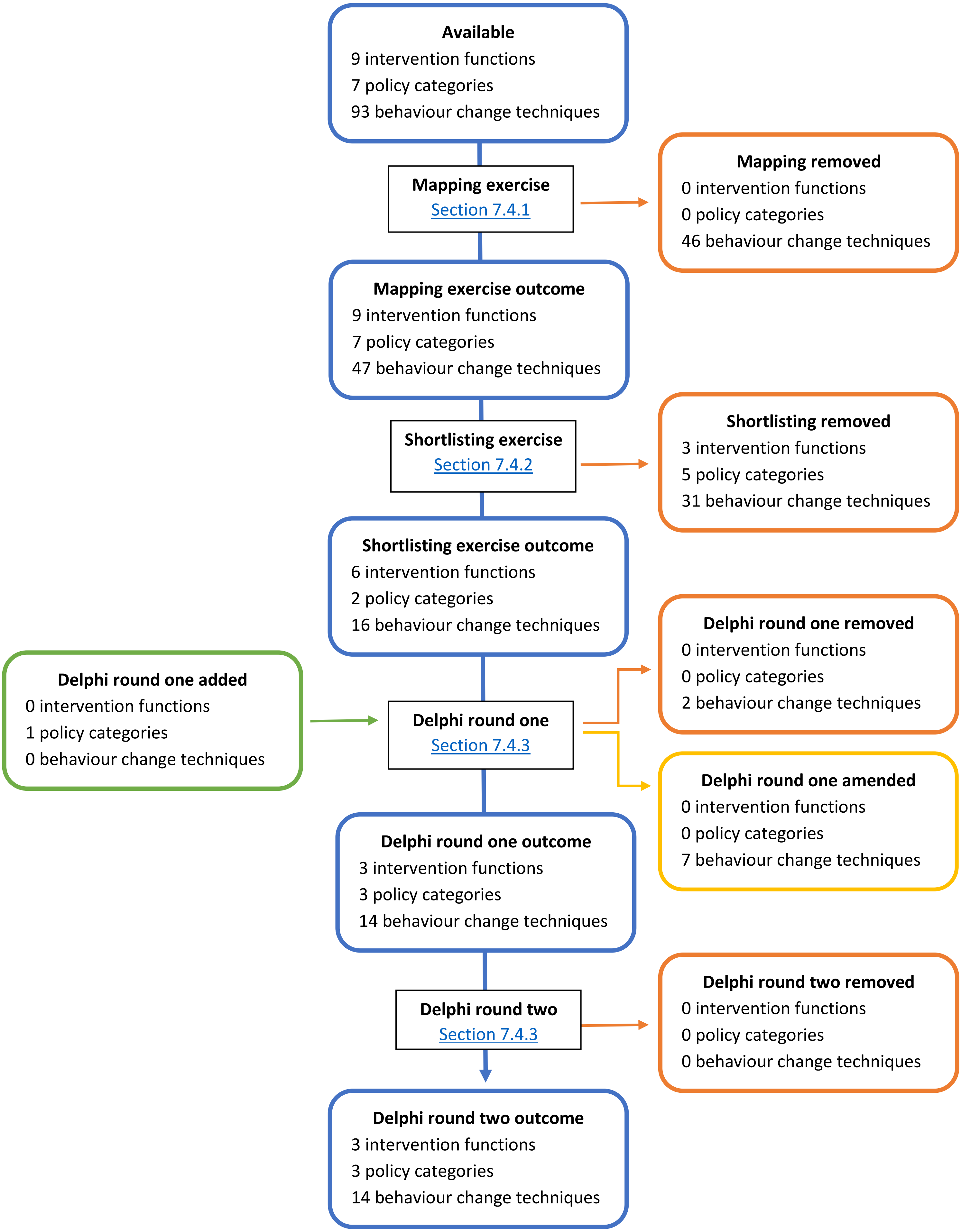


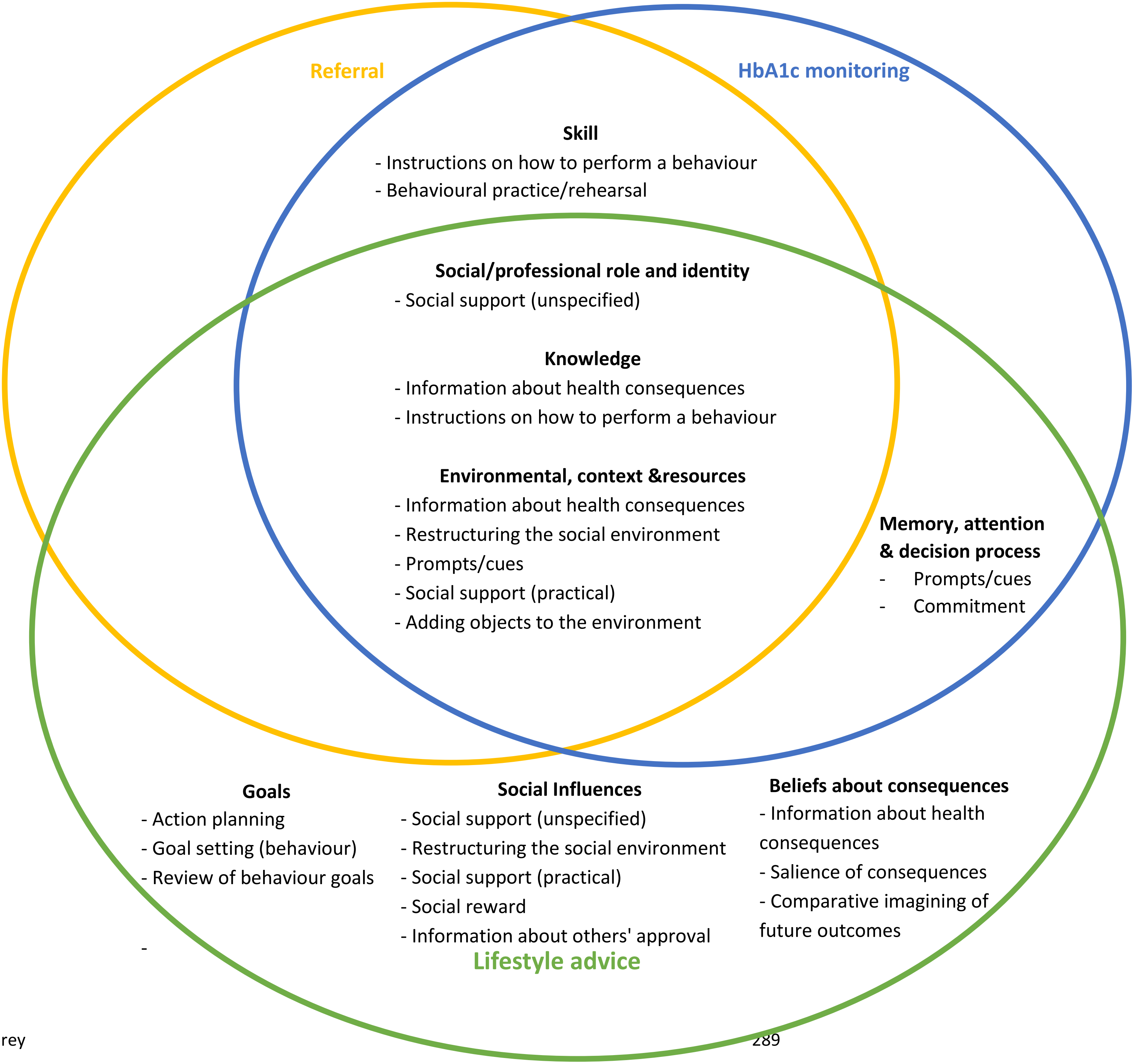
Figure 14: Intervention strategy development through each stage - mapping, shortlisting, and refinement

7.4.1 Mapping exercises

Initial mapping exercises identified that all intervention functions and policy categories could be considered to target lifestyle advice. Two functions (Incentivisation and Coercion) could not be considered for HbA1c monitoring and referrals. There were 47 behaviour change techniques identified which target the seven important Theoretical Domains Framework domains identified in Chapter 6 (Section 6.4.2.1). The outcomes of the mapping exercises can be found in Appendix 29.

7.4.2 Shortlisting exercise

Shortlisting resulted in six intervention functions and one policy categories being retained to support creation of the first draft intervention strategy. The APEASE assessments for both intervention functions and policy categories are provided in Appendix 29. The intervention functions *incentivisation, coercion* and *restriction* were all judged inappropriate for the intervention on the grounds of practicability, effectiveness and acceptability in the NHS setting for professionals, this has been identified in previous literature[117,316]. The policy categories *Communication/marketing*, E*nvironmental/social planning, Regulation, Guidelines, Fiscal measures,* and *Legislation* were deemed unacceptable to the NHS context. *Guidelines and Communication/marketing* was considered as important owing to the need for clarity around professional role and responsibility, however such large-scale changes were initially deemed outside the scope of this intervention but could be considered in further work. The remaining policy category service provision were utilised to draft the first intervention strategy, represented through he changes to service provision central to the intervention strategy. Independent review (by TD and MH) of behaviour change techniques resulted in the shortlisting of 16 unique techniques (Figure 15). The independent review of all techniques can be found in Appendix 30.



Referral

HbA1c monitoring

Skill

- Instructions on how to perform a behaviour
- Behavioural practice/rehearsal

Social/professional role and identity

- Social support (unspecified)

Knowledge

- Information about health consequences
- Instructions on how to perform a behaviour

Environmental, context &resources

- Information about health consequences
- Restructuring the social environment
- Prompts/cues
- Social support (practical)
- Adding objects to the environment

Memory, attention & decision process

- Prompts/cues
- Commitment

Goals

- Action planning
- Goal setting (behaviour)
- Review of behaviour goals
-

Social Influences

- Social support (unspecified)
- Restructuring the social environment
- Social support (practical)
- Social reward
- Information about others' approval

Beliefs about consequences

- Information about health consequences
- Salience of consequences
- Comparative imagining of future outcomes

Lifestyle advice

Figure 15: Target behaviours, Theoretical Domains Framework domains and candidate behaviour change techniques

At least one behaviour change technique was identified to target each important domain identified in in the qualitative study (Chapter 6. Section 6.4.2.1). The domain targeted by the most techniques was *Social influence (*5 techniques*),* and the least was S*ocial/professional role and identity (*1 technique*)*. The outcome of hypothesised links taken from the Theory and Techniques Tool[144], the assessments of practicability and acceptability and the decisions made by TD and MH regarding taking the behaviour change techniques forwards to participants in the Delphi are provided in Appendix 30.

Collectively, this content was combined to produce intervention draft Strategy Information Pack version 1.0 (Appendix 27) which was taken forwards for consideration in the Delphi study (outcome detail in the following section).

7.4.3 Refinement: Delphi

7.4.3.1 Participant characteristics

Recruitment methods preclude a clear statement of the number of individuals approached or exposed to the study. Six participants (75% of recruitment target) participated in the Delphi consensus exercise. One participants had participated in both the first Delphi study and the interview study, two participants had participated in the interview study only. The majority were male (n=4, 67%), worked as a mental health nurse (n4, 67%), with half the sample working for more than 10 years with over 30 being the maximum. Other roles undertaken by the sample noted as relevant to completion (by participants) were a support worker and healthcare assistant. It was not possible to confirm for one participant their professional role, however given the recruitment strategy and the unlikeliness of completion by an individual who was not a mental health professional it was decided that their data would remain in the study. Three participants (50%) from round one participated in the second round. Reasons for non-participation are unknown as participants were free to withdraw without giving reason. Participant characteristics for each round of the panel are provided in Table 36

Table 36: Study 5: Participant characteristics from Study 5

Round one *n*=6		Round two n=3
Gender	Male n=4 (67) Female n=2 (33)	Male n=2 (66) Female n=1 (34)
Age (*Average (range))*	41 (30-58)	48 (34-58)
Ethnicity	White British n=3 (50) Black British n=1 (17) Black n=1 (17) Asian British n=1 (17)	White British n=2(66) Black n=1(34)
Role	Mental health nurse n= 3 (50) Assistant General Manager Adult Mental Health Services/Mental health nurse n=1(17) Physical health coordinator n=1 (17) Not specified n=1(17)	Mental health nurse n=1 (33) Assistant General Manager Adult Mental Health Services/Mental health nurse n=1(33) Physical health coordinator n=1 (33)
Years of experience	>5 years n=3 (50) 10-20 years n=2 (33) >30 years n=1 (17)	>5 years n=1 (33) 10-20 years n=1 (33) >30 years n=1 (17)

7.4.3.2 Delphi outcome

The draft intervention strategy (Version 1.0, December 2022) and outcomes from both round one and round two of the Delphi are provided in Table 37. Following round one of the Delphi, seven behaviour change techniques remained as initially proposed, two were removed and seven amended, giving a total of 14 techniques. Responses from round one were used to review the underpinning intervention functions, policy categories and modes of delivery.

Changes to three behaviour change techniques prompted amendments to the mode of delivery. The main amendment included the addition of a change to the care planning process which resulted in the addition of the mode of delivery - *Printed publication (BCIO:011008)*. This change also required the addition of the policy category *Guidelines*, as it was identified by one participant that it is these which govern behaviour. The responses to round one were used to group together behaviour change techniques (with the underpinning intervention functions and policy categories) into four intervention strategies. The strategies were labelled 1) Appointment of a T2D/relapse champion, 2) Targets and feedback, 3) Changes to care planning and environment and 4) Training session. This brought clarity to the intervention package which is important for future implementation.   Participants were provided with the updated Strategy Information Pack (Version 2.0 May 2023; Appendix 28) which comprised of 14 behaviour change techniques (16 applications) detailed the four intervention strategies.

Table 37: Draft intervention strategy version 1.0 and outcomes from the first and second round of the Delphi

Intervention Strategy Draft 1.0 (Dec 2022)			**Delphi round one**				**Delphi round two**		
Behaviour targets	**Behaviour change technique** ***Intervention function***	**Proposed application** ***Mode of delivery***	**Feasible (n=6)**	**Practicable (n=6)**	**Outcome**	**Responses and amendments made**	**Mode APEASE score P1**	**Mode APEASE score P2**	**Mode APEASE score P3**
HbA1c monitoring Lifestyle advice	Information on health consequences (5.1) *Education* *Persuasion*	Provide information about the possible health consequences of providing T2D lifestyle advice during relapse - positive and negative[112] Provide information about the health consequences of suboptimal/optimal HbA1c levels and how this could be exacerbated during a relapse[112] *Face to face (BCIO:011003)* *Group-based (BCIO:011057)* *Asynchronous (BCIO:011601)* *Uni-directional (BCIO:011058)*	6	6	✓	All agree feasible and acceptable therefore no amendment	4	-	4
HbA1c monitoring Lifestyle advice	Instructions on how to perform behaviour (4.1) *Education* *Training*	Provide guidance on how to amend generic lifestyle advice for more tailored T2D advice[112] Provide blood taking training where required[112] *Face to face (BCIO:011003)*	5	5	✓	No suggestions made for changes therefore no amendments to the applications	4	-	4

		Group-based (BCIO:011057) *Asynchronous (BCIO:011601)* *Uni-directional (BCIO:011058)*							
HbA1c monitoring Lifestyle advice Referrals	Social support (unspecified) (3.1) *Persuasion* *Modelling* *Environmental restructuring*	Identify a T2D/relapse "champion" or "lead" within teams (MHN role) who will act as mentor/educator to peers and champion/encourage/support T2D management during relapse. The role can also act as a link between the Diabetes Nurse Specialist and MH team as needed.[314] *Face to face (BCIO:011003)* *Group-based (BCIO:011057)* *Synchronous (BCIO:011060)* *Interactional (BCIO:011059)*	6	5	✓	No suggestions made for changes therefore no amendments to the application practicability	4	4	4
Lifestyle advice	Review goals (behaviour) (1.5) *Persuasion*	*As part of mentoring/yearly reviews with appropriate individual (e.g., line manager) review goals set regarding provision of T2D lifestyle advice. Discuss impact of these goals and decide on whether the goals should be re-set, changed slightly or overhauled. The aim of the goal (whether slightly changed or overhauled) should still meet the aim of providing lifestyle advice for T2D during relapse* *Face to face (BCIO:011003)* *Individual-based (BCIO011055)* *Asynchronous (BCIO:011061)*	6	5	✓	No suggestions made for changes therefore no amendments to the applications	5	4	4

		Interactional (BCIO:011059)							
HbA1c monitoring Lifestyle advice Referrals	Restructuring social environment (12.2) *Environmental restructuring* *Modelling*	Use clinical cases during appropriate frequent meetings (e.g., morning huddle) as a stimulus for discussion around monitoring of HbA1c, provision of T2D lifestyle advice and appropriate referrals during relapse *Face to face (BCIO:011003)* *Group-based (BCIO:011057)* *Synchronous (BCIO:011060)* *Interactional (BCIO:011059)*	5	5	✓	No suggestions made for changes therefore no amendments to the applications	4	4	4
Lifestyle advice	Social reward (10.4) *Environmental restructuring* *Modelling*	Champion/lead to provide positive reinforcement/praise when discussing/raising issues of T2D lifestyle advice provided during relapse *Face to face (BCIO:011003)* *Group-based (BCIO:011057)* *Synchronous (BCIO:011060)* *Interactional (BCIO:011059)*	5	5	✓	No suggestions made for changes therefore no amendments to the applications	4	4	4
Lifestyle advice	Information about others' approval (6.3) *Persuasion* *Modelling*	Ask service users to provide information/feedback on the collaborative care process during relapse (this could be before or after) paying particular attention to the lifestyle advice provided during relapse *Face to face (BCIO:011003)*	4*	5*	✓	No suggestions made for changes therefore no amendments to the applications	5	4	4

		Group-based (BCIO:011057) *Asynchronous (BCIO:011601)* *Uni-directional (BCIO:011058)* Show video clip of other MHNs/senior staff/colleagues describing their approval of T2D lifestyle advice being provided during relapse. *Face to face (BCIO:011003)* *Audio (BCIO:011030)* *Visual (BCIO:011031)* *Group-based (BCIO:011057)* *Asynchronous (BCIO:011601)* *Uni-directional (BCIO:011058)*							
HbA1c monitoring	Behavioural practice/rehearsal (8.1) *Training*	As part of workshop have staff practice the discussion and approach to blood taking for blood glucose monitoring. Focus on ensuring that relationship and rapport are maintained during this aspect of care. *Face to face (BCIO:011003)* *Group-based (BCIO:011057)* *Asynchronous (BCIO:011601)* *Uni-directional (BCIO:011058)*	6	6	✓	All agree feasible and acceptable – no amendment		4	4

Lifestyle advice	Salience of consequences (5.2) *Education*	Show videos of service users speaking about the negative/positive consequences of not providing T2D lifestyle guidance during a relapse on their health and wellbeing and describing the impact of this support on their experience and engagement with mental health services and on their SMI *Face to face (BCIO:011003)* *Audio (BCIO:011030)* *Visual (BCIO:011031)* *Group-based (BCIO:011057)* *Asynchronous (BCIO:011601)* *Uni-directional (BCIO:011058)*	4	5	?	Participants raised issues about the practicality and data protection. Keep video but allow for case studies if needed. **Amended application:** Provide case study of service user discussing impact of T2D care during relapse discussing both positive and negative outcomes of providing T2D lifestyle advice	4		4
Lifestyle advice	Goal setting (Behaviour) (1.1) *Persuasion*	Create goal(s) using "If...then" statements which are focussed on provision of T2D lifestyle advice during relapse *Face to face (BCIO:011003)* *Group-based (BCIO:011057)* *Asynchronous (BCIO:011601)* *Uni-directional (BCIO:011058)*	6	5	?	Confusion over the target of goal setting **Amended application:** Set target of 95% provision of T2D lifestyle advice during relapse	4	4	4
Lifestyle advice	Action Planning (*Goal*) (1.4) *Enablement*	Ask staff to consider cues that could help them to provide more detailed T2D advice. Staff then asked to produce "if…then" statements linking a cue to the provision of T2D care. *Face to face (BCIO:011003)* *Group-based (BCIO:011057)*	6	6	?	Recommendations for the importance of involving service users in care planning highlighted in feedback. Laminated cues seen as irrelevant and official documentation more impactful. Amalgamated these two applications and amended application to include changes to care planning document.	4	4	4

		Asynchronous (BCIO:011601) *Uni-directional (BCIO:011058)* *This will be linked to the goal setting (behaviour) and review goals (behaviour)*				**Amended application:** Amendment or addendum appropriate Care Plan document to add a specific focus provision of the amended T2D lifestyle advice during relapse and HbA1c measurement. Discussed in collaboration with service users/carer **Mode of delivery amendment:** **Removed -***Group-based (BCIO:011057)* as no longer as part of group session. **Added** - Printed publication (*BCIO:011008*) as care planning document amendments			
HbA1c monitoring Lifestyle advice	Action Planning (MADP) (1.4) *Environmental restructuring*	Ask staff to consider cues that help them to decide to intervene in T2D management during a relapse. Staff then asked to produce "if…then" statements linking a cue to the provision of T2D care. These statements will be laminated and provided to staff *Face to face (BCIO:011003)* *Group-based (BCIO:011057)* *Asynchronous (BCIO:011601)* *Uni-directional (BCIO:011058)*	5	4	?	Merge with the above amended rather than have two separate applications			
HbA1c monitoring Lifestyle advice	Prompts/cues (7.1) *Environmental restructuring*	Use of laminated cue card/sticky notes that provide the "I…will" statements created during workshop. In addition to these statements include a focus on ensuring appropriate referrals despite workload	4	4	?	Post-it notes as the prompt is inappropriate as Guidelines and care planning guide care. Add in Policy: *Guidelines*	4	4	4

Referrals		challenges. These should be attached to or included with a diary/notebook etc. That the staff member will use *when supporting individuals during a relapse.* *Informational (BCIO:011001)* *Synchronous (BCIO:011060)*				**Amended application:** Identify specific prompt/cue for providing T2D in relapse care for service user and document in care plan. Changes to care document also acts as prompt **Policy category amendment**: Add in *Guidelines* **Mode of delivery amendment:** **Added** - Printed publication (*BCIO:011008*) as care planning document amendments			
HbA1c monitoring Lifestyle advice Referrals	Social support (practical) (3.2) *Enablement* *Environmental restructuring*	Is there anything practical that an individual (either T2D lead/champion or other staff) could do to support T2D care (specifically blood glucose monitoring, referrals or T2D lifestyle advice)?	NA	NA	?	Advanced planning involving service users and carers highlighted as important. Linked with the importance of care planning documentation (Policy: *Guidelines)*. Importance of diabetic nurse also highlighted and utilised to add additional element to training session. **Amended application #1:** During care planning meeting the involvement of service users/carers will focus on any practical help that could be provided when the plan is enacted during relapse **Mode of delivery additions:** Interactional (BCIO:011059) Asynchronous (BCIO:011061)	4	4	4

						Amended application #2: Diabetic nurse/T2D champion to lead training session and provide practical support as needed			
HbA1c monitoring Lifestyle advice Referrals	Add object to the environment (12.2) *Environmental restructuring*	The addition of prompts/checklists as pop ups on a computer system to facilitate T2D specific checks. Is there anything that could be added to the environment that could make monitoring of blood glucose simpler? Any technology or equipment that you think would help? Similarly, is there anything that could be added that would make referrals easier (i.e., mobile phone/iPad etc)? *Computer (BCIO:011013)* *Environmental (BCIO:011033)*	NA	NA	?	Value of IT prompts identified and clarified. No other suggestions provided. **Amended application:** Add prompts to computer system relating to monitoring of HbA1c, provision of lifestyle advice and appropriate referral	4	4	4
Lifestyle advice	Comparative imagining of future outcomes (9.3)	Ask staff to think about and compare possible or likely outcomes of providing versus not providing T2D lifestyle advice during a relapse *Face to face (BCIO:011003)* *Group-based (BCIO:011057)* *Asynchronous (BCIO:011601)* *Uni-directional (BCIO:011058)*	5	5	X	Removed as changes to other behaviour change techniques mean that this not required and not possible to provide during workshop.			

HbA1c monitoring Lifestyle advice	Commitment (1.9)	Ask staff to make a commitment using an "I will" statement as part of the action planning. The statement will relate to the provision of T2D care during relapse. The statement will be either written on a post it notes or a laminated sheet. (Not about an intention but about commitment to the decision to monitor HbA1c and provide T2D lifestyle advice during a relapse HbA1c monitoring *Face to face (BCIO:011003)* *Group-based (BCIO:011057)* *Asynchronous (BCIO:011601)* *Uni-directional (BCIO:011058)*	4	5	X	Removed as inappropriate commitment particularly the mode of delivery, additionally the domain targeted by commitment is targeted by remaining behaviour change techniques.

No score provided by participant: "-"

Across the intervention strategies, the most common response to all criteria was "Agree", with participants agreeing most frequently that the intervention would be acceptable to professionals working in an NHS setting (*APEASE: Acceptability*) and would help to reach the intended audience without disadvantaging others (*APEASE: Equity*). Most neutral responses were in relation to whether the intervention strategy was practicable at scale within the NHS with appropriate materials and human resources (*APEASE: Practicability*). Conversely practicality was also the second highest criteria for strongly agreeing, which suggests some divergence in views. Participants strongly agreed most frequently with the assumption that the intervention would be affordable when delivered at scale within the NHS setting (APEASE: Affordability).

Exploring this in more detail helped to gain a better understanding of whether certain intervention strategies were more well received by the participants. Across all four techniques, the proposed changes to care process and the environment were generally agreed to be appropriate across all six APEASE criteria. Whilst the inclusion of the strategy 'T2D relapse champion' was included as the techniques all met the criteria for consensus and thus inclusion, the techniques did demonstrate variability across the APEASE criteria. This was particularly so for the criteria practicability. This was a neutral score and not a disagreement, which would indicate that this idea was impractical, and was commented by the participant(s) that they had not worked with a Champion so found making this decision challenging. Figure 16 illustrates the APEASE scores across the four strategies. The strategy 'T2D relapse champion' contains three behaviour change techniques; the panel consists of three participants therefore the maximum frequency of scores available per each APEASE criteria is nine. 'Targets and feedback' also contain three techniques thus a maximum frequency of nine. 'Care process and environment' contains four techniques creating a maximum of 12.

The maximum frequency for the ‘Training session’ strategy is twelve, as although it contains six behaviour change techniques only two participant’s scores were recorded.

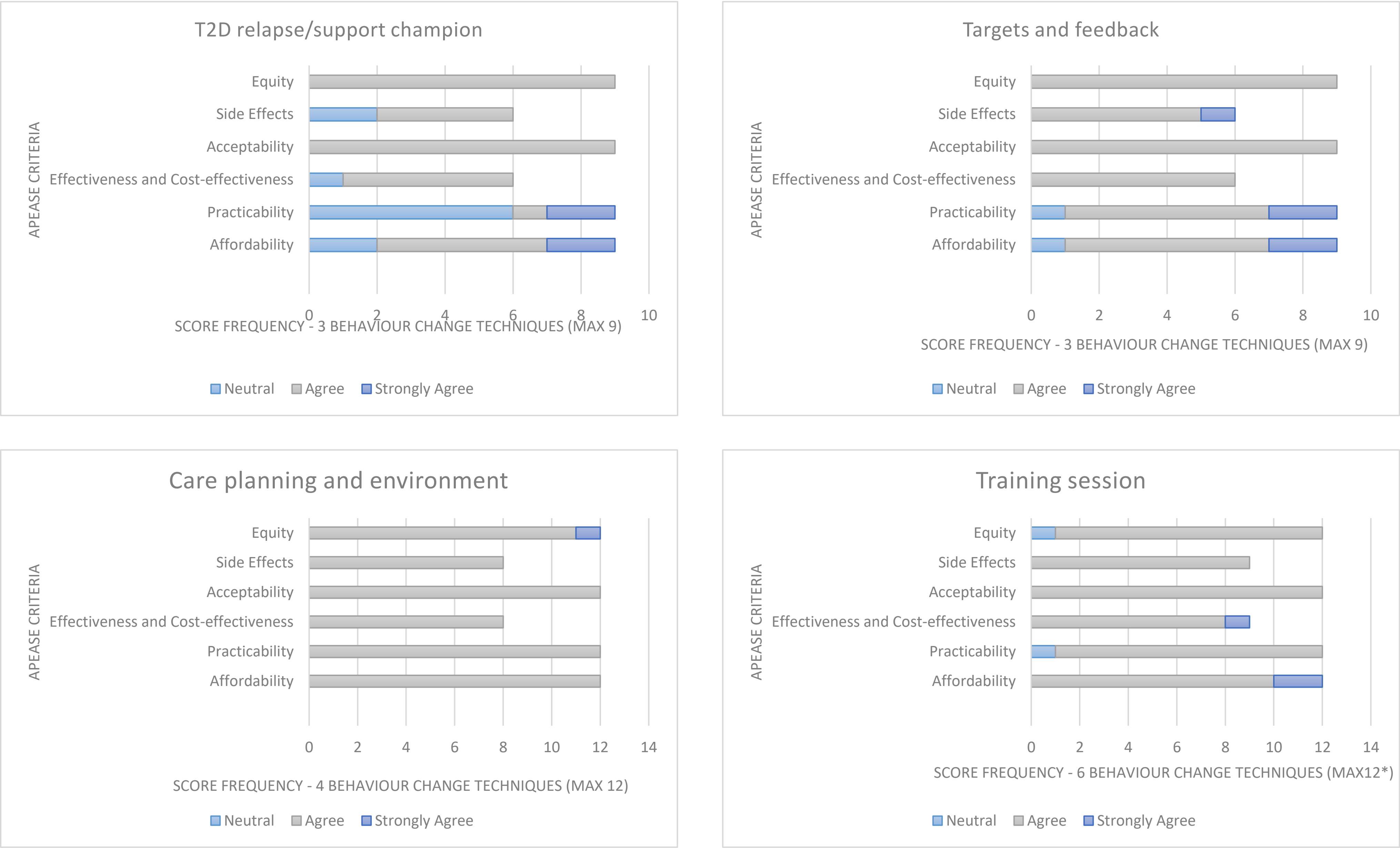


Figure 16: Graphs illustrating the total APEASE ratings across each behaviour change technique within the four strategies

The criteria for consensus was met for all behaviour change techniques, therefore the second version of the draft intervention strategy was deemed suitable with no further rounds required. The final draft proposal including the target behaviours, intervention functions, policy categories, behaviour change techniques and modes of delivery is provided in Table 38. A detailed description of how these outcomes are proposed to be delivered are outlined in the next section.

Table 38: Final proposed draft intervention strategy

Target Behaviour	Theoretical Domains Framework Domains	Intervention Functions	Policy categories	Behaviour Change Techniques	Mode(s) of delivery
Intervention Strategy: Training session					
HbA1c monitoring Referral Lifestyle advice	Knowledge	Education	Guidelines	Information on health consequences (5.1) Instructions on how to perform the behaviour (4.1) Salience of consequences (5.2)*	Face to face (BCIO:011003) Audio (BCIO:011030)* Visual (BCIO:011031)* Group-based (BCIO:011057) Asynchronous (BCIO:011601) Uni-directional (BCIO:011058)
Lifestyle advice	Beliefs about consequences			Information on health consequences (5.1) Salience of consequences (5.2)*	
HbA1c monitoring Referral	Skill	Training		Instructions on how to perform the behaviour (4.1) Behavioural practice/rehearsal (8.1) Social support- practical (3.2)	
HbA1c monitoring Referral Lifestyle advice	Environmental Context and Resources			Social support (practical) (3.2)	
Lifestyle advice	Social Influence	Persuasion		Information about others' approval (6.3)*	
Intervention Strategy : T2D Relapse Champion					
HbA1c monitoring Referral Lifestyle advice	Social/professional role and identity	Persuasion Modelling	Service provision	Social support (Unspecified) (3.1)	Face to face (BCIO:011003) Group-based (BCIO:011057) Synchronous (BCIO:011060) Interactional (BCIO:011059)

HbA1c monitoring Referral Lifestyle advice	Environment, context, and resource	Environmental restructuring		Restructuring the social environment (12.2)	
Lifestyle advice	Social influence	Environmental restructuring Modelling		Social support (Unspecified) (3.1) Restructuring the social environment (12.2) Social reward (10.4)	
Intervention Strategy: Targets and feedback					
Lifestyle advice	Social influence	Modelling	Guidelines	Information about others' approval (6.3)	Face to face (BCIO:011003) Individual-based (BCIO011055) Asynchronous (BCIO:011061) Interactional (BCIO:011059)
	Goals	Persuasion		Goal setting - behaviour (1.1) Review goal - behaviour (1.5)	
Intervention Strategy: Changes to care planning and environment					
HbA1c monitoring Lifestyle advice	Memory, attention, and decision process	Environmental restructuring	Guidelines Service provision	Action planning (1.4) Prompts/cues (7.1)	Prompt/Cues (7.1): Computer (BCIO:011013) Environmental (BCIO:011033) Informational (BCIO:011001) Synchronous (BCIO:011060) Uni-directional (BCIO:011058) All others: Printed (BCIO:011008) Asynchronous (BCIO:011061) Interactional (BCIO:011059)
HbA1c monitoring Referral Lifestyle advice	Environment, context, and resource	Environmental restructuring		Prompts/cues (7.1) Add objects to the environment (12.5) Social support - practical (3.2)	
Lifestyle advice	Social influence	Enablement		Social support - practical (3.2)	
	Goals			Action planning (1.4)	

* = mode of delivery applicable to specific behaviour change technique only

7.5 INDEX key considerations

All the key considerations of the INDEX guidance were relevant within this chapter including the Delphi and design and refinement of the initial proposed intervention strategy (Table 39). Whilst the completion of this study illustrates completion of this design phase there is the need for further testing and refinement through feasibility testing which is detailed further in Section 8.4.1.

Table 39: INDEX key considerations in the completion of steps 5-8 of the Behaviour Change Wheel[1], including the Delphi study

Key Issue	Included	Evidence
Plan the development	✓	Completion of steps 5-8 of the Behaviour Change Wheel[108] support the development of the intervention
Involve stakeholders	✓	Health professionals recruited
Bring together a team and establish decision making processes	✓	Independent review of belief statements and consideration of behaviour change technique inclusion
Review published research evidence	✓	Published existing evidence used to aid discussion of findings of the interview study
Draw on existing theories	✓	Theoretical Domains Framework[91], behaviour change technique taxonomy V1 and Theory and techniques tool all supported development and articulation of programme theory
Articulate programme theory	✓	Programme theory articulated in the initial proposed draft intervention and resulting logic model (Section 7.6)
Undertake primary data collection	✓	Interview
Understand the context	✓	Inherent in the involvement of stakeholder and use of APEASE criteria
Pay attention to future implementation of the intervention in the real world	✓	Inherent in the involvement of stakeholder and use of APEASE criteria
Design and refine the intervention	✓	Intervention designed and refined using multiple sources including existing evidence, APEASE criteria and input of stakeholders in the Delphi
End the development phase	✓	Completion of the initial proposed draft signifies the end of this development phase. It is however important to note that further revisions will be required through feasibility testing

The reporting of the intervention development process

7.6 The Intervention proposal: Final draft strategy and programme theory (logic model)

The final proposed intervention is depicted in Figure 17 with the provisional logic model of the intervention illustrated in Figure 18. This logic model was informed by a logic model created for an intervention to support integrated care for frail adults living at home[324], utilised as it presented a similar level of complexity that demanded clear illustration. The logic model outlines the proposed inputs required prior to intervention delivery, these will support effective delivery of the intervention and help to ensure context is supportive of the changes proposed[325]. It serves as an illustration of the proposed programme theory of the draft intervention strategy. These inputs are informed in part by prior literature detailing inputs for interventions in a healthcare setting[324], as well as personal knowledge of supporting delivery of interventions in a research capacity in the NHS context. The proposed immediate, intermediate, and long-term outcomes were informed by previous literature which provides evidence of opportunities for change. This includes published findings from this project[269], and the barriers and enablers to delivery of T2D care during relapse detailed in chapter 6. It is informed by evidence on the experiences of care of service users[57,58,60,201,202], which details challenges with managing diet/exercise during relapse as well as impacts on ability to self-manage. The outcomes for professionals are informed by wider literature on T2D support for individuals with an SMI broadly[269], as well as the barriers and enablers identified through the interview study reported in Chapter 6. The broader literature supporting suggested outcomes was detailed in the earlier chapters related to lack of role clarity impacting retention, morale and staff well-being[196]. Finally, the long-term impacts are informed by the wider literature on the outcomes for service users who have this dual morbidity(For example[13,16,18,326]). The logic model has been designed to demonstrate the potential for outcomes, which will serve as guidance for designing data collection and primary and secondary endpoints for consideration in both feasibility and full trials as part of post-doctoral work. It is important to note that the logic model is not expected to be static nor capture all aspects of the intervention. Notably the interaction with context is not depicted. Further iterations of the logic model are expected to be developed throughout the lifecycle of the developing intervention; this is the representation following initial design.

T2D in Relapse Intervention Programme

T2D/Relapse Champion

Aim

To provide peer support and encouragement, during facilitation of the training session and during daily meetings

Intervention functions

Persuasion, Modelling, and Environmental restructuring

Policy categories

Service provision

Behaviour change techniques

Social support practical (3.2); Restructuring the social environment (12.2); Social reward (10.4)

Mode of delivery

Face to face (BCIO:011003)
Group-based (BCIO:011057)
Synchronous (BCIO:011060)
Interactional (BCIO:011059)

Targets and Feedback

Aim

To set goals for lifestyle advice provision and provide feedback

Intervention functions

Persuasion and Modelling

Policy categories

Guidelines

Behaviour change techniques

Goal setting – behaviour (1.1); Review behaviour goals (1.5); Information about other's approval (6.3

Mode of delivery

Face to face (BCIO:011003)
Individual-based (BCIO:011055)
Asynchronous (BCIO:011061)
Interactional (BCIO:011059)

Changes to care planning and environment

Aim

Make changes to appropriate care plans, collaborating with service users and carers and add specific computerised prompts to cue behaviour

Intervention functions

Environmental restructuring and Enablement

Policy categories

Service provision and guidelines

Behaviour change techniques

Action planning (1.4); Prompts/cues (7.1); Social support (practical) (3.2); Add object to the environment (12.2)

Mode of delivery (Care planning):
Printed (BCIO:011008)
Asynchronous (BCIO:011061)
Interactional (BCIO:011059)
Mode of delivery (Prompt):
Computer (BCIO:011013)
Environmental (BCIO:011033)
Informational (BCIO:011001)
Synchronous (BCIO:011060)
Uni-directional (BCIO:011058)

Training Session

Aim

To support knowledge, understanding and skills of mental health professionals

Intervention functions

Education, training, and persuasion

Policy categories

Guidelines

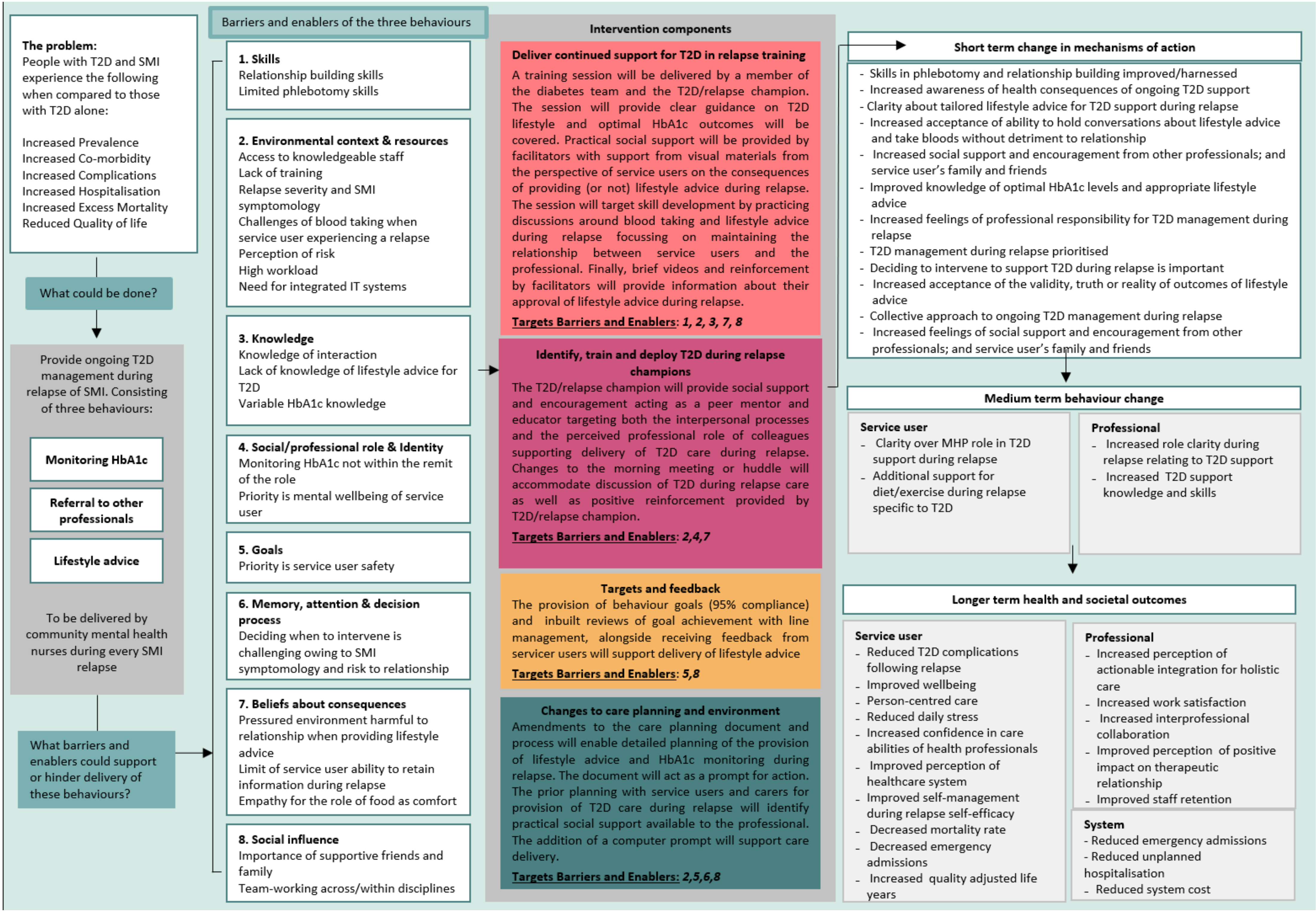
Behaviour change techniques

Information on health consequences (5.1); Instructions on how to perform behaviour (4.1); Salience of consequences (5.2); Information about others' approval (6.3); Behavioural practice/rehearsal (8.1); Social support (practical) (3.2)

Mode of delivery

Face to face (BCIO:011003)
Audio (BCIO:011030)
Visual (BCIO:011031)
Group-based (BCIO:011057)
Asynchronous (BCIO:011601)
Uni-directional (BCIO:011058)

Figure 17: Final proposed draft intervention strategy



The problem:
People with T2D and SMI experience the following when compared to those with T2D alone:

Increased Prevalence
Increased Co-morbidity
Increased Complications
Increased Hospitalisation
Increased Excess Mortality
Reduced Quality of life

What could be done?

Provide ongoing T2D management during relapse of SMI. Consisting of three behaviours:

Monitoring HbA1c

Referral to other professionals

Lifestyle advice

To be delivered by community mental health nurses during every SMI relapse

What barriers and enablers could support or hinder delivery of these behaviours?

Barriers and enablers of the three behaviours

1. Skills
Relationship building skills
Limited phlebotomy skills

2. Environmental context & resources
Access to knowledgeable staff
Lack of training
Relapse severity and SMI symptomology
Challenges of blood taking when service user experiencing a relapse
Perception of risk
High workload
Need for integrated IT systems

3. Knowledge
Knowledge of interaction
Lack of knowledge of lifestyle advice for T2D
Variable HbA1c knowledge

4. Social/professional role & Identity
Monitoring HbA1c not within the remit of the role
Priority is mental wellbeing of service user

5. Goals
Priority is service user safety

6. Memory, attention & decision process
Deciding when to intervene is challenging owing to SMI symptomology and risk to relationship

7. Beliefs about consequences
Pressured environment harmful to relationship when providing lifestyle advice
Limit of service user ability to retain information during relapse
Empathy for the role of food as comfort

8. Social influence
Importance of supportive friends and family
Team-working across/within disciplines

Intervention components

Deliver continued support for T2D in relapse training

A training session will be delivered by a member of the diabetes team and the T2D/relapse champion. The session will provide clear guidance on T2D lifestyle and optimal HbA1c outcomes will be covered. Practical social support will be provided by facilitators with support from visual materials from the perspective of service users on the consequences of providing (or not) lifestyle advice during relapse. The session will target skill development by practicing discussions around blood taking and lifestyle advice during relapse focussing on maintaining the relationship between service users and the professional. Finally, brief videos and reinforcement by facilitators will provide information about their approval of lifestyle advice during relapse.

Targets Barriers and Enablers: ***1, 2, 3, 7, 8***

Identify, train and deploy T2D during relapse champions

The T2D/relapse champion will provide social support and encouragement acting as a peer mentor and educator targeting both the interpersonal processes and the perceived professional role of colleagues supporting delivery of T2D care during relapse. Changes to the morning meeting or huddle will accommodate discussion of T2D during relapse care as well as positive reinforcement provided by T2D/relapse champion.

Targets Barriers and Enablers: ***2,4,7***

Targets and feedback

The provision of behaviour goals (95% compliance) and inbuilt reviews of goal achievement with line management, alongside receiving feedback from servicer users will support delivery of lifestyle advice

Targets Barriers and Enablers: ***5,8***

Changes to care planning and environment

Amendments to the care planning document and process will enable detailed planning of the provision of lifestyle advice and HbA1c monitoring during relapse. The document will act as a prompt for action. The prior planning with service users and carers for provision of T2D care during relapse will identify practical social support available to the professional. The addition of a computer prompt will support care delivery.

Targets Barriers and Enablers: *2,5,6,8*

Short term change in mechanisms of action

- Skills in phlebotomy and relationship building improved/harnessed
- Increased awareness of health consequences of ongoing T2D support
- Clarity about tailored lifestyle advice for T2D support during relapse
- Increased acceptance of ability to hold conversations about lifestyle advice and take bloods without detriment to relationship
- Increased social support and encouragement from other professionals; and service user's family and friends
- Improved knowledge of optimal HbA1c levels and appropriate lifestyle advice
- Increased feelings of professional responsibility for T2D management during relapse
- T2D management during relapse prioritised
- Deciding to intervene to support T2D during relapse is important
- Increased acceptance of the validity, truth or reality of outcomes of lifestyle advice
- Collective approach to ongoing T2D management during relapse
- Increased feelings of social support and encouragement from other professionals; and service user's family and friends

Medium term behaviour change

Service user
- Clarity over MHP role in T2D support during relapse
- Additional support for diet/exercise during relapse specific to T2D

Professional
- Increased role clarity during relapse relating to T2D support
- Increased T2D support knowledge and skills

Longer term health and societal outcomes

Service user
- Reduced T2D complications following relapse
- Improved wellbeing
- Person-centred care
- Reduced daily stress
- Increased confidence in care abilities of health professionals
- Improved perception of healthcare system
- Improved self-management during relapse self-efficacy
- Decreased mortality rate
- Decreased emergency admissions
- Increased quality adjusted life years

Professional
- Increased perception of actionable integration for holistic care
- Increased work satisfaction
- Increased interprofessional collaboration
- Improved perception of positive impact on therapeutic relationship
- Improved staff retention

System
- Reduced emergency admissions
- Reduced unplanned hospitalisation
- Reduced system cost

Figure 18: Initial logic model of proposed intervention strategy

7.7 Discussion

Utilising the Behaviour Change Wheel[108], Stages 2 (Identify intervention options) and 3 (Identify content and implementation options) were completed to support development of the intervention. Mapping exercises, existing evidence, consultation with the supervisory team and a modified Delphi with participants who have experience of supporting individuals with SMI/T2D were undertaken to inform the design process.

The resulting intervention consists of six intervention functions (Education, Persuasion Training, Modelling, Enablement, and Environmental restructuring), two policy categories (Guidelines, Service provision) and 14 unique behaviour change techniques, delivered across four intervention strategies. The four strategies are 1) a training session, 2) appointment of a T2D relapse champion, 3) goals and feedback and 4) changes to care planning and the environment. The development of the intervention was reported using the GUIDED reporting checklist[142] (Appendix 31).

It is acknowledged that this is a proposed intervention strategy that will require further refinement. This can be achieved through feasibility testing, as per the MRC guidance[97,106], and is discussed further in section 8.4.1.

7.7.1 Strengths and limitations

A strength of this study is the involvement of health professionals with a wide range of experiences to support the design of the intervention. This enabled an experience-based response to the proposed intervention strategy and resulted in several refinements which significantly shaped the final draft intervention. There may however be the need to consider the intervention further with stakeholders with senior experience of finance management within the NHS. For example, interventions to support healthcare practitioners' behaviour change have been found to be heavily weighted towards workshops for delivery, which are felt to be expensive and only deliverable to small numbers[327]. Within this current study the affordability and cost effectiveness of the training session was not identified as inappropriate in APEASE assessments by the panel. This may however reflect the experiences of participants, as the participant within this current study who has had experience of senior level management felt they could not answer the questions surrounding cost effectiveness and affordability owing to limited evidence or experience. It may be that inclusion of senior management or those who would be responsible for taking on the costs of such an intervention would yield different outcomes.

Clarity and guidance around moving from identification of behaviour change techniques to applications is limited[327]. In this study a Delphi was utilised. It was selected to allow for asynchronous participation that was suggested to soften the potential for interpersonal conflicts and allow flexible participation, important given the identified workload challenges of the target participants. A disadvantage of this method however was the inability to discuss ideas with participants, the opportunities to do so could have been advantageous in this design process, for example to clarify the goal setting target (i.e. the professional as the target and not service users) or create discussion between participants on cost-effectiveness and affordability as part of the APEASE criteria. It would also allow for collaborative discussions which may have further shaped the intervention. Other methods that have been used in other studies to identify behaviour change techniques and move to application include the use of alternative consensus techniques (nominal group technique) delivered via remote workshop[314], a mixture of consensus methods (not specified) and in-person co-design workshops[267], and in-person focus groups[289]. Crucially these examples all allow for additional discussion as they include a face-to-face element (either remote or in-person). It has been suggested that qualitative work following on from Delphi studies could be advantageous[328], however this potentially creates overlap with nominal group techniques. Thus, whilst an intervention was developed with the input of stakeholders using the selected method, further work will be required to continue the refinement of the intervention strategy. This is discussed further in suggested next steps for the intervention (Section 8.4.1).

The use of a theoretical approach was a strength of this study as it enabled identification of additional intervention functions (Persuasion and Modelling), policy categories (Guidelines), and eight additional behaviour change techniques when compared to the published interventions in Chapter 4. The overlap in identified intervention functions, policy categories and techniques are likely a result of environment appropriateness, i.e., the healthcare setting which is prohibitive to certain intervention functions (e.g., Coercion) and policy categories (e.g., Fiscal). Similarly, the overlap in behaviour change techniques is likely owing to the context similarities, i.e., health professional behaviour change within the health and care environment, as well as the use of a training package within this intervention strategy. A further potential strength of this intervention is the additional strategies which incorporate more social norms and experiential legitimation of practice which have been missing previously and are suggested to be more influential in changing professional behaviour (for example: *Social Reward*[228], as discussed in Chapter 4. Finally, the intervention function *Persuasion* was included in this intervention and was identified as a missed opportunity from previous interventions (Chapter 4). Whilst it is noted that interventions delivered using P*ersuasion* which seek to reshape the attitudinal landscape in which professional behaviours are enacted, are less likely to lead to professional practice behaviour change[228], this is suggested to be when persuasion is used alone and not in combination with other intervention functions as selected in this current intervention.

The use of the Theory and techniques tool[144] alongside the Theoretical Domains Framework/behaviour change technique matrix[108] enabled a comprehensive identification of potential behaviour change techniques, a strength of this study. As discussed in the methods (Section 7.3.1), the Theoretical Domains Framework/behaviour change technique matrix[108] was used to identify potential behaviour change techniques alongside the Theory and techniques tool[144] . The use of the Theory and techniques tool presents opportunities to explore mechanisms of action beyond those identified within the Theoretical Domains Framework[91]. Within the 14 behaviour change techniques selected in this intervention, 8 have proposed links to other mechanisms of action. For example, the behaviour change technique *Prompts/cue (7.1)* is proposed to affect the domains *Memory, Attention and Decision Processes* and *Environment context and resources* but also the mechanism of action 1) *Behavioural cueing.* This provides guidance as to other mechanisms of action which could be explored during subsequent theory-based evaluation.

The systematic review[269] (Chapter 3) of barriers and enablers of T2D care for adults with an SMI led to the suggestion of a need to focus on providing a collaborative healthcare environment which actively supports T2D, improved communication between professionals and service users, clarity around roles and responsibilities and the development of individual knowledge and skills, alongside confidence building as opportunities to improve T2D care. Whilst the intervention in this current study was developed to target the domains and specific beliefs identified surrounding HbA1c monitoring, lifestyle advice and appropriate referrals for T2D during an SMI relapse, the broader challenges (and Theoretical Domains Framework domains) are largely congruent. For example, all seven of the domains identified as important in the systematic review (Section 3.5.5) were identified in the study of the barriers and enablers of the target behaviours during relapse (Section 6.4.2.1). It is therefore suggested that this intervention which targets the specific timepoint of relapse may provide a clear opportunity to impact some of the pervasive and enduring challenges especially surrounding roles and responsibilities in T2D management more generally in adults with an SMI as identified in the systematic review[269] (Chapter 3). This is discussed further in Chapter 8 (Section 8.3.5).

As recruitment in Study 3 and 4, there were challenges with recruitment and a pragmatic decision to move forwards with intervention design was undertaken to allow completion of the project. The initial round consisted of six participants, which exceeds the proposed minimum number for Delphi[263], however only half of the respondents completed the second ranking survey. Challenges with retention within Delphi studies are well known[263], therefore attrition is not unexpected. The limited number of initial participants does however mean that the second round was completed by fewer participants than normally acceptable for Delphi studies[263], a limitation of this study. Recruitment challenges may impact the validity and appropriateness of the resulting intervention. Having a limited (number) of participants may mean that the chosen components are not appropriate more broadly, reflecting a limited experience. Several of the participants held roles outside of the community mental health care team currently therefore drawing on prior experience may mean that suggestions for the intervention may not be suitable for the current context especially considering the current changes to the community care environment. The limitations can be addressed, in part, through continued refinement in feasibility testing post PhD and is discussed further in section 8.4.1. It is however noteworthy that as discussed in earlier sections of this thesis (Chapter 5. Section 5.3.4.2 and Chapter 7. Section 7.3.1.3.2.2) there is debate as to the need to provide and adhere to a specified sample size as the Delphi is concerned not with a generalisable sample but on the input of a purposively sampled panel[250]. The sample identified within this study had multiple experiences covering decades as well as multiple roles ranging from healthcare assistant to senior management, thus bringing to the Delphi both a range of experiences and expansive accumulated knowledge. The information provided by participants was invaluable in generating insights into how best to apply the behaviour change techniques in the NHS context (the applications) and their involvement heavily shaped the proposed final design, a strength of this study. Furthermore, the use of the APEASE criteria has provided detailed assessment of the behaviour change technique applications and provides guidance for exploring the behaviour change techniques when feasibility tested in more detail, e.g., the practicability of the T2D/relapse champion.

Related to the potential limitations of the sample is the inability to confirm the professional role of one participant. The decision was taken to include their data as it was judged that with the recruitment strategy (i.e., targeting only mental health professionals) the completion of the survey was unlikely to be by professional working outside of mental health. Supporting this argument are the challenges in recruitment, thus given how difficult it was to recruit it is unlikely that an individual working outside of this field and without an interest in the area, would complete the survey. It is however not possible to verify this and as the participant did not complete the second survey their data may not be relevant. Removing their responses would however not impact the intervention strategy and thus the impact of their inclusion is not judged to negatively impact the outcome.

It is a potential limitation of the study that consideration of all specific intervention content (i.e., intervention functions, policy categories, behaviour change techniques and modes of delivery) were not undertaken by participants within the Delphi study. This may result in the absence of content which is considered important by stakeholders. Participants were instead provided with applications (round one) and overall intervention strategies (round two) for their considered judgements. This decision was taken for two reasons: firstly, the lack of context when providing the plain English descriptions of intervention content (i.e., without an application or strategy) was judged to be challenging for individuals with limited knowledge or experience of the Behaviour Change Wheel. This was reinforced by the selected method which was asynchronous and thus limited the ability to provide more information and clarify. Secondly, the low levels of retention and challenges in recruitment more generally suggested that additional rounds would likely have been poorly completed. All content and subsequent applications were independently reviewed by a second reviewer (MH) who brings considerable knowledge and expertise of the NHS environment to shortlisting, supporting this decision. Furthermore, this method is arguably appropriate, and not detrimental to the proposed resulting intervention strategy, as it was possible to assess the shortlisted intervention content and make amendments to their inclusion (i.e., the addition of the policy category *Guidelines* and mode of delivery *Printed publication (BCIO:011008*)) without the need to provide the content separately.

A potential limitation of the work was the presentation of candidate behaviour change techniques separately. Interventions are delivered as a whole and asking the participants to reflect on the individual behaviour change techniques may have decontextualised them. The APEASE ratings may change when presented as a package of behaviour change techniques. This was partially addressed by grouping the behaviour change techniques into the four overarching strategies in the Strategy Information Pack (Version 2.0) (Appendix 28). The outcomes may however have differed however with a different approach to presentation, e.g. a discussion of the strategies broadly without breaking down into individual techniques.

This can be addressed through post-doctoral work and the presentation of the intervention as a package, using the APEASE criteria to again review. This step is also important given the challenges of recruitment and chosen inclusion criteria, discussed further in the next paragraph.

It is possible that the inclusion criteria adopted was too broad and did not specify that the health care professional had to be a community mental health nurse nor one with experience of T2D care. This is arguably an important caveat as the “light touch” care package is designed to be delivered by this particular care group. The criteria were designed to be broad to try to ensure that those with a wider care experiences, e.g. of management, were included. The included sample (excluding the individual for whom it was not possible to identify their professional role), all had experience of working as a community mental health nurse alongside other roles (e.g. in management or as a physical health nurse working with service users in the community). The additional knowledge and experience, alongside direct experience of the role targeted by the intervention, is thought not to have a detrimental effect on the outcome of the intervention, i.e. the chosen intervention content is identified by those with appropriate experience. Given however that further work is required to refine the package, it would be appropriate to ensure that subsequent feedback is identified from those working currently as a community mental health nurse. It may be more difficult to identify those who may have provided some T2D care in previous roles , or in community mental health nursing, as this is not typically care provided by this professional group. This underscores the importance of feasibility testing given that the intervention requires additional care behaviours from this population (Discussed further in Section 8.4.1)

7.8 Summary

This chapter outlines the design of a theoretically informed, evidence-based and context-sensitive intervention to support delivery of three target behaviours of T2D management during relapse of an SMI. It completes steps 5 -8 of the Behaviour Change Wheel[269].It is populated by six intervention functions, two policy categories and 14 behaviour change techniques delivered through four intervention strategies. The knowledge and skills of mental health professionals are targeted during a training session (Strategy 1). Beyond training packages, the intervention targets social norms with the appointment of a T2D/relapse champion (Strategy 2). The champion acts as a facilitator and provides practical guidance and support promoting positive change within the healthcare environment. The legitimation of new practice norms through experience are essential and achieved through amendments to the care planning process, including detailed planning of lifestyle advice and the use of computerised prompts, supporting integration into routine practice (Strategy 3). Finally, goals and feedback, including tailored performance comparators are included to help drive the behaviour change (Strategy 4).

Mapping exercises, existing literature including the outcomes of the content analysis (Chapter 4), discussion with supervisory team members and information provided by healthcare professional participants in a two-round Delphi was utilised to inform decisions regarding intervention content. The systematic review[269] (Chapter 3) supported identification of short, medium and long term outcomes illustrated in the proposed intervention logic model. Recruitment challenges and the suitability of the Delphi method are limitations of the study. The final chapter of this thesis will outline the contributions of this PhD, detail next steps for intervention refinement in post-doctoral work and make recommendations for future research.

8 Chapter 8: Discussion

8.1 Prologue

The previous chapter concluded with the design of a draft intervention consisting of four interacting strategies to target barriers and utilise enablers of T2D care (HbA1c monitoring, lifestyle advice and referral) for individuals experiencing a relapse of their severe mental illness. This concluded the independent research of this PhD.

The final chapter of this thesis will summarise the five studies of this PhD. The individual chapters provided discussion around the specific projects, however general themes across the project will now be discussed and situated within the broader NHS context. The strengths and limitations of the PhD will be explored with recommendations for future and complementary research. Finally, a conclusion summarising the project will be provided.

8.2 Overview

Five studies were completed as part of this PhD. Study 1, a systematic review of 28 studies identifying health professionals' perceived barriers to and enablers of delivering and organising T2D care for people with SMI. Barriers and/or enablers of T2D care for people with a severe mental illness were explored using the Theoretical Domains Framework[91] . Overall, seven theoretical domains were identified as important 1) *environmental context and resources 2) social influence*, 3) *skills*, 4) k*nowledge,* 5) *social/professional role and identity*, 6) *goals and 7) Beliefs about capabilities)*. Barriers and enablers were identified at individual, interpersonal and organisational levels. Focussing on providing a collaborative healthcare environment which actively supports T2D care, fostering improved communication both between professionals and service users, ensuring clear boundaries around roles and responsibilities as well as individual skill and knowledge support alongside confidence building were all suggested as potential opportunities to improve T2D. [108].

Study 2 analysed the content of eight interventions targeting delivery and organisation of T2D care and explored the theoretical congruence between the intervention content and previously identified barriers and enablers from Study 1. Intervention content was organised using the intervention functions, policy categories and behaviour change techniques as described in the Behaviour Change Wheel[108] and the behaviour change techniques Taxonomy v1[112]. The congruence between the domains and the intervention content was explored using the matrices provided in the Behaviour Change Wheel[108] and the Theory and techniques tool[144]. Retrospective content analysis of the eight studies identified the use of three intervention functions, three policy categories and eight behaviour change techniques. *Education* and *Training* were the most frequent intervention functions and *Communication/marketing* the most frequent policy category. Eight different behaviour change techniques were identified across the interventions, with the most frequent being *Instructions on how to perform the behaviour* and *Information about health consequences*. Assessment of theoretical congruence suggested that, whilst behaviour change techniques were limited in number, they were highly conrgruent with the retrospectively identified Theoretical Domains Framework domains which act as barriers and/or enablers of T2D care. There are however opportunities to target other domains identified as important to the delivery and organisation of T2D care and to consider a wider range of intervention functions and behaviour change techniques for any future intervention. Results from the content analysis identified four promising behaviour change techniques 1) *Instructions on how to perform the behaviour, 2) Information about health consequence, 3) Behaviour* *practice/rehearsal, and 4) Restructuring the social environment,* which were all included in over 25% of included studies which reported a statistically significant effect. These were given high priority in intervention design and included in the final proposed intervention strategy. The results also influenced the substantial focus on social norms with the inclusion of a T2D relapse champion and targets and feedback and the selection of two behaviour change techniques proposed to underpin social norm interventions[227] 1) *Social reward* and 2) *Information about others' approval.*

Studies 3, 4 and 5 were designed to support completion of the 8 steps of Behaviour Change Wheel[108], which was selected to guide intervention development because it provides a systematic and theoretically informed, yet parsimonious, method for designing behaviour change interventions. **Step 1** required a definition of the problem in behavioural terms with existing literature guiding completion. The broad behavioural problem was defined as the need to improve the delivery and organisation of T2D care for adults with an SMI, with care taking place in both primary and secondary care being provided by a range of professionals. It was kept purposefully broad as it was important to enable participants to suggest ideas for improving T2D care for adults with an SMI without constraint in the Delphi study. Participants in the Delphi study (Study 3) supported completion of Step 2. Twenty-one participants (service users, carers, and healthcare professionals) participated in a modified Kantian Delphi. The results of the Delphi completed **Step 2** of the Behaviour Change Wheel (Select target behaviour) with results guiding selection of the broad area of "a proactive approach to diabetes care during times of difficulty such as a mental health breakdown". Existing literature and discussion with two health professionals supported completion of Step 3 (Specify the target behaviour). Three target behaviours were specified (**Step 3**) - the monitoring of HbA1c, provision of lifestyle advice and appropriate onward referrals (*what*) undertaken by community (*where*) mental health nurses (*who*) supporting adults with T2D (*with whom*) during every SMI relapse (*when/how often*).

The fourth study identified what needs to change to achieve the desired change in behaviour, completing **Step 4** of the Behaviour Change Wheel[108]. Potential barriers and enablers to implementing the three T2D care behaviours specified in the previous study during relapse were identified from interviews undertaken with ten mental health professionals with experience of supporting individuals with an SMI in a community setting. Using a combined deductive and inductive analysis approach enabled identification of Theoretical Domain Framework domains of importance and potential contextual moderators of intervention effectiveness. The results of the importance assessments determined that eight Theoretical Domains Framework domains are important across the three target behaviours completing **Step 4** of the Behaviour Change Wheel (Identify what needs to change). Three of these domains *1) Knowledge, 2) Social/professional role and identity and 3) Environmental Context and Resources* were important to all three target behaviours. The domain *4) Skills* was important to HbA1c monitoring and referral; and domain *5) Memory, Attention and Decision Processes* was important to lifestyle advice and HbA1c monitoring. The remaining domains *6) Beliefs about consequences, 7) Social influence and 8) Goals* were important to lifestyle advice only. Inductive analysis using a codebook thematic analysis supported the understanding of the centrality of *social/professional role and* identity in the challenges surrounding T2D care for adults with an SMI by community mental health professionals.

The fifth study completed Steps 5 – 8 of the Behaviour Change Wheel[108] resulting in a theoretically-informed and evidence-based intervention, co-designed with appropriate stakeholders. A Lockean modified Delphi with six mental health professionals alongside a mapping exercise, discussion with supervisory team and existing literature all contributed to the completed final draft intervention strategy. This process identified six intervention functions (**Step 5**), three policy categories (**Step 6**) and sixteen behaviour change techniques delivered through nineteen applications (**Step 7**). Mode of delivery (**Step 8**) was used to inform the creation of applications and was revised following input from participants. These were incorporated into an intervention that consists of four overarching strategies 1) training session, 2) identification of a T2D/relapse champion, 3) goals and feedback and 4) changes to care planning and the environment. The intervention strategies when combined offer opportunities to target individual health professional behaviour, teams, and systems to maximise the potential for intervention effectiveness.

8.2.1 Identification of key domains and behaviour change techniques across the studies

Nine domains from the Theoretical Domains Framework were identified as of greater importance, or targeted by interventions, across the four studies. These are Environmental Context and Resource, Social Influence, Knowledge, Skills, Social/Professional Role and Identity, Goals, Memory, Attention, and Decision Process, Beliefs about Capabilities and Beliefs about Consequences. Figure 19 (following page) depicts the differing identification of the domains across four of the studies within the PhD. This includes the systematic review detailed in Chapter 3, content analysis and assessment of theoretical congruence (Chapter 4), domains of importance to the target behaviours identified in qualitative interviews (Chapter 6) and the domains targeted by the final intervention content (Chapter 7). The domain, *Social/professional role and identity* was identified as important to T2D care generally in the systematic review and was central to all three target behaviours (Chapter 6) but was not identified in existing interventions. The involvement of the T2D relapse champion as an intervention strategy is critical to targeting this domain in the resulting intervention. Similarly, the domain *Goals* is now targeted in the resulting intervention, it was also identified as important to T2D care generally and to the target behaviours but had not been identified in existing interventions. The domain *Beliefs about Consequences* is targeted in the resulting intervention but had not been identified in previous interventions nor was it identified as important in the provision of T2D care more generally. It was however identified as important to the target behaviours. This process highlights the importance of a nuanced understanding of important domains and the utilisation of explicit theory to identify theoretically-congruent intervention content to support the development of interventions which target known determinants of behaviour.

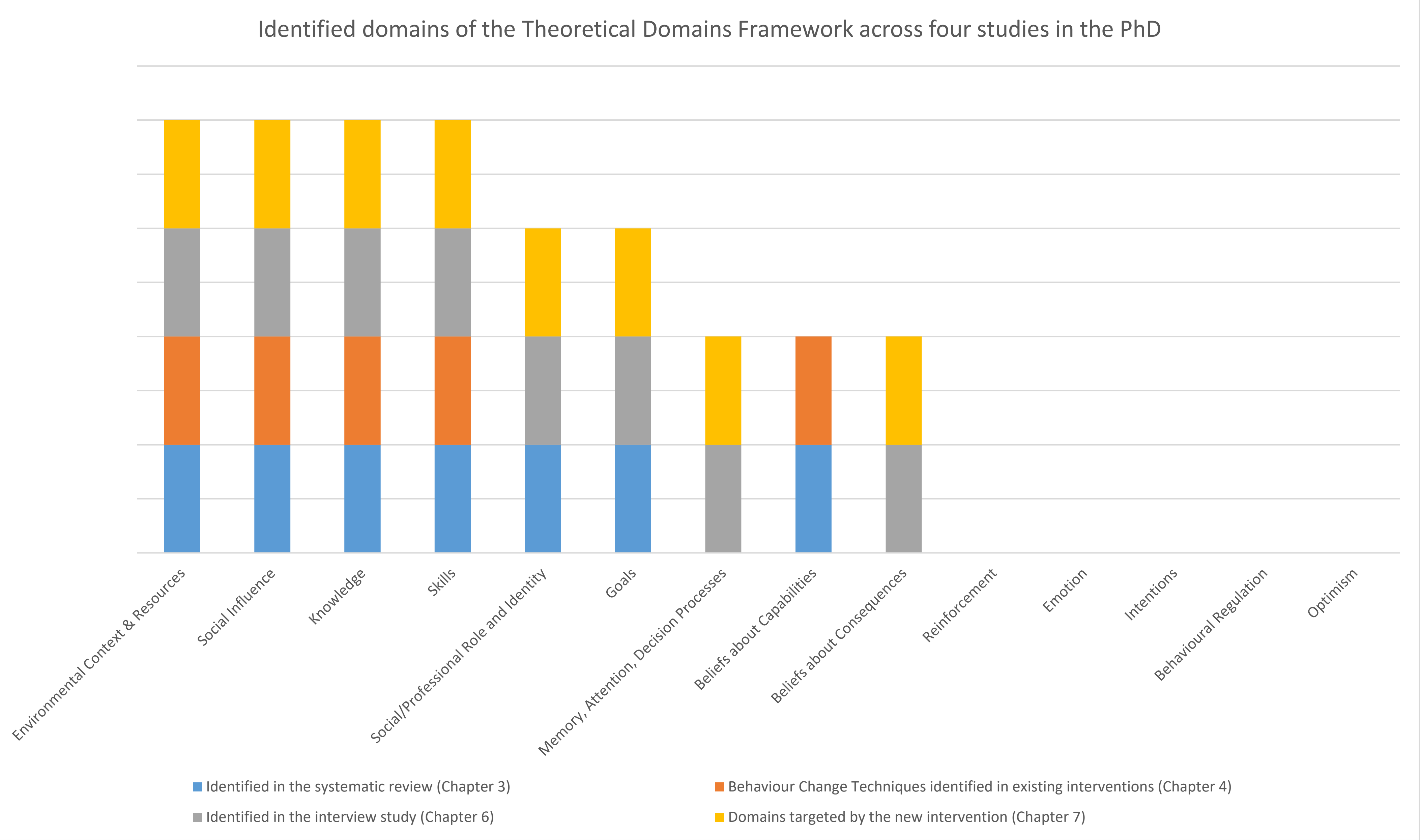


Figure 19: Bar chart showing the domains of the Theoretical Domains Framework identified across four studies within the PhD

The final item to note is the lack of explicit content which targets the important domains of T2D care generally but are not included in the resulting intervention of this PhD, i.e. *Beliefs about capabilities* is important to T2D care generally and had been identified as targeted by previous interventions but is not explicitly indicated in the resulting intervention because the domain was not identified as of importance to the three target behaviours. Although not explicitly included in this intervention, some of the behaviour change techniques included (e.g. Instructions on how to perform a behaviour) do target *Beliefs about capabilities*. Whilst this domain was not identified as important to the target behaviours, its importance to care generally is important to note. It is possible that this intervention, whilst designed to target specific aspects of T2D care delivered at a particular time point by community mental health nurses, may have effects on T2D care more widely and the use of theory helps to elucidate how this may occur. This offers opportunities for additional data collection during intervention feasibility and wider assessment of effectiveness to identify any spillover effects, as well as consideration of mechanisms of impact.

8.3 Strengths and limitations

In this section some of the methods utilised and underpinning methodology are considered. Whilst each individual chapter discussed some of the strengths and limitations of the methods relating to the study, this will add further insights and draw comparisons across the studies and the PhD as a complete project.

8.3.1 Stakeholder involvement

The involvement of stakeholders throughout intervention development was a key strength of this PhD. Servicer users, carers and health professionals guided the broad area of focus identified in Study 3 (Chapter 5), with two health professionals providing their expertise in specification of the target behaviour. Health professionals were also involved in the design of the intervention in a modified Delphi (Study 5 Chapter 7). Existing literature outlined limited evaluation and empirical evidence of the involvement of stakeholders[130]. Evidence from the fields of Implementation Science and healthcare generally demonstrated that multi-stakeholder collaborations intended to support evidence-based practices are relatively unverified in their effectiveness, and there were concerns surrounding tokenism[133–135,329,330]. To address this, clarity surrounding the level of involvement was necessary from the outset. The decisions about the focus of stakeholder involvement were based on feasibility and designed to avoid tokenistic use of service user input. It was considered best use of expertise and experience for service users and carers to be involved in the earlier stages to aid prioritisation and support selection of the target behaviours; whilst for the latter stages concerning decision making surrounding intervention design, only health professionals were involved.

The involvement of service users and carers in initial stages supported identification of the target behaviour and provided evidence of areas of overlap and differences in prioritisation areas for research. Overlap occurred in the importance of collaborative care between mental health and diabetes teams as well as the importance of health professionals at the critical time of relapse for managing T2D. Differences occurred particularly in the need for dietary advice outlined by service users but not rated as important by health professionals. It was also noted that the importance of this was reflected in the wider literature with experiences of service users[57,60,202]. The involvement of service users therefore supported identification of this as a target area for priority in this intervention which would have been missing if prioritisation was solely identified by health professionals.

The resulting intervention will involve changes to the care planning process which directly impact service users and carers. Ethical approval for the involvement of service users and carers had not been requested for the design stages (Study 5) and therefore it was not possible to gain the perspectives of service users and carers on this proposed change to the care planning process. On reflection, this input would have been useful given the direct impact and the wider literature which has indicated differences in the opinions of health professionals and service users of the role of informal carers in their care. The lack of insight from service users and carers for the proposed changes to care planning may affect the intervention acceptability therefore further input from service users and carers surrounding this aspect will be beneficial. Consideration of how best to involve stakeholders was undertaken during initial conception of the project prior to the creation of the intervention strategies, thus service user and carer involvement was integral to early decision making but not later stages of design. This was an important distinction to avoid tokenistic involvement of service users and carers by inviting them to participate in research which asked questions that were not relevant to them i.e., asking about the operationalisation of behaviour change techniques in service delivery would have been inappropriate. With the inclusion of changes to the care planning documentation now identified it would however be beneficial to gain their insights and thus it would be advantageous and appropriate during early feasibility work to gain the insight of service users and carers particularly related to this intervention strategy.

8.3.2 Sample and sizes

A key strength of this study was the involvement of service users, carers, and health professionals in the design of the intervention. Benefits included the identification of the target behaviour and context-sensitive intervention refinement. The samples were however small with challenges in recruitment and retention of health professionals.

Recruitment of health professionals into research is notoriously difficult, often requiring greater amounts of time and effort than originally expected[331]. Multiple strategies were utilised in this research to recruit health professionals including liaison with the funder (ELFT) through senior management and research advocates, attendance at clinical meetings to promote engagement with the research study, introductions made by supervisory team members to staff within ELFT utilising pre-existing relationships, direct contact with Trusts local to the researcher and known contacts to the researcher from prior work in a Research and Development department in efforts to set up additional sites, utilisation of recruitment websites, contact with charities (e.g. Diabetes UK, MQ Mental Health) and professional bodies (e.g. Royal Colleges) to promote the research, the use of snowball sampling and the use of social media including Facebook posts and Twitter. Despite these multiple avenues recruitment was challenging, and the achievement of target sample sizes was slow and in the case of the co-design study (Chapter 7) unattainable.

The approval of the DIAMONDS study[267] (detailed in Chapter 5. Section 5.6) and their recruiting of similar samples was cited by a Research and Development department, responsible for local approvals, as the rationale for why other Trusts could not support the study, with concerns for over-burdening professionals. Additionally, the limited incentive for Trusts to be involved in this study as it was not adopted onto the NIHR Clinical Research Network portfolio likely impeded these efforts. The role of key contacts in the organisation is noted[331], these individuals can promote research and provide a level of credibility to the study; particularly where student researchers are leading the project as was the case with this research. The approval requirements for research within the NHS for student projects necessitates the identification and involvement of a Local Collaborator[332]. Initially this role was fulfilled by the Senior Operational Lead for the Community Mental health Teams. Their involvement was invaluable as they provided access to the senior level professionals across multiple Community Mental Health Teams and facilitated dissemination of the study and recruitment in the first study. Unfortunately, the collaborator left the Trust at a similar time to my maternity leave. Upon my return there had been no new appointment into this role. Through multiple channels a senior psychiatrist consultant who was research active within the Trust was identified and was willing to act as a research champion. Recruitment however was still challenging. It is also suggested that face-to-face interactions and relationship building at the initial conceptualisation of research are important aspects of engaging health professionals to support recruitment[332]. The initial stages of this project were enacted during the COVID-19 pandemic and restrictions on travel and face-to-face interactions impeded this approach to engagement. In place of face-to-face interactions, video conferencing using Microsoft Teams was utilised to engage individuals. The limited face-to-face interactions and physical presence is potentially a contributor to the recruitment challenges.

Furthermore, the context of COVID on the NHS system is likely to have affected recruitment to Study 3 (Recruitment period: January 2021 – May 2021), with post-COVID effects impacting recruitment and retention to studies 4 and 5 (Recruitment period: September 2022 – May 2023). There were limits placed on interactions between individuals from December 202 until 21st June 2021 owing to the 'lockdown' within the UK[333]. Within the NHS, staff were redeployed where possible to enable critical care responses with community health, primary care, and mental health all significantly affected[334]. The reduced staff numbers and high levels of strain on services meant engaging health professionals sensitively was important, accepting the limits to their available time and resource to participate in research. Although lockdown was removed through the second recruitment period, the ongoing impact of COVID is apparent with the enduring impact of strain, drain and diminished morale on both the provision of service and those who provide the service[79], with systems remaining under sustained pressure[23]. The current context within the NHS demonstrates high levels of staff sickness and absence. Utilising data from the NHS Sickness Absence Rates: January 2023[80], Figure 20 demonstrates that sickness and absence in mental health and disability organisations is consistently amongst the higher recordings. Anxiety, stress, depression, and other psychiatric illness accounts for the largest proportion of reasons for absence, equating to 23.3% of all reported absences. Anecdotally, as discussed in Chapter 6, withdrawals from participation or introductions through snowball sampling were related to workload stress and absence. In addition, reported barriers to the provision of T2D care during relapse (Chapter 6) and examination of wider literature[269], highlighted high levels of staff turnover, insufficient levels of staff and high workloads are all factors. Collectively, this demonstrates a context whereby professionals are over-worked and struggling to meet the demands of the service they provide. Participation in research is therefore likely to be relegated to lower importance given the difficult circumstances faced. It is not without merit to suggest that this may be an influential factor in recruitment challenges. Beyond recruitment challenges it also provides a difficult backdrop for implementing any intervention.

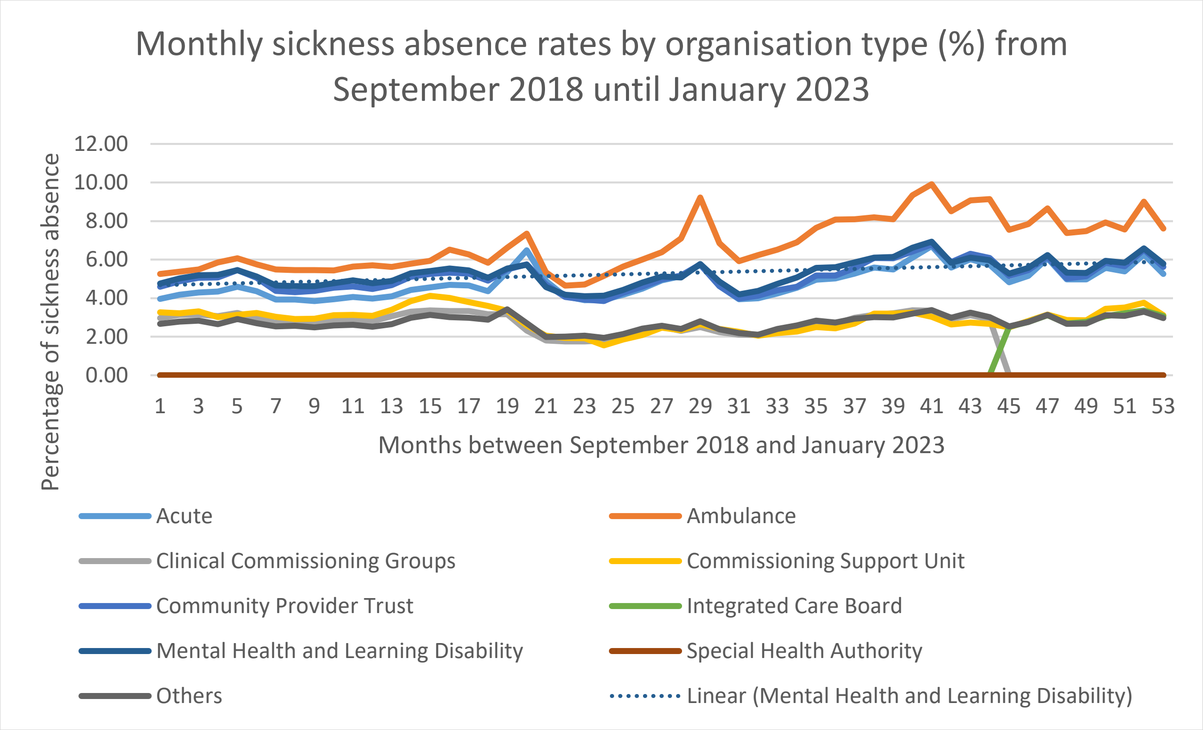


Figure 20: Trend chart for & levels of reported sickness and absence in staff in different organisations across the NHS.

The second proposed factor affecting recruitment is the prevalence of the domain *Social/professional role and identity*. This domain was highlighted in both Chapter 6 relating to T2D care during relapse as well as in the systematic review of barriers and enablers of T2D care for individuals with an SMI[269] (Chapter 3). Anecdotally, when liaising with potential individuals identified through snowball sampling, several mental health professionals commented that they were unable to participate as T2D was not their responsibility. It is plausible that these findings provide contextual information on why recruitment was challenging, i.e., recruitment was stilted as those targeted did not feel that the topic area is relevant to them (it is not their role). Whilst the challenges of co-production/co-design are discussed widely in the literature (e.g.[136,335]) there is limited discussion on how to engage stakeholders who may feel that they are not responsible for the care that is the target of the research. Given the importance of *social/professional role and identity* in this project, but equally identified in wider literature across several countries and professional groups[269], further exploration of the potential for impact of this on recruitment as well as strategies to overcome this would be beneficial.

Whilst recruitment was challenging, the recruitment target was exceeded in the prioritisation study (Chapter 5) and met in the interview study (Chapter 6). It was not achieved in the co-design study (Chapter 7) with 75% of the target recruited. It was intended that the health professionals who participated in the prioritisation study would go on to participate the co-design study, however there was considerable drop out. This challenge with retention is frequently identified[263,328] and is also likely impacted by the extended time between the two studies (18 months owing to maternity leave). Recruiting individuals, as discussed above, was challenging, and owing to the extensive experience brought by those participating, the decision was taken to continue with the study with reduced numbers. The sample size of six is appropriate for a Delphi[263], as well as co-design[322], and those that did participate had a wide range of experience in mental health over a considerable time . This decision was further informed by the understanding that intervention development is iterative, and that feasibility and pilot testing would provide further insights into the design of the intervention in post-doctoral work. . Furthermore the recruited sample is similar in size to that obtained for the DIAMONDS study group's intervention development with workshop sizes of *n=5* to *n=10* , with substantially greater resources[267].

8.3.3 Intervention acceptability

During project inception it was proposed that a fourth study would explore intervention acceptability using realist principles to shape understanding. Given the involvement of stakeholders throughout the PhD and in particular the use of the APEASE criteria (inclusive of acceptability) in Study 5 (Chapter 7), the decision was taken to remove this study. This decision was also informed by the experienced recruitment challenges and the likelihood that being able to recruit individuals would likely take a long time with limited return. Updated MRC guidance on the development of complex interventions[97] has highlighted the importance of developing and (re)testing programme theory. A central tenet of which is to understand how the intervention might be affected by the system, and wider context, as well as how the intervention affects the wider context and system[336]. Developing this understanding can support the refinement of decisions around the intervention content and its subsequent acceptability that can only be achieved once immersed in the NHS context. It is proposed that this can be achieved through feasibility testing (Discussed in Section 8.4.1.5).

It will also be prudent to explore the wider context of integration, especially at an organisational or senior management level. It is clear from the systematic review (Chapter 3. Section 3.6) that organisational buy-in is a critical feature of T2D care more broadly. As outlined in Chapter 6 (Section. 6.4.3) from those with management experience, the challenges of finance and contracts often constrain activities, i.e., the provision of physical health care by GPs is contractually arranged. Therefore, exploring and, where possible, targeting these broad contextual moderators will potentially convey success to the intervention.

8.3.4 Behaviour Change Wheel

The Behaviour Change Wheel, INDEX and MRC guidance all supported the development of the intervention. These were selected as a published approach as it was proposed that it enabled a structured, systematic, and transparent process of intervention development

(Chapter 2. Section 2.4). Specifically, a theory and evidence-based approach to intervention development (using the Behaviour Change Wheel) was selected to enable a transparent, systematic, and reportable intervention development process, which is limited in existing interventions targeting T2D care for adults with an SMI (Chapter 1. Section 1.3). Broadly these approaches achieved these aims, the steps taken to design the intervention are transparent and replicable. The structured approach to intervention development enabled consideration of a wide-range of intervention content and the consideration and selection of these is clearly outlined. Using this approach has also supported a clear programme theory to be developed that outlines how the intervention is proposed to work. The strengths and limitations of specific aspects of the Behaviour Change Wheel are now considered in more detail.

The Behaviour Change Wheel guidance[108] suggest that when developing an intervention and selecting a target behaviour the selection should be limited to just one, or at most a few behaviours, as incremental change is likely to be more effective[108]. This project targeted three behaviours 1) monitoring HbA1c, 2) provision of lifestyle advice and 3) appropriate referrals. The decision to focus on these behaviours was based on discussions with a diabetes specialist nurse, mental health professional, the data collected in the prioritisation study (Chapter 5) and existing literature. They reflect a pragmatic set of behaviours that could be feasibly enacted by mental health professionals during relapse to provide a framework of ongoing T2D support for individuals with an SMI. There is limited guidance available on the analysis and development of interventions targeting multiple behaviours, which represents a limitation of the guidance generally. This is pertinent in a health care setting when targeting co or multi-morbidity, with multiple professionals across primary, secondary, and tertiary organisations, as to reflect reality, the design frameworks would be advantageous if they were able to handle this level of complexity. Whilst a limitation of the guidance, it is worth noting that several studies have utilised the Behaviour Change Wheel and/or Theoretical Domains Framework to explore behaviour "bundles" [208,209,316,337] and development of interventions[314]. In this project, to capture the potential for differences and similarities between barriers and enablers, each target behaviour was discussed with participants. This level of questioning was situated within a broad interview schedule to allow fluid and flexible questioning, using a typical "funnelling" pattern[291], and judgement to probe further where required. Subsequent analysis also sought to parse out the domains perceived to underpin the target behaviours, this resulted in an output which specified the interaction between domains and target behaviours. It also enabled identification of domains of importance across the three target behaviours. Subsequent intervention development also kept the target domains separate whilst developing a collective intervention strategy. This has made it possible to outline which strategy and behaviour change techniques are impacting the individual target behaviours. This is a strength of this work and demonstrates that it is possible to develop interventions which target multiple behaviours, and the Behaviour Change Wheel[108] can cope with the demands of an increased degree of complexity. It is however necessary to be cautious in this summation as it is possible that certain target behaviours, in this case lifestyle advice, were explored more extensively which is why there are a greater number of domains identified for this behaviour (n=7) rather than the more conservative number of identified domains for HbA1c monitoring and referrals (n=5 and n=4 respectively). The increased number of domains for lifestyle advice may also be reflective of the combined nature of the advice e.g., discussing diet, exercise, and smoking advice, within the target behaviour. Whilst questioning participants, efforts were made to discuss diet and exercise separately, however often participants referred to lifestyle advice, which reflects the reality of practice. It may be that this resulted in some of the lifestyle advice components being more prominently discussed or “in mind” when being discussed by participants and this influenced the domains, subsequent mapping, and the proposed initial intervention, which is a potential limitation of this work. There is rationale that identifying similarities and differences across behaviours can be advantageous as it provides real-world understanding as well as the potential to design interventions that can target multiple behaviours simultaneously[305,338].

The combination of the Behaviour Change Wheel[108] and involvement of stakeholders is a strength of this project. The ability to incorporate the voices, opinions, experiences, and priorities of those affected by the research; both provider and service user, is important on multiple levels[339]. Whilst there is a lack of clear guidance within the Behaviour Change Wheel on the incorporation of stakeholders in the design of interventions, the early stages of the Behaviour Change Wheel (Stage 1, Step 1-3 – selecting, identifying, and specifying a target behaviour(s)) is amenable to the involvement of stakeholders with a focus on identifying the target behaviours. The use of a modified Delphi to answer these initial questions enabled a combination of service users, carers, and health professionals to shape the research and direct the focus. It enabled an equitable partnership between service users, researchers and professionals as well as meaningful contributions by service users and carers in setting the research question which is foundational for successful and true coproduction[339], which is currently lacking within the literature on the physical health of individuals with mental illness[340]. The latter stages of the Behaviour Change Wheel were also symbiotic with stakeholder involvement, (Stage 2 and 3, Chapter 7), as again through a modified Delphi consensus on the intervention functions, policy categories, behaviour change techniques and modes of delivery could be identified. The involvement of health professionals in these steps enabled intervention design which is sensitive to the realities of care provision in the NHS. Initial mapping exercises, and suggested applications and modes of delivery, were undertaken prior to involvement of health professionals. This decision was pragmatic as outcomes of these identified multiple options for intervention functions, policy categories and behaviour change techniques which would have likely been overwhelming and unable to deliver practically to participants using the software. The combination of research team and stakeholder decision-making has been utilised in other intervention design[267,314] and likely reflects the challenges of condensing a wide-range of options into research activities which are practical and feasible for stakeholder involvement. This compromise may be a limitation of the combined approach of the Behaviour Change Wheel (and theory in general) the strategies removed (e.g., intervention functions, policy categories and behaviour change techniques) potentially an important omission. It is contended however that these processes are reflective of the pragmatic approach suggested by the authors of the Behaviour Change Wheel[108] who assert the need for comfort with making judgements(p.103). This approach has also been utilised in other research[267,314] reflecting the pragmatic decisions required whilst employing the Behaviour Change Wheel to design interventions. Finally, the contribution of the stakeholders to selecting and providing practical application suggestions were invaluable and methods to make their involvement achievable, such as making selection processes acceptable, were necessary.

The use of asynchronous consensus method of data collection (Delphi[234]) was relatively successful for both Study 3 and 5 and enabled the objectives of each study to be met, however having the ability to interact with panel members would have been of benefit. For example, in Study 5 feedback and subsequent changes to the design of the intervention may have benefitted from active discussion with participants to shape the design more rapidly and areas of confusion (i.e., around the technique *Goal setting*) could have been clarified. The use of qualitative methods following consensus exercises for intervention design have been reported elsewhere[328]. This approach was utilised by Monforte et al. in the development of a physical activity training programme prototype, as the initial consensus activity was insufficient to design an initial intervention[328]. The authors described how the qualitative study resulted in a refined initial iteration of the intervention with additional sections and evolved teaching resources[328]. Furthermore, they asserted that this approach can be utilised to recognise conflict in ideas and avoid superficial agreements[328]. Whilst the results of Study 5 certainly needed further exploration and refinement, the study has enabled development of an initial intervention proposal. Additional qualitative work may support exploration of further steps of intervention development (discussed further in section 8.4.1) and related questions (as discussed above). The guidance on complex intervention development is sensitive to the need for refinement in intervention development[97]. There are opportunities as part of an ongoing process evaluation whilst feasibility testing to address these questions, whilst also providing additional information which may impact intervention development. Doing so in the naturally occurring clinical environment will likely provide more information that can be used to shape the intervention than qualitative examination prior to feasibility alone.

A potential limitation of the Behaviour Change Wheel is the applicability of step 6 (identify policy categories) to the NHS context, particularly in the constraints of PhD research, and the appropriateness of completion. It is recommended by the Behaviour Change Wheel[108] that identifying policy categories should be done by those with access to policy levers and that they reflect decisions of “authorities”. Access to these was limited within the context of the NHS and PhD research and thus arguably completion of this step may not be appropriate. The policy categories were however considered, and recommendations made for how policy categories could be used to support the intervention. This was particularly relevant for the policy category *Guidelines* which was identified in Study 5 (Chapter 7. Section 7.4.3.2), with participants identifying that changes to care planning would be advantageous. It may be that whilst the recommendations to policy categories are included in this intervention the ability to implement these are a wider "authority" level is not possible. This reflects a limitation of the chosen method for the context, however exploring the possibility of implementing the policy category changes could support future intervention success. Particularly given that it was highlighted that guidelines are a primary influence in directing behaviour of health professionals by participants in Study 5 (Chapter 7. Section 7.4.3.2). Whilst systematic and all steps were followed the authors are clear that steps can be missed if not appropriate thus offering a flexible approach to a systematic development process.

The Behaviour Change Wheel is a systematic and transparent method for developing interventions[108]. This is particularly useful where the initial area of research is broad, as with this PhD. Following the steps of the approach enabled the identification of a specific focus, an in depth understanding of the determinants of the behaviour and systematic selection of intervention components. The use of a theory and evidence-based approach enabled identification of clear proposed pathways to effect, invaluable for developing a robust evaluation plan as well as addressing identified gaps in the literature (see Chapter 1. Section 1.3 for discussion).

Although, as has been detailed previously[341–343], the use of the Behaviour Change Wheel was time consuming and exacting, this was not considered to be to the detriment of the final intervention. The systematic approach has enabled a thorough understanding of the challenges of improving T2D care for people with an SMI. It supported systematic selection of intervention content which is far more comprehensive than previous interventions (see

Chapter 4 for full discussion). If intervention development is very time consuming, it is a potential concern that the resulting intervention will be no longer fit for purpose. That is not considered to be the case for the current research. The current context of the healthcare in the UK is focussed on reducing inequalities, ensuring clarity around roles and responsibilities, improving the physical health (particularly related to cardiovascular disease and thus T2D) for people with an SMI, and ensuring continuity of care in the community[344]. This intervention offers a potential means to address these current issues for a single aspect of T2D care (ongoing T2D care during relapse). It is also arguable that the length of time taken to develop the intervention is acceptable. Given the intractability of improving the physical health of people with an SMI, researched over several decades, underscored by recent evidence which suggests that the gap is widening[15]. Given this pervasiveness, it is vitally important that careful consideration is given to better understanding the problem, identifying appropriate intervention content, and if interventions are found to be effective there is a clear understanding of the causal pathways to support evaluation and scalability. This is all offered by the Behaviour Change Wheel[108].

Although the Behaviour Change Wheel does not provide guidance on co-designing interventions with stakeholders, this research found that following this approach was amenable to the involvement of stakeholders. The outcomes of studies three and five were heavily influenced by the involvement of stakeholders but supplemented with additional evidence sources. Whilst involvement of stakeholders was possible, it is debatable as to the extent to which true co-design was achieved, particularly in the final study. Participants were presented with a selection of intervention content and proposed applications and therefore their input was constrained by theory and the evidence-base which was used to provide the intervention. It is however important to note that decisions were heavily influenced by stakeholders with amendments made to the intervention content reflecting the input of stakeholders. It could also be argued to be a strength of this study, in which the outcomes for each stage of the Behaviour Change Wheel are informed by multiple sources, which increases the validity of the findings. This is underscored by recent research that utilised participatory methods (solely) to develop an intervention to increase delivery of preventative health behaviour interventions by community mental health clinicians[345]. The authors state that further work is required to identify optimal participatory design methods to develop effective implementation support strategies. A strength of the approach used in this PhD is suggested to be the combination of stakeholder input in combination with a theory and evidence based approach.

Finally, there are several theory informed and evidence-based approaches to intervention development. These were considered in Chapter 2 (See Section 2.4). The use of Intervention Mapping may have further prolonged the intervention development thus further supporting the choice of the Behaviour Change Wheel. It is important to balance the need for careful intervention development with the importance of understanding how an intervention will work in context. The Behaviour Change Wheel was selected as a more parsimonious approach in comparison to Intervention Mapping. Given that this approach was still time-consuming and research in similar fields has demonstrated the importance of testing interventions in context[343], supports this selected approach.

8.3.5 Relapse as a teachable moment – the potential strengths of identifying a critical timepoint

The selection of the target behaviour was significantly informed by the involvement of service users and carers, as well as existing evidence (Section 5.6). The specific focus on T2D care during relapse is suggested to provide a unique catalyst for change, as relapse can be conceptualised as a teachable moment. A teachable moment is a naturally occurring event which is suggested to provide an opportune moment to engender a positive response to education messaging and adopt new behaviours. Teachable moments are characterised as health events which can 1) increase individuals' perception of risk and outcome expectancy, 2) prompt an emotional response and 3) produce a redefinition of social role or self-concept; it does not have to meet all three criteria[346] . Although the majority of literature on teachable moments has focussed on cancer, smoking cessation and surgical events, more recent work has demonstrated that diagnosis of T2D can be likened to a teachable event[347]. More recently, teachable moments have been conceptualised as co-constructed between health professionals and service users through interaction[348]. This definition is relevant for dynamic and socially constructed interactions such as medical encounters during relapse, with a focus on communication between provider and recipient of care[348]. A conceptualisation of a constructed teachable moment allows for the importance of health professionals' cognitions, perceptions and motivations to be influenced by cues to action[348]. Perception of an increase in the threat of disease, significant benefit of change, or perception that barriers to change are low for service users can be used to prompt action at this timepoint. This conceptualisation also helps to provide a focus for the shifting of responsibility for the management of T2D, for this timepoint, to mental health professionals. This is likely a significant contribution given the proposed centrality of the perceived responsibilities of the role of a mental health professional, acting as a barrier to T2D care for individuals with T2D and an SMI both within the moment of relapse. Evidence for this is both apparent in the importance of the domain *Social/professional role and identity* as a barrier to the provision of the three target behaviours during relapse (Section 6.4.2.1) and in the wider literature reported in the systematic review[269](Section 3.5.5).

A number of recommendations were made following completion of the systematic review which included multi-skill training of healthcare providers delivered collectively, clarity over roles and responsibilities, a focus on the service user–health professional interaction, support for integrated and holistic care as well as demonstrable active prioritisation of T2D care for people with an SMI by organisations. The intervention developed in this PhD is congruous with several of these suggestions, for example multi-skill training delivered by both mental health and diabetes professionals and clarity over roles and responsibilities which further underscores the potential for targeting a narrow range of behaviours during relapse as a catalyst for broader change. Whilst this project considers the need T2D care during relapse and how to support implementation of it, further work is needed on the appropriateness of the lifestyle advice given (Discussed in section 8.4.2).

8.4 Further Research Opportunities

This section will briefly outline the proposed next steps regarding continued development and refinement of the intervention as well as suggestions for additional research which has the potential to impact linked longer-term outcomes.

8.4.1 Next steps for the intervention

The programme theory of the initial proposed draft intervention has been described, and visually depicted in a provisional logic model (Figure 18). Following on in post-doctoral work a feasibility study is proposed to continue to refine and develop the proposed intervention.

A feasibility study can be used to examine the intervention and enable further refinement[97], it can explore optimal content and delivery, acceptability, adherence, and capacity to deliver. It is proposed that the initial feasibility testing of the intervention would be best placed to take a theory-based evaluation to explore how and under what circumstances the intervention leads to change by refining and (re)testing the proposed programme theory[336] (Logic Model, Figure 18). It would also seek to establish whether the intervention is practical and feasible in its current proposal or whether further refinement of both the intervention content and the programme theory is needed. Contextual moderators including the mode of delivery require further consideration. Areas for consideration in the feasibility study arranged around the four strategies are detailed in the subsequent sections.

8.4.1.1 Strategy 1: Training session

Previous interventions targeting health professionals and the provision of T2D care for individuals with an SMI demonstrated low uptake of training particularly by those already in post (as opposed to students)[92,93]. Challenges have also been identified around staffing levels, staff sickness, lack of time and increased workload[269]. It is therefore possible that uptake, and agreement, for a training session may be suboptimal and should be considered as part of feasibility testing.

The use of an inverted classroom model could ameliorate some of these difficulties. The model allows for a self-directed learning phase such as through an online module, podcast etc. before an in-person phase to allow assimilation and implementation of information previously provided[349]. Benefits of this model of learning include clinical reasoning, critical reasoning, communication behaviour and capacity for team-work[350]. Therefore the in-person phase with its focus on interactions and tasks[349], would allow for connections to be made between the diabetes and mental health teams, the provision of practical social support (*Social support - practical)* as well as space to practise skills such as blood taking and maintaining optimum relationships (*Behavioural practice/rehearsal).* Whilst evidence suggests a significant improvement in student learning in the field of health profession education[351] using an inverted-classroom method, there is less evidence of its effectiveness and acceptability in the use of continuous professional development. Further work to determine its suitability is necessary and would be an important element of feasibility.

It is currently proposed that the training session will be delivered by the T2D relapse champion and a member of the diabetes care team (training session facilitators). The competencies of the facilitators can play an important role in the success of an intervention[352,353], and should be actively engaged with alongside design of intervention content[352]. For example, an element of the proposed training session is to show video clips (or case studies) of service users speaking about the health and wellbeing consequences of not providing T2D lifestyle support during a relapse (*Salience of consequences*). This behaviour change technique content could be delivered as part of the pre-session materials in an inverted classroom model. During the in-person session the facilitators could utilise relational techniques such as '*overshooting*' which can be effectively used in conjunction with the behaviour change technique *salience of consequences*[352]. This relational technique supports change by exaggerating the benefits, or minimising the risk of harm (e.g. "So you see no benefit in changing XX"[352]) and reducing sustain talk (i.e. the person's own arguments for not changing, maintaining the status quo[354]). Exploring in more detail how to optimally deliver the behaviour change techniques will be important as part of feasibility and intervention refinement.

8.4.1.2 Strategy 2: T2D/relapse champion and huddles

The use of champions has been identified as a key enabler in successful change in healthcare environments[355,356]. Champions are individuals who are appointed, or volunteer, to promote and facilitate the implementation of an intervention[357]. In nursing they are often described as highly professional individuals who help to promote improvements from within an organisation[357]. The individual appointed as champion is envisaged to be someone within the existing mental health team, with an important aspect of feasibility being identifying an appropriate individual to fulfil this role.

One method for selecting a champion could include identifying an individual within the existing team with an interest in T2D/SMI comorbidity. This may be possible as interviews conducted as part of his research (Chapter 6) as well as the review of wider literature[269] identified individual differences in the delivery of T2D care. This was in part reflective of past training history (qualifying in both physical and mental health) as well as a personal level of interest (P007, Study 4, Chapter 6). A further option could be to identify an individual who has key attributes associated with Champion "success" - 1. Influence, 2. Ownership, 3. Physical presence, 4. Grit, 5. Persuasiveness and 6. Participative leadership style. These key attributes are associated with supporting new practices and driving "down-stream" implementation[358]. Some of these (grit, persuasiveness and leadership style) are potentially teachable skills[358], thus an identified champion could be provided with training to upskill in these areas.

The training of the T2D relapse champion in both delivery of the training session (discussed in section 8.4.1.1) and in champion skill building will require the buy-in of the management and wider organisation. This may however be supported in environments where the use of champions, or similar roles, have been successfully deployed in other teams, for example within East London NHS Foundation Trust there has been deployment of pressure ulcer facilitators within the tissue viability service to help improve pressure ulcer care. Building on existing success may be one approach to embed such changes into other services. Exploring how these services successfully embedded the Champion within the service would also be beneficial to support the strategy proposed in this intervention, particularly given that the APEASE rating for practicality was predominantly neutral (see Chapter 7. Section 7.4.3.2). As detailed, whilst the scores were neutral this was largely owing to a lack of experience of this type of role and not necessarily indicative of perceived problems with the strategy.

8.4.1.3 Strategy 3: Goals and feedback

This strategy proposed a benchmark target (e.g., 95% delivery of lifestyle advice during relapse) with feedback from line management during annual feedback. This target example was suggested based on previous literature[108,117,316]and was well received by participants.

During feasibility testing consideration should be paid to the potential for emotional responses to the use of feedback in healthcare settings[359,360]. Failure to address this has been suggested to impact the effectiveness of stratgies[359] similar to the proposed strategy 3. These tensions are reported to result from discordance between patient-centred care and system-level quality improvement initiatives[359,361]. The current context of community mental health care with high levels of staff sickness[80], challenges surrounding staff retention, morale, available time and resources to provide care[269]; and the general consensus that community mental health teams are the “dumping ground”, could provide fertile ground for adverse emotional responses to this intervention strategy.

One suggestion for ameliorating this potential issue would be the use of peer discussion to provide feedback rather than the current suggestion of feedback from the line manager. Opportunities to discuss feedback with peers has been identified as beneficial in impacting feedback success[362]. Currently the most effective delivery of a peer discussion/feedback sessions is unknown[362], thus utilisation of the T2D Relapse Champion to facilitate sessions could be a pragmatic solution. This suggestion would also offer another context, alongside the daily meeting/huddle, for the Champion to enact the behaviour change techniques *1) Social support (practical)*, 2) *Social support (unspecified) and 3) Social reward.*

Further work would be needed to ascertain the feasibility of this suggestion as it was not part of the strategy agreed as appropriate by the panel in Study 5. Given the general acceptability of the T2D in relapse champion however it is not unrealistic to assert (from a staff level) such a suggestion would be permissible. It would however require additional buy-in from senior management to release staff and provide opportunities for these sessions.

8.4.1.4 Strategy 4: Care process and environment

Amendments to the care planning process, including the involvement of service users and carers, were broadly acceptable as an intervention strategy. As detailed in Chapter 1 (Section 1.2), there is a shift in the context of community mental health care. Relevant to this strategy is the greater focus on involvement of carers and family in care planning[22]. An important aspect of feasibility testing will be to understand the acceptability of this proposed strategy to service users and carers given their lack of involvement in Study 5 has been discussed earlier (Section 8.3.1). Additionally, previous literature has identified that family involvement in care for individuals with mental illness demonstrates both positive and negative experiences[363]. This may be in part because service users have concerns regarding burdening their families and highlighted that additional support and training for families is important to them[363].Providing some brief training for families and carers on optimal support could be a useful complementary study (discussed further in section 8.4.2), in addition this may ameliorate some of the concern surrounding burden as service users may feel that their families are provided with tools to support them.

The second aspect of this strategy was the introduction of a computerised prompt during relapse. As highlighted in the discussion in chapter 7, the use of point-of-care prompts to guide health professional behaviour has a wide body of evidence demonstrating success[364–366]. There is however scepticism related to their uptake[367], although data capturing level of uptake is low. Larger effect sizes are seen where health professionals are required to enter a response[365] and where the prompts are personalised, i.e. not "off the shelf"[367]. Systematic exploration of the barriers and enablers of computerised prompts (or decision aids) identified design features important to clinicians including the need for prompts which were not overly simplistic, were symbiotic with workflows, with high levels of functionality and attractive aesthetics[368]. These factors can be used to guide the design of the prompt which can be examined further during feasibility testing.

Finally, an evaluability assessment is proposed which would be beneficial to identify whether and how the intervention can be usefully evaluated[97]. This would enable collaboration with stakeholders to discuss the proposed outcomes (depicted in the provisional logic model) and gain their feedback on the data that could be collected to assess the processes and outcomes[369]. Practicalities of the deployment of computerised prompts will be central to this process to identify how best to capture this data using existing systems. This level of detail will be required not just to develop the evaluation plan but provide sufficient detail to develop a comprehensive intervention protocol for feasibility assessment.

8.4.1.5 Developing understanding of context during feasibility testing

As highlighted in section 8.3.3 developing a deeper understanding of the impact of context on the intervention will be useful during feasibility testing. How the system affects the intervention and vice versa[336], is an important component of developing programme theory and exploring how wider context mediates/interacts with the effect of the intervention. Currently there are huge shifts in the community mental health service[78] such as the changes to the Care Planning Approach and a push to ensure continued care in the community. Understanding how these changes impact the intervention delivery, as well as how the intervention may impact these changes, will be imperative to longer-term roll out. This will only be possible however with a programme theory that is sensitive to the role of wider context and provides clarity on the proposed interaction and (re)testing of these assumptions through iterative phases of assessment. More qualitative work will be important to further explore the contextual moderators of the intervention and can be used successfully to refine programme theories[370]. Furthermore the programme theory as intended may be at odds with how those delivering or receiving the intervention may perceive the intervention to work[370]. Therefore, programme theories can be amended and refined considering the experiential input of those impacted by the intervention when delivered[371]. Taking forward the suggestion that qualitative work can support consensus activities[328], it is contended that such work would be further benefitted from being undertaken at the time of feasibility testing

Finally, feasibility testing can also be used as a time to explore potential complementary research opportunities, including the appropriateness of the lifestyle advice provided during relapse and the involvement of carers and family on the advanced care planning strategy. These are briefly discussed in the next section.

8.4.2 Complementary research opportunities

Whilst this research focussed on the provision of lifestyle advice as provided routinely it was highlighted in the qualitative study (Chapter 6) that the provision of an amended lifestyle advice for during relapse would be advantageous. This was important as it was noted that relapse was associated with low motivation and poor self-care in service users with consideration of what advice could be provided that would be “easiest” until their mental health improves(P008). In particular this was referenced as dietary advice, which is supported by literature on the experiences of individuals with an SMI and T2D, with multiple examples of the challenges of managing diet in particular[57,202,267]. Recent research has indicated that individuals with schizophrenia and T2D perceived differences in managing the two conditions, with T2D management described as following the rules[58]. This offers opportunities to explore lifestyle advice given during relapse and examine whether it is effective or whether tailoring would be advantageous.

The DIAMONDS research programme has developed a tailored self-management intervention underpinned by the Mechanisms of Action framework[267]. The support for individuals who are ‘at risk or may become unwell’ is highlighted as part of the intervention[267], however this is for the purpose of managing their mental health and not on delivery of T2D care during a relapse. The intervention provides tailored and person-centred support for setting behavioural goals, action planning, problem solving, access to peer support and increasing physical activity[267]. Individuals who had recently experienced a relapse were excluded from participating in the development workshops[267]. Whilst it is imagined that this is an ethical decision to protect those who have recently experienced difficulties in their mental health, it does pose a missed opportunity to involve those who have recent experience of needing additional support in management of their T2D which could have been valuable. It may however be possible to tailor the DIAMONDS intervention[267] and the advice provided to shape the guidance provided by mental health professionals during a relapse..

Additionally, further research is likely beneficial focussing on the involvement of carers and families to support service users and health professionals in management of T2D during relapse. This intervention draws on the feedback by participants to include service users' family and carers to support care planning. This may be particularly5lcxq advantageous in reference to dietary advice and provision of food. Systematic reviews of interventions targeting informal carers demonstrate positive outcomes for carers including quality of life, experience of caring and reduced psychological distress[372,373]; they are however inconclusive on the evidence for combining these interventions and impact on self-help and self management[372]. These reviews focus on the mental health of individuals and not the combination of T2D and SMI. The 2016 Cochrane review of self-management interventions[216] identified only one randomised controlled trial, which had a sole focus on supporting the service user and not the family or informal carers. This provides opportunities for further research on how best to involve informal carers to support T2D management in individuals with an SMI. In particular, ensuring that carers and family do not feel that they are responsible for policing or modifying service users' unhealthy behaviours, as has been previously reported[374].

8.5 Contributions

The content analysis of interventions aimed at improving T2D care for individuals with an SMI (Chapter 4) identified few studies. The focus of interventions included training for existing staff, the introduction of computerised prompts, reorganisation of care pathways and the introduction of new staff or programs. There was no reported use of theory in design nor evaluation and no explicit identification of stakeholder involvement in intervention development. This research adds to the literature through the development of a theory, research, and practice informed intervention. Contributions include:

The explicit use of theory in the design process has enabled an initial programme theory detailing how the intervention is intended to "work" and through which mechanisms of action. The use of theory to develop the intervention has provided the opportunity to select intervention content which is underpinned by evidence and previous literature supporting confidence in the intervention as designed. The opportunity to utilise these methods has been invaluable owing to limited available reported interventions.

The intervention further enhances the available interventions and literature by building on previously used strategies such as increasing knowledge and skills. The strategies in the intervention which harness collective action and provide legitimation of new practice norms through experience are integral. They have demonstrated potential in previous research[228] and as yet have not been reported or tested in this field. The strategies also harness social norms including behaviour change techniques which help to deliver this change including prompts/cues and social reward.

Exploration of the literature prior to intervention development identified limited interventions but a wealth of studies exploring the perspectives of health professionals which were utilised to explore the barriers and enablers of T2D care. This suggests that whilst there is understanding that there are challenges in these areas there has, to date, been limited exploration of how best to target these challenges. There is a long and equivocal wealth of data on the physical healthcare of those with an SMI.

A unique focus of this study is the focus on T2D care during relapse. It is proposed that focussing on practical to the practice of mental health professionals during this time has multiple benefits. It is conceptualised that relapse is a teachable moment offering opportunities to target complex care. The inclusion of this critical timepoint was important to service users and serves as an exemplar of why involvement of service users, and carers is important when deciding research priorities and questions on T2D care provision during relapse.

When organisations and teams have long established systems and processes including methods of care delivery and technical infrastructure, change can be difficult to achieve[362]. The current climate of change offers the perfect opportunity to examine the intervention. Additionally input from mental health professionals will continue to be required during relapse. This intervention explicitly asks them to momentarily carry the responsibility of monitoring T2D. The actions required are amendments to existing behaviours, for example, behaviour 1: HbA1c monitoring: bloods are already taken, and this behaviour will require an additional test and importantly a review and responsibility for collating the information to build a picture of the T2D status of the individual. Behaviour 2: The provision of lifestyle advice pertinent to T2D: lifestyle advice is provided during relapse however this is general and often focussed on supporting avoidance of future relapse. Results from Study 4 suggest that there may be benefit in amending the lifestyle advice provision to be more sensitive to the context of relapse, this could be in addition to the advice provided and discussed pertaining to relapse. Behaviour 3: this behaviour would require communication with other appropriate services such as the GP and/or diabetes team to ensure that responsibility is passed to the appropriate team, i.e., for more intensive T2D support. Such action may also help to support continuity of care which is important to service users.

8.6 Summary

The proposed intervention aims to support delivery of a brief T2D intervention deliverable during relapse for people with an SMI, by mental health nurses in the community setting. A systematic review identified 28 studies which reported perceived barriers and enablers (from the perspective of health professionals) with barriers and enablers identified at the individual, interpersonal and organisational level. Content analysis identified that of the eight existing interventions there was a narrow range of theoretically congruent intervention function, policy category and behaviour change techniques utilised with scope to explore many more options for intervention design. The three stages of the Behaviour Change Wheel were undertaken. Overall, 38 participants were recruited, including 4 service users and 9 carers. Study one identified and specified three target behaviours 1) monitoring of HbA1c, 2) lifestyle advice and 3) appropriate referrals, which could be delivered during a relapse by mental health nurses in the community setting was important to service users, carers, and health professionals. The opinions of providing these three target behaviours during relapse was explored with mental health professionals. Across all three target behaviours eight important domains were identified and the importance of social/professional role and identity and the need to shift responsibility was highlighted. The shifting of responsibility was important in conceptualising relapse as a teachable moment with the aim of using this to support shifting responsibility in a multidisciplinary team. Existing literature, mapping exercises, and the input of mental health professionals across a two-round modified Delphi were used to select six intervention functions, two policy categories and 14 behaviour change techniques. The resulting intervention consists of four overarching strategies. This novel, theory-informed, evidence-based and co-designed intervention collectively aims to improve the knowledge and skills of mental health professionals, enhance teamwork and support systems, set goals, and provide feedback, and modify the care planning process and environment to facilitate the provision of T2D care during a relapse of SMI. Focussing on the delivery of brief T2D care during relapse is an opportunity to provide a catalyst to support change. Whilst these strategies demonstrate promise it is important to consider contextual factors such as staff readiness for change, the emotional response to feedback, wider organisational impacts, and the overall context of changing community mental health care. Ongoing evaluation and refinement of these strategies is needed and can be progressed through future feasibility testing.

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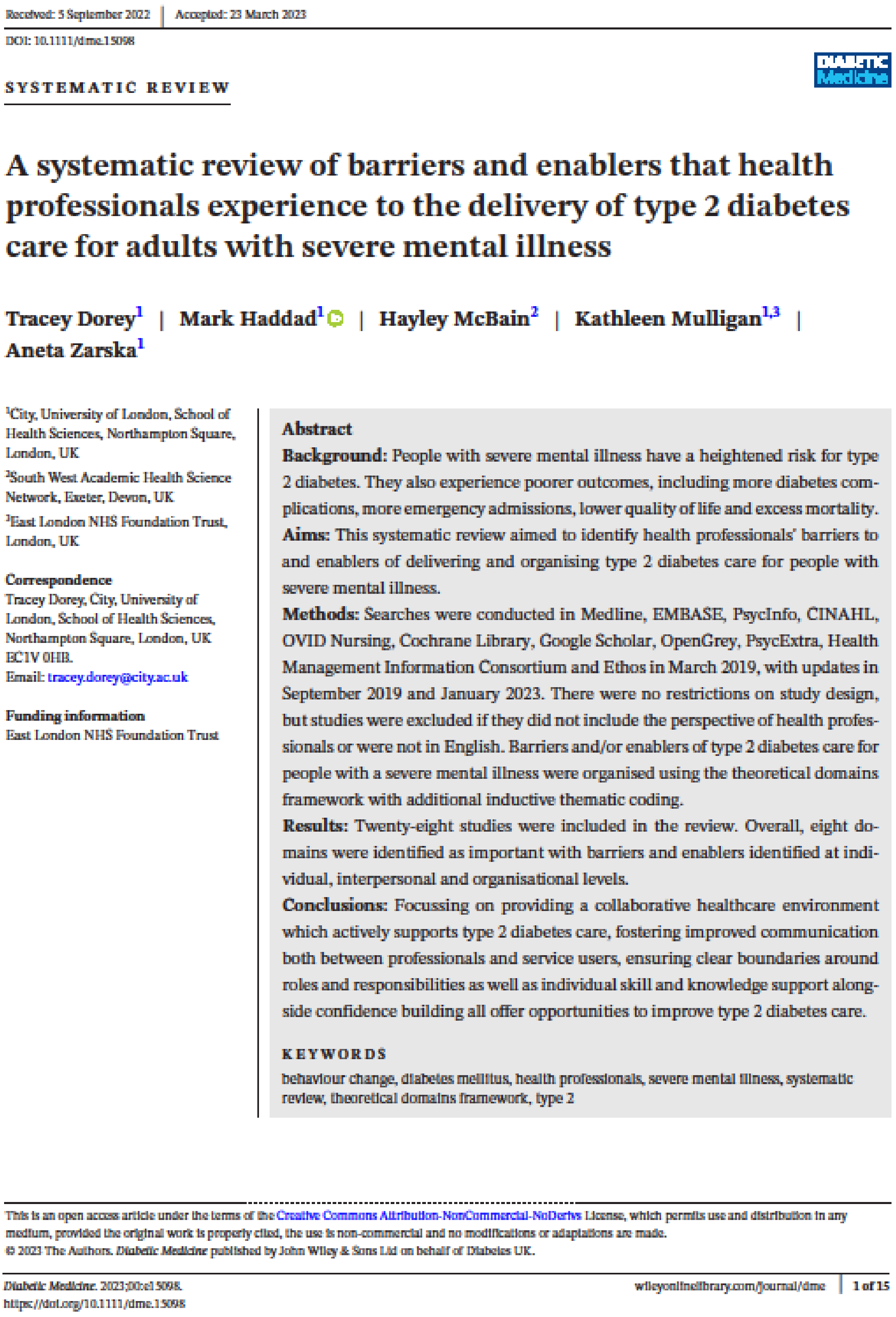
Appendix 1: Actions undertaken in intervention development mapped against each approach.

Green square indicates that an action labelled 1-18 is recommended by an approach, with the blue lines highlighting the theory-informed and evidence-based approaches

Domain	**Action**	*Co-design*	*User driven*	*EBCD*	*Person-based*	*User-centred*	*Human-centred*	*MRC Guidance*	*BCW*	*IM*	*MAP-IT*	*NPT*	*TDF*	*RE-AIM*	*MOST*	*6SQUID*	*ORBIT*	*IEAS*	*Decision aids*	*Group*	*PAR-BCP*
Conception	1															🟩	🟩				
Planning	2	🟩		🟩						🟩							🟩	🟩	🟩		
	3	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩		🟩			🟩	🟩	🟩	🟩	🟩		🟩
	4									🟩											🟩
	5				🟩			🟩	🟩	🟩				🟩			🟩	🟩		🟩	
	6								🟩	🟩			🟩								
	7					🟩	🟩	🟩		🟩		🟩		🟩							
	8							🟩						🟩							
Designing	9	🟩	🟩	🟩	🟩		🟩	🟩	🟩	🟩	🟩							🟩			
	10				🟩			🟩	🟩	🟩						🟩	🟩		🟩	🟩	🟩
	11								🟩	🟩			🟩	🟩		🟩		🟩	🟩	🟩	
	12									🟩				🟩							
Creating	13	🟩	🟩		🟩	🟩	🟩			🟩							🟩	🟩	🟩		🟩
Refining	14				🟩					🟩						🟩	🟩	🟩	🟩		
	15		🟩		🟩											🟩	🟩		🟩		
	16														🟩		🟩				
Documenting	17				🟩			🟩	🟩					🟩							
Plan full evaluation	18	🟩								🟩			🟩	🟩					🟩		

Appendix 2: Study 1 - Systematic Review published manuscript



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SYSTEMATIC REVIEW

A systematic review of barriers and enablers that health professionals experience to the delivery of type 2 diabetes care for adults with severe mental illness

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Abstract

Background: People with severe mental illness have a heightened risk for type 2 diabetes. They also experience poorer outcomes, including more diabetes complications, more emergency admissions, lower quality of life and excess mortality.

Aims: This systematic review aimed to identify health professionals' barriers to and enablers of delivering and organising type 2 diabetes care for people with severe mental illness.

Methods: Searches were conducted in Medline, EMBASE, PsycInfo, CINAHL, OVID Nursing, Cochrane Library, Google Scholar, OpenGrey, PsycExtra, Health Management Information Consortium and Ethos in March 2019, with updates in September 2019 and January 2023. There were no restrictions on study design, but studies were excluded if they did not include the perspective of health professionals or were not in English. Barriers and/or enablers of type 2 diabetes care for people with a severe mental illness were organised using the theoretical domains framework with additional inductive thematic coding.

Results: Twenty-eight studies were included in the review. Overall, eight domains were identified as important with barriers and enablers identified at individual, interpersonal and organisational levels.

Conclusions: Focussing on providing a collaborative healthcare environment which actively supports type 2 diabetes care, fostering improved communication both between professionals and service users, ensuring clear boundaries around roles and responsibilities as well as individual skill and knowledge support alongside confidence building all offer opportunities to improve type 2 diabetes care.

KEYWORDS
behaviour change, diabetes mellitus, health professionals, severe mental illness, systematic review, theoretical domains framework, type 2

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Appendix 3: Study 1 and 2 - Search Strategy

MEDLINE (Ebscohost)

EXP = Explode
/=MeSH Heading
N = Near X words of each other (any order)
W = Within X words of each other (in order written)
* = Truncation

Health Care Professional or Setting Terms

1. EXP Health Personnel/
2. EXP Allied Health Personnel/
3. EXP Physicians/
4. EXP Nurses/
5. EXP Medical Staff/
6. EXP Nurse Practitioner
7. Endocrinologists/
8. Psychiatry/
9. Psychiatric Nursing/
10. Community Mental Health Services/
11. EXP Mental Health Services/
12. EXP Primary Health Care/
13. Secondary Care/
14. EXP Health Services/
15. Healthcare W2 (professional or provider or personnel or staff or practitioner)
16. General practitioner or GP or doctor or nurse or psychiatrist or diabetologist or dietician or physiotherapist or physician or “primary care physician” or endocrinologist
17. Nurse N2 (district or practice or “mental health” or diabet* or “diabetes specialist” or practitioner)
18. “allied health” W2 (professional or personnel or practitioner or provider)
19. “Psychiatric Nursing” or “Community Mental Health Service” or “Mental Health Service” or “Health Service”
20. Care N3 (Primary or Secondary)
21. Or/1-20

Severe Mental Illness Search Terms

22. EXP Mental Disorders/
23. EXP Schizophrenia Spectrum and Other Psychotic Disorders/
24. Mental Health/

25. Mentally Ill Persons/
26. Affective Disorders, Psychotic/
27. Bipolar Disorder/
28. Depressive Disorder, Major/
29. “Mental Disorder” N2 (severe or serious or chronic)
30. “Mental Illness” N2 (severe or serious or chronic)
31. “Mental Health Condition” N2 (severe or serious or chronic)
32. schizo* or psychos?s or psychotic
33. “Disorder” N2(bipolar or affective)
34. Depress* N2 (clinical or major)
35. Or/22-34

Barriers & Enablers Search Terms

36. EXP Attitude of Health Personnel/
37. EXP Professional- Patient Relations/
38. EXP Delivery of Health Care Integrated/
39. Health Knowledge, Attitude, Practice/
40. Clinical Decision Making/
41. Barrier or obstacle or facilitat* or enable*
42. Belief or attitude or view or opinion or feeling or perception or perceive or factor or determinant or experience*
43. Uptake or takeup or adhere* or utilis* or utiliz* or delivery or provision
44. Knowledge or skill or role or identity or capabilit* or optimis* or consequence or reinforcement or intention or goal or memory or attention of context or resource or emotion
45. Decision* W2 process*
46. Behaviour* W2 regulation
47. Competence or “self efficac*” or “self-confidence” or incentive or reward or anxiety or fear or habit
48. Outcome W2 expectanc*
49. Action W2 plan*
50. Decision W2 mak*
51. Social W2 (support or norm)
52. Engage* or communicat* or interaction or training awareness or hope or despond* or responsibilit* or confidence
53. ((Integrat*) W3 (care) W3(pathway))
54. Or/36-53
55. 21 AND 35 AND 54

Diabetes Care – General

56. Diabetes N3 (management or Care or control or intervention)

57. 55 AND 56

Diabetes Search Terms

58. EXP Diabetes Mellitus, Type 2/
59. (Type W2 (2 or “II” or two) W3 (diabet*)
60. (Onset N2 (late or adult or Matur* or slow) W3 (diabet*)
61. (Depend* N2 (Non-insulin or Noninsulin*) W3 (diabet*)
62. NIDDM
63. Metabolic Disease
64. Or/58-63

General Physical Care Terms

65. EXP Quality of Health Care/
66. Delivery of Healthcare/
67. Harm Reduction/
68. “Health screening” or “physical health” or “physical health care” or “physical healthcare” “harm reduction” or “intervention” or “Delivery of health care” or “delivery of healthcare” or “quality of health care” or “”quality of healthcare” or “Health Care Delivery” or “healthcare delivery”
69. Or/65-68
70. 55 AND 64 AND 69

Specific Diabetes Care Terms

71. EXP Treatment Adherence and Compliance/
72. Diabetic Nephropathies/
73. Diabetic Foot/
74. Diabetic Retinopathy/
75. ((HbA1C or “blood glucose” or “glucose control” or “serum cholesterol” or “serum creatinine” or “urine albumin” or “creatinine ratio” or f??t) N3 (monitor* or review or examination or target)
76. “Kidney function” or “kidney disease”
77. (foot N3 risk N3 ulcer)
78. ((Diabet* or proliferative or non-proliferative) N4(retinopath*))
79. (Retinopath* or eye* or vision or sight or visual)
80. “Treatment adherence”

81. Body Mass Index/
82. Weight Loss/
83. Obesity Management/
84. Diet, Diabetic/
85. Exercise/

86. BMI or “body mass index” or “obesity management”
87. (Management or loss or reduction or control) N2 weight)
88. Diet* or food or nutrition* or calori* or “energy intake” or carbohydrate or fat or sugar
89. Physical activit* or exercise* or activity or physical or walk* or run* or swim* or aerobic or fitness or sport* or “strength training” or “resistance training” or “weight training”

90. EXP Smoking/
91. EXP Tobacco Smoking/
92. EXP Tobacco Use/
93. Smoking Cessation/
94. Smoking Reduction/
95. Stop* or quit or quitting or advice or guidance or reduction or cessation
96. “Cessation intervention” N3(smoking or tobacco or cigarette or nicotine)

97. EXP Patient Education as Topic/
98. EXP Health Promotion/
99. EXP Health Education/
100. EXP Health Behavior/
101. EXP Life Style/
102. EXP Healthy Life Style/
103. Self-Management/
104. “Health promotion” or “health behavior” or “health behaviour” or “health knowledge” or educat* or knowledge or intervention or program or programme or life-style or lifestyle or “structured education” or “healthy living program*”
105. Or/71-104
106. 55 AND 64 AND 105

Search Strategy - PsycInfo

EXP = Explode
/=Thesaurus Term
N = Near X words of each other (any order)
W = Within X words of each other (in order written)
* = Truncation

Health Care Professional or Setting Terms

1. EXP Health Personnel/
2. EXP Physicians/

3. EXP Nurses/
4. EXP Mental Health Services/
5. Allied Health Personnel/
6. Primary Health Care/
7. Psychiatry/
8. Healthcare W2 (professional or provider or personnel or staff or practitioner)
9. General practitioner or GP or doctor or nurse or psychiatrist or diabetologist or dietician or physiotherapist or physician or “primary care physician” or endocrinologist
10. Nurse N2 (district or practice or “mental health” or diabet* or “diabetes specialist” or practitioner)
11. “allied health” W2 (professional or personnel or practitioner or provider)
12. “Psychiatric Nursing” or “Community Mental Health Service” or “Mental Health Service” or “Health Service”
13. Care N3 (Primary or Secondary)
14. Or/1-13

Severe Mental Illness Search Terms

15. EXP Mental Disorders/
16. EXP Schizophrenia /
17. Mental Health/
18. Affective Disorders/
19. Bipolar Disorder/
20. Major Depression/
21. “Mental Disorder” N2 (severe or serious or chronic)
22. “Mental Illness” N2 (severe or serious or chronic)
23. “Mental Health Condition” N2 (severe or serious or chronic)
24. schizo* or psychos?s or psychotic
25. “Disorder” N2(bipolar or affective)
26. “Depress*” N2 (clinical or major)
27. Or/15-26

Barriers & Enablers Search Terms

28. EXP Health Personnel Attitude /
29. Barrier or obstacle or facilitat* or enable*
30. Belief or attitude or view or opinion or feeling or perception or perceive or factor or determinant or experience*
31. Uptake or takeup or adhere* or utilis* or utiliz* or delivery or provision

32. Knowledge or skill or role or identity or capabilit* or optimis* or consequence or reinforcement or intention or goal or memory or attention of context or resource or emotion
33. Decision* W2 process*
34. Behaviour* W2 regulation
35. Competence or “self efficac*” or “self-confidence” or incentive or reward or anxiety or fear or habit
36. Outcome W2 expectanc*
37. Action W2 plan*
38. Decision W2 mak*
39. Social W2 (support or norm)
40. Engage* or communicat* or interaction or training awareness or hope or despond* or responsibilit* or confidence
41. ((Integrat*) W3 (care) W3(pathway))
42. Or/28-41
43. 14 AND 27 AND 42

Diabetes Care – General

44. Diabetes N3 (management or Care or control or intervention)
45. 43 AND 44

Diabetes Search Terms

46. Type 2 Diabetes /
47. (Type W2 (2 or “II” or two) W3 (diabet*)
48. (Onset N2 (late or adult or Matur* or slow) W3 (diabet*)
49. (Depend* N2 (Non-insulin or Noninsulin*) W3 (diabet*)
50. NIDDM
51. Metabolic Disease
52. Or/46-51

General Physical Care Terms

53. EXP Quality of Health Care/
54. “Health screening” or “physical health” or “physical health care” or “physical healthcare” “harm reduction” or “intervention” or “Delivery of health care” or “delivery of healthcare” or “quality of health care” or “”quality of healthcare” or “Health Care Delivery” or “healthcare delivery”
55. Or/53-54
56. 43 AND 52 AND 55

Specific Diabetes Care Terms

57. EXP Treatment Adherence and Compliance/

58. ((HbA1C or “blood glucose” or “glucose control” or “serum cholesterol” or “serum creatinine” or “urine albumin” or “creatinine ratio” or f??t) N3 (monitor* or review or examination or target)
59. “Kidney function” or “kidney disease”
60. (foot N3 risk N3 ulcer)
61. ((Diabet* or proliferative or non-proliferative) N4(retinopath*))
62. (Retinopath* or eye* or vision or sight or visual)
63. “Treatment adherence”

64. Body Mass Index/
65. Weight Loss/
66. Exercise/
67. BMI or “body mass index” or “obesity management”
68. (Management or loss or reduction or control) N2 weight)
69. Diet* or food or nutrition* or calori* or “energy intake” or carbohydrate or fat or sugar
70. Physical activit* or exercise* or activity or physical or walk* or run* or swim* or aerobic or fitness or sport* or “strength training” or “resistance training” or “weight training”

71. Tobacco Smoking/
72. Smoking Cessation/
73. Stop* or quit or quitting or advice or guidance or reduction or cessation
74. “Cessation intervention” N3(smoking or tobacco or cigarette or nicotine)

75. EXP Patient Education as Topic/
76. EXP Health Promotion/
77. EXP Health Education/
78. EXP Health Behavior/
79. EXP Life Style/
80. “Health promotion” or “health behavior” or “health behaviour” or “health knowledge” or educat* or knowledge or intervention or program or programme or life-style or lifestyle or “structured education” or “healthy living program*”
81. Or/57-80
82. 43 AND 52 AND 81

Search Strategy – CINAHL (Ebscohost)

EXP = Explode
/=CINAHL Subject Headings
N = Near X words of each other (any order)

W = Within X words of each other (in order written)
* = Truncation

Health Care Professional or Setting Terms

1. EXP Health Care Personnel/
2. EXP Physician/
3. EXP Nurse/
4. EXP Medical Staff/
5. EXP Nurse Practitioner
6. Endocrinologist/
7. Psychiatry/
8. Psychiatric Nursing/
9. EXP Mental Health Services/
10. EXP Primary Health Care/
11. Secondary Health Care/
12. EXP Health Services/
13. Or/1-12

Severe Mental Illness Search Terms

14. EXP Mental Disease/
15. EXP Mental Health/
16. EXP Mood Disorder/
17. Affective Disorders, Psychotic/
18. EXP Schizophrenia
19. EXP Psychotic Disorders/
20. Bipolar Disorder/
21. Depression/
22. “Mental Disorder” N2 (severe or serious or chronic)
23. “Mental Illness” N2 (severe or serious or chronic)
24. “Mental Health Condition” N2 (severe or serious or chronic)
25. schizo* or psychos?s or psychotic
26. “Disorder” N2(bipolar or affective)
27. “Depress*” N2 (clinical or major)
28. Or/14-27

Barriers & Enablers Search Terms

29. EXP Attitude of Health Personnel/
30. EXP Professional- Patient Relations/
31. Delivery of Health Care Integrated/
32. Health Knowledge/
33. Decision Making, Clinical/

34. Barrier or obstacle or facilitat* or enable*
35. Belief or attitude or view or opinion or feeling or perception or perceive or factor or determinant or experience*
36. Uptake or takeup or adhere* or utilis* or utiliz* or delivery or provision
37. Knowledge or skill or role or identity or capabilit* or optimis* or consequence or reinforcement or intention or goal or memory or attention of context or resource or emotion
38. Decision* W2 process*
39. Behaviour* W2 regulation
40. Competence or "self efficac*" or "self-confidence" or incentive or reward or anxiety or fear or habit
41. Outcome W2 expectanc*
42. Action W2 plan*
43. Decision W2 mak*
44. Social W2 (support or norm)
45. Engage* or communicat* or interaction or training awareness or hope or despond* or responsibilit* or confidence
46. ((Integrat*) W3 (care) W3(pathway))
47. Or/29-46
48. 13 AND 28 AND 47

Diabetes Care – General

49. Diabetes N3 (management or Care or control or intervention)
50. 48 AND 49

Diabetes Search Terms

51. Diabetes Mellitus, Type 2/
52. (Type W2 (2 or "II" or two) W3 (diabet*)
53. (Onset N2 (late or adult or Matur* or slow) W3 (diabet*)
54. (Depend* N2 (Non-insulin or Noninsulin*) W3 (diabet*)
55. NIDDM
56. Metabolic Disease
57. Or/51-56

General Physical Care Terms

58. EXP Quality of Health Care/
59. EXP Health Care Delivery/
60. Harm Reduction/
61. "Health screening" or "physical health" or "physical health care" or "physical healthcare" "harm reduction" or "intervention" or "Delivery of health care" or

“delivery of healthcare” or “quality of health care” or “”quality of healthcare” or “Health Care Delivery” or “healthcare delivery

62. Or/58-61
63. 48 AND 57 AND 62

Specific Diabetes Care Terms

64. Diabetic Nephropathies/
65. Diabetic Foot/
66. Diabetic Retinopathy/
67. ((HbA1C or “blood glucose” or “glucose control” or “serum cholesterol” or “serum creatinine” or “urine albumin” or “creatinine ratio” or f??t) N3 (monitor* or review or examination or target)
68. “Kidney function” or “kidney disease”
69. (foot N3 risk N3 ulcer)
70. ((Diabet* or proliferative or non-proliferative) N4(retinopath*))
71. (Retinopath* or eye* or vision or sight or visual)
72. “Treatment adherence”

73. Body Mass Index/
74. Weight Loss/
75. Diet, Diabetic/
76. Exercise/
77. BMI or “body mass index” or “obesity management”
78. (Management or loss or reduction or control) N2 weight)
79. Diet* or food or nutrition* or calori* or “energy intake” or carbohydrate or fat or sugar
80. Physical activit* or exercise* or activity or physical or walk* or run* or swim* or aerobic or fitness or sport* or “strength training” or “resistance training” or “weight training”

81. EXP Smoking/
82. EXP Tobacco
83. Smoking Cessation/
84. Stop* or quit or quitting or advice or guidance or reduction or cessation
85. “Cessation intervention” N3(smoking or tobacco or cigarette or nicotine)

86. Patient Education/
87. EXP Health Promotion/
88. EXP Health Education/
89. EXP Health Behavior/
90. EXP Life Style/

91. Self-Management/
92. “Health promotion” or “health behavior” or “health behaviour” or “health knowledge” or educat* or knowledge or intervention or program or programme or life-style or lifestyle or “structured education” or “healthy living program*”
93. Or/62-92
94. 48 AND 57 AND 93

Search Strategy - EMBASE (OVID)

EXP = Explode
/=Emtree Subject Headings
ADJ = Near X words of each other (any order)
* = Truncation

Personnel or Setting

1. EXP Health Personnel/
2. EXP Physician/
3. EXP Nurse/
4. EXP Medical Staff/
5. EXP Nurse Practitioner
6. Endocrinologist/
7. Psychiatric Nursing/
8. EXP Mental Health Service/
9. EXP Primary Health Care/
10. Secondary Care/
11. Health Service/
12. Healthcare adj2 (professional or provider or personnel or staff or practitioner)
13. General practitioner or GP or doctor or nurse or psychiatrist or diabetologist or dietician or physiotherapist or physician or primary care physician or endocrinologist
14. Nurse adj2 (district or practice or mental health or diabet* or diabetes specialist or practitioner)
15. allied health adj2 (professional or personnel or practitioner or provider)
16. Psychiatric Nursing or Community Mental Health Service or Mental Health Service or Health Service
17. Care adj3 (Primary or Secondary)
18. Or/1-17

Severe Mental Illness Search Terms

19. EXP Mental Disease/
20. EXP Mental Health/
21. EXP Mentally Patient /
22. EXP Mood Disorder
23. EXP Schizophrenia/
24. EXP Psychosis
25. Bipolar Disorder/
26. Major Depression/
27. schizo* or psychos?s or psychotic
28. Disorder adj2 (bipolar or affective)
29. Depress* adj2 (clinical or major)
30. Mental Disorder adj2 (severe or serious or chronic)
31. Mental Illness adj2 (severe or serious or chronic)
32. Mental Health Condition adj2 (severe or serious or chronic)
33. Or/19-32

Barriers & Enablers Search Terms

34. EXP Health Personnel Attitude/
35. EXP Professional- Patient Relationship/
36. EXP Integrated Health care system/
37. Clinical Decision Making/
38. Barrier or obstacle or facilitat* or enable*
39. Belief or attitude or view or opinion or feeling or perception or perceive or factor or determinant or experience*
40. Uptake or takeup or adhere* or utilis* or utiliz* or delivery or provision
41. Knowledge or skill or role or identity or capabilit* or optimis* or consequence or reinforcement or intention or goal or memory or attention of context or resource or emotion
42. Decision* adj2 process*
43. Behaviour* adj2 regulation
44. Competence or self efficac* or self-confidence or incentive or reward or anxiety or fear or habit
45. Outcome adj2 expectanc*
46. Action adj2 plan*
47. Decision adj2 mak*
48. Social adj2 (support or norm)
49. Engage* or communicat* or interaction or training awareness or hope or despond* or responsibilit* or confidence
50. (Integrat*) adj3 (care) adj3 (pathway))
51. Or/34-51

52. 18 AND 33 AND 51

Diabetes Care – General

53. Diabetes adj3 (management or Care or control or intervention)
54. 52 AND 53

Diabetes Search Terms

55. EXP Non-Insulin Dependent Diabetes Mellitus
56. ((typ? 2 or typ? II or typ?2 or typ?II) adj3 diabet*)
57. (Onset adj2 (late or adult or Matur* or slow) adj3 (diabet*))
58. ((non-insulin* depend* or noninsulin* depend* or noninsulin?depend* or non-insulin?depend*)
59. NIDDM
60. Metabolic Disease
61. Or/55-60

General Physical Care Terms

62. EXP Health Care Quality/
63. EXP Health Care Delivery /
64. Harm Reduction/
65. Health screening or physical health or physical health care or physical healthcare harm reduction or intervention or Delivery of health care or delivery of healthcare or quality of health care or quality of healthcare or Health Care Delivery or healthcare delivery
66. Or/62-65
67. 52 AND 61 AND 66

Specific Diabetes Care Terms

68. EXP Patient Compliance/
69. Diabetic Nephropathy/
70. Diabetic Foot/
71. Diabetic Retinopathy/
72. HbA1C or blood glucose or glucose control or serum cholesterol or serum creatinine or urine albumin or creatinine ratio or f??t adj2 monitor* or review or examination or target
73. Kidney function or kidney disease
74. foot adj3 risk adj3 ulcer
75. Diabet* or proliferative or non-proliferative adj4 retinopath*
76. Retinopath* or eye* or vision or sight or visual

77. Treatment adherence

78. Body Mass Index/
79. Body Weight Loss/
80. Obesity Management/
81. Diabetic Diet/
82. Exercise/
83. BMI or body mass index or obesity management
84. Management or loss or reduction or control adj2 weight
85. Diet* or food or nutrition* or calori* or energy intake or carbohydrate or fat or sugar
86. Physical activit* or exercise* or activity or physical or walk* or run* or swim* or aerobic or fitness or sport* or strength training or resistance training or weight training

87. EXP Smoking/
88. Tobacco Use/
89. Smoking Cessation/
90. Smoking Reduction/
91. Stop* or quit or quitting or advice or guidance or reduction or cessation
92. Cessation intervention adj3 smoking or tobacco or cigarette or nicotine

93. EXP Patient Education /
94. EXP Health Promotion/
95. EXP Health Behavior/
96. EXP Lifestyle/
97. EXP Healthy Lifestyle/
98. Self-Care/
99. Health promotion or health behavior or health behaviour or health knowledge or educat* or knowledge or intervention or program or programme or life-style or lifestyle or structured education or healthy living program*
100. Or/68-99
101. 52 AND 61 AND 100

Search Strategy – OVID Nursing (OVID)

EXP = Explode
/=OVID Nursing Subject Thesaurus
ADJ = Near X words of each other (any order)
* = Truncation

Personnel or Setting

1. EXP Health Personnel/
2. EXP Physician/
3. EXP Nurse/
4. EXP Medical Staff/
5. EXP Nurse Practitioner
6. EXP Allied Health Personnel/
7. Psychiatric Nursing/
8. Psychiatry
9. EXP Community Mental Health Services
10. EXP Mental Health Service/
11. EXP Primary Health Care/
12. Health Service/
13. Healthcare adj2 (professional or provider or personnel or staff or practitioner)
14. General practitioner or GP or doctor or nurse or psychiatrist or diabetologist or dietician or physiotherapist or physician or primary care physician or endocrinologist
15. Nurse adj2 (district or practice or mental health or diabet* or diabetes specialist or practitioner)
16. allied health adj2 (professional or personnel or practitioner or provider)
17. Psychiatric Nursing or Community Mental Health Service or Mental Health Service or Health Service
18. Care adj3 (Primary or Secondary)
19. Or/1-18

Severe Mental Illness Search Terms

20. EXP Mental Patient /
21. EXP Mood Disorder
22. EXP Schizophrenia/
23. EXP Psychosis
24. EXP Bipolar Disorder/
25. schizo* or psychos?s or psychotic
26. Disorder adj2 (bipolar or affective)
27. Mental Disorder adj2 (severe or serious or chronic)
28. Mental Illness adj2 (severe or serious or chronic)
29. Mental Health Condition adj2 (severe or serious or chronic)
30. Depress* adj2 (clinical or major)
31. Or/20-30

Barriers & Enablers Search Terms

32. EXP Health Personnel Attitude/
33. EXP Professional- Patient Relationship/
34. EXP Integrated Health care system/
35. Clinical Decision Making/
36. Barrier or obstacle or facilitat* or enable*
37. Belief or attitude or view or opinion or feeling or perception or perceive or factor or determinant or experience*
38. Uptake or takeup or adhere* or utilis* or utiliz* or delivery or provision
39. Knowledge or skill or role or identity or capabilit* or optimis* or consequence or reinforcement or intention or goal or memory or attention of context or resource or emotion
40. Decision* adj2 process*
41. Behaviour* adj2 regulation
42. Competence or self efficac* or self-confidence or incentive or reward or anxiety or fear or habit
43. Outcome adj2 expectanc*
44. Action adj2 plan*
45. Decision adj2 mak*
46. Social adj2 (support or norm)
47. Engage* or communicat* or interaction or training awareness or hope or despond* or responsibilit* or confidence
48. (Integrat*) adj3 (care) adj3 (pathway))
49. Or/32-48
50. 19 AND 31 AND 49

Diabetes Care – General

51. Diabetes adj3 (management or Care or control or intervention)
52. 50 AND 51

Diabetes Search Terms

53. EXP Non-Insulin Dependent Diabetes Mellitus
54. ((typ? 2 or typ? II or typ?2 or typ?II) adj3 diabet*)
55. (Onset adj2 (late or adult or Matur* or slow) adj3 (diabet*))
56. ((non-insulin* depend* or noninsulin* depend* or noninsulin?depend* or non-insulin?depend*)
57. NIDDM
58. Metabolic Disease
59. Or/53-58

General Physical Care Terms

60. EXP Health Care Quality/

61. EXP Health Care Delivery /
62. Harm Reduction/
63. Health screening or physical health or physical health care or physical healthcare harm reduction or intervention or Delivery of health care or delivery of healthcare or quality of health care or quality of healthcare or Health Care Delivery or healthcare delivery
64. Or/60-63
65. 50 AND 59 AND 64

Specific Diabetes Care Terms

66. EXP Patient Compliance/
67. Diabetic Nephropathy/
68. Diabetic Foot/
69. Diabetic Retinopathy/
70. HbA1C or blood glucose or glucose control or serum cholesterol or serum creatinine or urine albumin or creatinine ratio or f??t adj2 monitor* or review or examination or target
71. Kidney function or kidney disease
72. foot adj3 risk adj3 ulcer
73. Diabet* or proliferative or non-proliferative adj4 retinopath*
74. Retinopath* or eye* or vision or sight or visual
75. Treatment adherence

76. Body Mass Index/
77. Body Weight Loss/
78. Obesity /
79. Diabetic Diet/
80. Exercise/
81. BMI or body mass index or obesity management
82. Management or loss or reduction or control adj2 weight
83. Diet* or food or nutrition* or calori* or energy intake or carbohydrate or fat or sugar
84. Physical activit* or exercise* or activity or physical or walk* or run* or swim* or aerobic or fitness or sport* or strength training or resistance training or weight training

85. EXP Smoking/
86. Tobacco/
87. Smoking Cessation/
88. Smoking Reduction/
89. Stop* or quit or quitting or advice or guidance or reduction or cessation

90. Cessation intervention adj3 smoking or tobacco or cigarette or nicotine

91. EXP Patient Education /
92. EXP Health Promotion/
93. EXP Health Behavior/
94. EXP Health Knowledge
95. EXP Lifestyle/
96. Self-Care/
97. Health promotion or health behavior or health behaviour or health knowledge or educat* or knowledge or intervention or program or programme or life-style or lifestyle or structured education or healthy living program*
98. Or/66-97
99. 50 AND 59 AND 98

Search Strategy – Grey Literature

1. Healthcare Professional
2. Type 2 Diabetes Mellitus
3. Severe Mental Illness
4. (Barrier OR facilitate* OR enable*)
5. 1 AND 2 AND 3 AND 4

Appendix 4: Study 1 - Coding Protocol

The coding manual utilises the refined TDF domains (Cane et al., 2012)

Domain: Definition *Constructs*	Examples relating to T2D Care in SMI
Knowledge: awareness of the existence of something *Knowledge of condition/scientific rationale, procedural knowledge and knowledge of task environment*	• Knowledge of NICE guidance • Knowledge of how to care for people with both SMI and T2D • Knowledge of T2D and/or SMI
Skills: ability or proficiency acquired through practice *Skill development, competence, ability, interpersonal skills, practice and skill assessment*	• The need for special skills to provide T2D care to people with SMI (communication and negotiation skills) • Additional training need
Social professional role and identity: a coherent set of behaviours and displayed personal qualities of an individual in a social or work setting *Professional identity, professional role, social identity, identity, professional boundaries, professional confidence, group identity, leadership, organisational commitment*	• Belief about who should manage care • Belief about certain aspects of care belonging to different professions
Beliefs about capabilities: acceptance of the truth/reality about or validity of an ability, talent or facility that a person can put to constructive use *Self-confidence, perceived confidence, self-efficacy, perceived behavioural control, beliefs, self-esteem, empowerment, professional confidence*	• HCPs having confidence in their ability to manage T2D or work with people with SMI
Optimism: confidence that things will happen for the best or that desired goals will be attained Optimism, pessimism, unrealistic optimism, identity	• Optimism about T2D health outcomes of those with SMI • Optimism about personal ability to manage T2D in people with SMI
Beliefs about consequences*:* acceptance of the truth/reality about or validity of outcomes of a behaviour in a given situation *Beliefs, outcome expectancies, characteristics of outcome expectancies, anticipated regret, consequents*	• Beliefs about the outcomes for people with SMI of managing/not managing T2D • Patient beliefs about outcomes affecting care provision
Reinforcement: *increasing the probability of a response by arranging a dependent relationship, or contingency, between the response and a given stimulus* *Rewards (proximal/distal, valued/not valued, probable/improbable), incentives, punishment, consequents, reinforcement, contingencies, sanctions*	• Use of performance indicators (CQUIN/ QoF) • Discipline if not managing T2D in those with SMI

Intentions: conscious decision to perform a behaviour or a resolve to act in a certain way *Stability of intentions, stages of change, TTM*	• Intention to follow NICE guidelines • Intention to provide care
Goals*:* mental representation of outcomes or end states that an individual wants to achieve *Distal/Proximal goals, goal priority, goal/target setting, autonomous controlled goals, action planning, implementation intention*	• Importance of managing T2D • Tailoring goals to people with SMI
Memory attention decision processes*:* ability to retain information, focus selectively on aspects of the environment and choose between two or more alternatives *Memory, attention, attention control, decision making, cognitive overload,*	• T2D care is part of my routine • Tailoring of treatment
Environmental context and resources: any circumstances of a person's situation or environment that discourages or encourages the development of skills and abilities, independence, social competence, and adaptive behaviour *Environmental stressors, Resources/material resources, organisation culture/climate, salient events/critical incidents, person x environment interaction, barriers and facilitators*	• IT system integration to improve ability • Having access to other professions to support care • Insufficient time
Social influences: interpersonal processes that can cause an individual to change their thoughts, feeling or behaviours. *Social pressure, social norms, group conformity, social comparison, group norms, social support, power, intergroup conflict, alienation group identity, modelling*	• Working as part of a team to provide care • Input from family/friends/carers • Level of engagement of patient
Emotion: *a complex reaction pattern, involving experiential, behavioural and physiological elements, by which the individual attempts to deal with a personally significant matter or event* *Fear, anxiety, affect, stress, depression, positive/negative affect, burn-out*	• Negative emotions e.g. worry, fear, apprehension, frustration which is related to T2D healthcare
Behavioural regulation: anything aimed at managing or changing objectively observed or measured actions *Self-monitoring, breaking habit, action planning*	• Specific plans or measures to guide management of diabetes care

Appendix 5: Study 1 - Individual critical appraisal of included studies

Key:

X = No evidence
✓ = Evidence
? = Unable to identify
N/A = Not applicable

Qualitative Studies

Author/Date	Aloudah (2021)	Cimo (2018)	Coblentz (2015)	Happell (2015)	Hultsjö (2013)	Kahn (2009)	Kaufman (2012)	Lawless (2016)	Lowndes (2013)	McBain (2016)	Papachristou Nadal (2019)	Papchristou Nadal (2019)	Wang (2016)	Wright (2006)
Clear Aim Statement	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Appropriate Qualitative Methodology	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Appropriate Research Design	✓	✓	✓	✓	✓	?	?	X	?	✓	✓	✓	✓	✓
Appropriate Recruitment Strategy	?	✓	✓	✓	✓	?	✓	✓	✓	✓	?	✓	?	?
Appropriate Data Collection	✓	✓	✓	✓	✓	✓	✓	X	✓	✓	✓	✓	✓	✓
Adequate Consideration of Relationship	?	✓	✓	?	✓	?	✓	X	?	✓	?	?	?	✓
Ethical Consideration	✓	✓	?	✓	✓	?	?		?	✓	✓	✓	?	✓
Sufficiently Rigorous Analysis	?	✓	?	?	✓	✓	✓	X	?	✓	?	✓	?	✓
Clear Findings Statement	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Cross-sectional studies

	Happell (2013)	Hemingway (2013)	Hemingway (2015)	Mangurian (2021)	McBain (2018)	MCDonnell (2011)	Nash (2009)	Newcomer (2004)	Parameswaran (2013)	Vaez (2017)	Vancampfort (2019)
Clear Aim	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Appropriate Study Design	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Justified Sample Size	X	X	X	X	✓	X	X	X	X	X	X
Clear Population	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Appropriate Sample Frame	X	X	X	X	✓	X	X	✓	X	X	X
Appropriate Selection process	X	X	X	X	X	X	X	✓	X	X	X
Non-Responders Address	X	X	X	X	X	X	X	X	X	X	X
Appropriate Risk/Outcome measures	✓	✓	✓	✓	✓	✓	✓	✓	X	✓	✓
Measurement Rigour	✓	X	X	X	✓	X	X	X	X	✓	✓
Clarity Statistical Threshold	X	X	X	X	✓	X	NA	NA	X	X	X
Appropriate Method Description	X	X	X	X	✓	X	X	P	X	X	X
Adequate Data Description	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Non-Response Bias	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Description Non-Responders	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Result Internal Consistency	✓	?	?	✓	✓	✓	?	?	✓	✓	✓
Result Presentation Appropriateness	✓	?	?	✓	✓	✓	?	?	?	✓	✓
Justified Conclusions	✓	✓	✓	✓	✓	✓	✓	✓	?	✓	✓
Limitations Discussed	✓	✓	✓	✓	✓	✓	✓	X	✓	✓	✓
Conflicts Disclosed	?	X	X	X	X	?	?	?	?	X	✓
Ethical Approval	✓	✓	✓	✓	✓	✓	✓	?	✓	✓	✓

Case Study

Author/Date	Adams (2008)
Demographics	×
History	×
Current clinical condition	×
Assessment methods & results	×
Treatment	✓
Post-intervention outcome	×
Adverse events	×
Takeaway lessons	✓

Pilot Randomised Controlled Trial

Author/Date	Chwastiak (2018)
Identification	×
Structured Summary	×
Background	×
Objectives	✓
Trial design	✓

Method changes	?
Eligibility	✓
Setting	✓
Consent procedure	✓
Intervention description	✓
Measures	×
Measure amendments	NA
Future trial	×
Sample size	×
Interim analysis/stopping	×
Random allocation sequence	×
Randomisation details	✓
Randomisation mechanism	×
Randomisation implementation	×
Blinding	×
Similarities between interventions	×
Participant Numbers	✓
Retention	✓
Recruitment	✓
Trial end date	✓
Baseline data	✓
Numbers analysed	✓
Outcomes/estimates	✓

Ancillary analyses	✓
Harm	×
Unintended consequences	×
Limitations	✓
Generalisability	✓
Interpretation	✓
Progression to future	✓
Registration	✓
Protocol	×
Funding	✓
Ethical approval	✓

Grey literature: Dissertation

Author/Date	Shannon 2017
Individual	
Reputable Organisation?	✓
Qualification/Experience?	?
Other Published Work?	×
Recognised Expert?	×
Cited by Others?	×
Student under Supervision?	✓
Organisation or group	
Reputable Organisation?	N/A
Organisation an Authority?	N/A
In all cases:	

Detailed References?	✓
Accuracy	
Clear Aim?	✓
Is this met?	✓
Clear Methodology?	✓
If so, is it adhered to?	✓
Peer-reviewed?	×
Edited by Reputable Authority?	×
Supported by Credible Sources?	✓
Representative?	✓
If no, Valid Counterbalance?	N/A
Explicit & Appropriate Data Collection?	✓
Appropriate Coverage of Secondary Material?	N/A
Coverage	
Clear Limits?	✓
Objectivity	
Author's Position Clear?	✓
Balanced Presentation?	✓
Date	
Clear Date?	✓
If no, valid reason for its absence?	N/A
Key Contemporary Materials Included?	✓
Significance	
Is the item meaningful?	✓

Does it add context?	✓
Does it enrich or add something unique to the research?	✓
Does it strengthen or refute a current position?	?
Would the research area be lesser without it?	?
Is it integral, representative, typical?	?
Does it have impact?	▯

Appendix 6: Study 1 - Full Thematic Table

Domain	Theme	Sample Quote
Knowledge	Theme 1: Perceived lack of T2D knowledge T2D Care Generally MHP Aloudah (2021) (B) Hemmingway (2015) (B) Hultsjö (2013) (B) McBain (2016) (B) McBain (2018) (B) Nash (2009) (B) Papachristou Nadal (2022) (B) Shannon (2017) (B) Happell (2015) (B) Vancampfort (2019) (B) Wright (2006) (B)* Diet/Nutrition Advice MHP Lowndes (2013) (B)	I have no idea how diabetes care work (Hultsjö, 2013)
	Theme 2: Having T2D Knowledge T2D Care Generally PCP McBain (2016) (E) McBain (2018) (E) MHP Newcomer (2004) (E) Papachristou Nadal (2022) (E) Vancampfort (2019) (E) Mixed Wright (2006) (E) T2D Education Mixed McBain (2018) (E)	[...]Six of the seven primary care or diabetes specialist clinicians reported being aware of diabetes guidelines, such as those developed by the National Institute for Health and Social Care Excellence (NICE) in England and Wales, and using them when managing diabetes in people with SMI albeit in an adapted or tailored format (McBain, 2016) The psychiatrists surveyed have an intensive awareness of key metabolic issues, which is consistent with numerous reports in the medical literature. (Newcomer, 2004)
	Theme 3: Knowledge of SMI and the effect on T2D care T2D Care Generally PCP Coblentz (2015) (B) Wright (2006) (B) * MHP Hultsjö (2013) (B)* Wright (2006) (E)*	CMHT has better access to and knowledge of people with SMI - CMHT GP N=8 (Wright, 2006) [...]Quality barrier: PCPs lack of comfort or training with mentally ill patients. As a result of insufficient funds, or insufficient understanding or education . . . we [primary care providers] don't understand schizophrenia. (Coblentz, 2015)
Goals	Theme 1: Ability to tailor individual goals T2D Care Generally PCP McBain (2018) (E) Mixed McBain (2016) (E) T2D Education Mixed Cimo & Dewa (2019) (E) T2D Referral to Retinopathy Screening McBain (2018) (E)	You've got to set realistic goals not try and set goals that are not achievable because that's setting people up to fail. So you have to tailor your goals and targets to that person sitting in front of you." (McBain, 2016)

	Theme 2: Prioritisation versus holistic treatment T2D Care Generally MHP Aloudah (2021) (B&E) Newcomer (2004) (B) Shannon (2017) (B&E) Wright (2006) (B&E) Mixed McBain (2016) (B&E) McBain (2018) (B) Xin Wang (2016) (B) Wright (2006) (B) T2D Education PCP Kahn (2009) (B) Mixed Cimo & Dewa (2019) (E) T2D Diet/Nutrition Advice MHP Adams (2008) (B&E)		For some participants, the risks associated with weight gain, and to some intend T2D, were viewed as less pressing. That's the thing with type 2 it's not an acute risk, it doesn't feel like an acute risk, it feels like a chronic thing… [Community nurse] (Shannon, 2017) I think it's holistic. Like I said, it's the whole package, isn't it? You can't just ignore people's physical health and concentrate on their minds. I guess, as a social worker, we're trained to kind of see the whole package, rather than separate little conditions ... or physical health and mental health being split into two (Social Worker 02). (Wright, 2006).
Environmental Context & Resources	Theme 1: Care Coordination	ST 1.1: Information Access T2D Care Generally MHP Aloudah (2021) (B&E) Happell (2015) (E) Hultsjö, (2013) (E) Shannon (2017) (E) Wright (2006) (B&E) Mixed Kaufman (2012) (B&E) Mangurian (2019) (B) McBain (2016) (B&E) McBain (2018) (E) McDonnell (2011) (B) Papachristou Nadal (2019) (E) Xin Wang (2016) (B) T2D Education MHP Chwastiak (2018) (B) Mixed Lawless (2012) (E)	Access to an integrated IT system between mental and physical health services was seen as an important way in which more unified care could be delivered, e.g. through improving access to test results. (McBain, 2016) Separation of medical & mental healthcare: [The ER] treated her but they never contacted us . . . she suffered two or three more days longer than she really needed to without the support I could have given her. (Hultsjö, 2013)
		ST 1.2: Access to staff to support care T2D Care Generally PCP Wright (2006) (E)* MHP Aloudah (2021) (B&E) Hultsjö, (2013) (E) Newcomer (2004) (B&E) Mixed Coblentz (2015) (B&E) Kaufman (2012) (B&E) McBain (2016) (E)	Mental health addressed by specialists: Lots of times, with me, I will actively listen to what they are talking about. And as I'm listening and listening, then I'm able to assess that this an area I need to move to the specialist. . .the mental health nurse. So my initial is paying attention to what they're saying and trying to separate the diabetes part. . .but then I will also bring to them the referral piece. That you have someone to support you more, that is specialized and knows what they are dealing with (provider group 2). (Cimo, 2018) Communication between providers: One thing would be having very open lines of communication between the providers at the CMHC and just the regular primary care clinic. So if medical conditions are

		McBain (2018) (E) Papchristou Nadal (2019) (B&E) Vaez (2017) (E) Wright (2006) (B) T2D Education Mixed Chwastiak (2018) (B&E) Cimo & Dewa (2019) (E)	brought up in that setting it could be discussed on the phone (Coblentz, 2015)
		ST 1.3: Referrals PCP Wright (2006) (B) MHP Parameswaran (2013) (B)	[...]difficulty arranging referral for medical follow-up [83% (68/82)] (Parameswaran, 2013)
	Theme 2: Healthcare Professionals	ST 2.1: Time T2D Care Generally MHP Aloudah (2021) (B) McDonnell (2011) (B) Papachristou Nadal (2022) (B) Parameswaran (2013) (B) Vancampfort (2019) (B) Mixed Coblentz (2015) (B&E) Kaufman (2012) (B) Mangurian (2019) (B) McBain (2016) (B) McBain (2018) (E) Wright (2006) (B)	Page 7: Overall 60% of the sample had sufficient time to manage this population; MHN and support workers were however more likely to agree that this was the case than GPs (P=0.04) (McBain, 2018) Providers don’t have enough time (4.03(1.12)) (McDonnell, 2011)
		ST 2.2: Insufficient staff and turnover T2D Care Generally PCP Wright (2006) (B) MHP Aloudah (2021) (B) McDonnell (2011) (B) Mixed Coblentz (2015) (B) Kaufman (2012) (B) Mangurian (2019) (B) Papachristou Nadal (2019) (B) Vaez (2017) (B) Xin Wang (2016) (B) T2D Education Mixed Lawless (2012) (B)	The first common barrier is insufficient medical staff with appropriate competencies to perform the respective duties, as well as high rates of staff turnover (Xin Wang, 2016)
		ST 2.3: Workload MHP Wright (2006) (B) Mixed Coblentz (2015) (E) Papachristou Nadal (2019) (B) Xin Wang (2016) (B) Wright (2006) (B)	[...] . . We’re a very small clinic. They get to know me very quickly, I’m the only provider they’re going to see down at that clinic. They get to know my staff very well . . . (Coblentz, 2015) The CMHT workload is already high – they lack the time for extra responsibilities - ALL N=19 (Wright, 2006)

	Theme 3: Service Provision Suitability T2D Care Generally PCP McDonnell (2011) (B) MHP Aloudah (2021) (E) Hultsjö, (2013) (B) Parameswaran (2013) (B) Wright (2006) (B&E) Mixed Coblentz (2015) (B&E) Kaufman (2012) (B&E) McBain (2016) (B&E) Vaez (2017) (B&E) Papachristou Nadal (2019) (B&E) Wright (2006) (E) T2D Education Mixed Lawless (2012) (B&E)	It was also felt that many persons missed out on diabetes appointments a couple of times, after which they were no longer called. Being on anti- psychotic medication and intake of sleeping pills was found to make it difficult for many persons to be active and get to the morning appointments that are often offered by diabetes nurses. MHCS stressed how important it is that diabetes nurses take the time to motivate, support and remind persons with psychosis about their appointments and encourage them to be self-confident enough to go there. (Hultsjö, 2013)
	Theme 4: Finance Challenges T2D Care Generally PCP Wright (2006) (B) MHP Happell (2013) (B&E) Mixed Coblentz (2015) (B&E) Kaufman (2012) (B) McDonnell (2011) (B) Wright (2006) (B) Xin Wang (2016) (B) T2D Diet/Nutrition Advice MHP Lowndes (2013) (B)	There was a moderate level of variation on perception of added costs of introduction of a CHN as a barrier: 30% disagreed, 37% neither agreed nor disagreed, and 33% agreed that costs would make it ‘impossible’ for implementation. (Happell, 2013)
	Theme 5: Organisation Priorities and Culture T2D Care Generally MHP Shannon (2017) (B&E) Wright (2006) (B) Mixed McBain (2016) (E) McBain (2018) (B) McDonnell (2011) (B) Papachristou Nadal (2019) (B) Wright (2006) (B)	[...] if you look at that teaching session that’s going on today down at [the hospital], physical health is much more on the agenda I think.” (McBain, 2016) Many HCPs felt that there was a lack of recognition from wider statutory bodies, such as NHS England. Participants felt that without the recognition of these bodies, it would be difficult to implement solutions to the problem of disconnected care (Papachristou Nadal, 2019)
	Theme 6: Resources T2D Care Generally PCP Wright (2006) (E) MHP Aloudah (2021) (B) Shannon (2017) (B) Wright (2006) (B) Mixed Coblentz (2015) (E)	I think people get a bit disheartened as well as they are contacting the necessary people saying we need a portable this and they’re told they will get it then it’s been several months and they still haven’t got the equipment and then they become demotivated, bearing in mind the people who are physical health leads they case load of 23 so it’s not like they’re just sitting around waiting to be a physical health lead person - Community nurse (Shannon, 2017)

	Theme 7: Specialist Role T2D Care Generally PCP Wright (2006) (E) MHP Happell (2013) (B&E) Happell (2015) (E) Papachristou Nadal (2022) (E) Wright (2006) (E) Mixed Coblentz (2015) (E) Kaufman (2012) (E) Papachristou Nadal (2019) (E)		When a specialist nurse-led service was suggested to participants who had not raised it spontaneously, they usually endorsed it. The perceived benefits were its flexibility, greater accessibility for patients, clarity of roles and ensuring good liaison between primary and secondary care, irrespective of individual patient or staff preferences for delivery of screening (Wright, 2006)
	Theme 8: Prescribing challenges T2D Care Generally Mixed Kaufman (2012) (B)		[...]Psychiatric ARNPs' inability to prescribe non-psychiatric medications in Washington State is a significant barrier to implementing more integrated models within the healthcare system. (Kaufman, 2012)
	Theme 9: Challenges in ability to contact Service Users T2D Education PCP Kahn (2009) (B) Mixed Lawless (2012) (B&E)		Some participants' phones are disconnected, their numbers are changed, or they have only limited minutes (Lawless, 2012)
Social Influence	Theme 1: Service User Engagement	ST 1: Motivation T2D Care Generally MHP Hultsjö (2013) (B) Shannon (2017) (B) Mixed McDonnell (2011) (B)	Patient barrier: Schizophrenia symptoms There is difficulty getting them to go see somebody either because of just amotivation or apathy or paranoia. (Coblentz, 2015)
		ST 2: Illness beliefs T2D Care Generally PCP Papachristou Nadal (2019) (B) MHP Hultsjö (2013) (B) Shannon (2017) (B) Mixed Coblentz (2015) (B) Kaufman (2012) (B) McBain (2016) (B) Papachristou Nadal (2019) (B) T2D Diet/Nutrition Advice MHP Lowndes (2013) (B)	Persons who believed they controlled their diabetes were perceived as most difficult to motivate to diabetes care and were seen as having difficulties with diabetes management (Hultsjö, 2013)
		ST 3: Disease Severity (SMI) T2D Care Generally PCP Papachristou Nadal (2019) (B) MHP Aloudah (2021) (B) Hultsjö (2013) (B)	Participants described evaluating service users' capability to self-manage their diabetes which informed their approach. I always encourage the client to do it, self-manage it… During the handover we do clarify, oh that person is able to do it by themselves he's got all his treatment, or if they can't do it and need more support or is it because of the mental states has deteriorated so they're unable to do it so we can do it for the mean time. [Community nurse] (Shannon, 2017)

		Shannon (2017) (E) Parameswaran (2013) (B) Happell (2015) (B) Mixed Papachristou Nadal (2019) (E) Coblentz (2015) (B) Kaufman (2012) (B) Mangurian (2019) (B) McBain (2016) (B) McDonnell (2011) (B) Wright (2006) (B) T2D Education PCP Kahn (2009) Mixed Lawless (2012) (B) Cimo & Dewa (2019) (B&E)	
		ST 4: Perceived Preferences T2D Care Generally MHP Wright (2006) (B&E)	Some service users mistrust psychiatric services and don't want their involvement - CMHT/SU N=4 (Wright, 2006)
		ST 5: Lack of resources T2D Care Generally Mixed McDonnell (2011) (B) Kaufman (2012) (B)	Patient’s lack of resources (4.25(0.94)) (McDonnell, 2011)
		ST6: Ability to advocate T2D Care Generally MHP Hultsjö (2013) (B) Shannon (2017) (B&E) Mixed Coblentz (2015) (E) Kaufman (2012) (B)	[...]Communication between providers: One thing would be having very open lines of communication between the providers at the CMHC and just the regular primary care clinic. So if medical conditions are brought up in that setting it could be discussed on the phone . . .I think some cross-over does occur but maybe a little more would be helpful for our schizophrenic patients who can’t voice for themselves what is going on, we have to be there for them and make sure each doc has each other’s information, so we can best treat these guys . . . (Coblentz, 2015)
		ST7: Lack of Engagement T2D Care Generally PCP Wright et al. (2005) (B) MHP Aloudah (2021) (B) Shannon (2017) (B&E) Vancampfort (2019) (B) Mixed Papachristou Nadal (2019) (B) Coblentz (2015) (B) Wright (2006) (B) McBain (2016) (B) T2D Examining Feet Mixed McBain (2018) (E) T2D Monitoring Cholesterol Mixed McBain (2018) (E)	The experiences of the HCPs highlight the poor health outcomes for people with diagnosis of SMI and diabetes, as well as patients having low engagement with diabetes care (Papachristou Nadal, 2019)

		ST8: Autonomy T2D Care Generally MHP Shannon (2017) (B) Mixed Papachristou Nadal (2019) (B) T2D Diet/Nutrition Advice MHP Adams (2008) (B&E)	Regarding diet and lifestyle, participants spoke about respecting service user autonomy and choice. "You can only encourage them and whether they want to that's up to them isn't it. But I think it's information, it's knowledge about what might affect them or how it will affect them if they don't." Inpatient nurse (Shannon, 2017)
		ST9: Non-compliance T2D Care Generally PCP Papachristou Nadal (2019) (B) Mixed Kaufman (2012) (B)	There is a lack of support for the patient which is further amplified with patients who are hard to pin down or who are poorly compliant. Many of these patients have chaotic lifestyles, lack personal capacity and refuse to acknowledge their diabetes. (Consultant Diabetologist). (Papachristou Nadal, 2019)
	Theme 2: Working as part of a team - benefits and challenges T2D Care Generally MHP Parameswaran (2013) (B) Hultsjö (2013) (B&E) Shannon (2017) (E) Mixed McBain (2018) (E) McBain (2016) (E)		All MHCS in this study thought that collaboration was necessary. Collaboration between diabetes care and psychosis care could further have benefits and give opportunities for staff to exchange knowledge with each other (Krein et al., 2006), which can result in fewer conflicts between different aspects of care. (Shannon, 2017)
	Theme 3: Social support T2D Care Generally MHP Aloudah (2021) (E) Hultsjö (2013) (E) Mixed Coblentz (2015) (E) McBain (2016) (B&E) McBain (2018) (E)		Of these 15 participants, three mental health professionals also described family members and carers helping them to manage and monitor diabetes for their loved ones. (McBain, 2016)
	Theme 4: Relationships T2D Care Generally MHP Hultsjö (2013) (B&E) Wright (2006) (B&E) Mixed Kaufman (2012) (B)		CMHT staff have a better rapport and understanding of people with SMI - ALL 12 (Wright, 2006)
	Theme 5: Stigma T2D Care Generally PCP Wright (2006) (B)* Mixed Kaufman (2012) (B) Wright (2006) (B)		Some GPs may be negative towards or disinterested in people with SMI and offer a poor service to them – it could be a 'patchy' service - CMHT & SU N=5 (Wright, 2006)
Intentions	Theme 1: Intention Variability T2D Care Generally MHP Hultsjö (2013) (B&E) Mixed McBain (2016)* (B&E)		Two participants intended to refer people with diabetes and SMI on to either community exercise programmes, or diabetic retinopathy screening and structured diabetes education (McBain, 2016)

	McBain (2018)* (B&E)	Some MHCS did not have any intention to become more involved in diabetes care, whereas others described themselves as interested in and active in diabetes care (Hultsjö, 2013)
Beliefs about Capabilities	Theme 1: Lack of Confidence T2D Care Generally PCP Wright (2006) (B)* Coblentz (2015) MHP Hultsjö (2013) (B) Shannon (2017) (B) Mixed McBain (2018) (B)	With diabetes obviously I understand that some people are on insulin or diet control, and you know that monitoring their BMs is really important and I know what the safe levels are. I guess anything further than that is a little bit overwhelming for me because I just don't know it's not something I've really learnt much about … So, I'm not that confident, obviously psychosis is what I live and breathe I could talk all day long about that, but not diabetes, I just know the basics that can cover a whole range of other illnesses too. [Community nurse] (Shannon, 2017)
	Theme 2: Having confidence T2D Care Generally Mixed McBain (2016) (E) McBain (2018) (E) MHP Vancampfort (2019) (E)	Nine explicitly stated that they felt confident about their ability to manage diabetes in people with SMI (McBain, 2016)
Social & Professional Role	Theme 1: Variability of Professional Responsibility T2D Care Generally PCP McBain (2018) (E) McDonnell (2011) (B) Wright (2006) (B&E) * MHP Aloudah (2021) (B&E) McDonell (2011) (B) Nash (2009) (E) Hultsjö (2013) (B&E) Parameswaran (2013) (B&E) Papachristou Nadal (2022) (B) Wright (2006) (B&E) * Shannon (2017) (B&E) McBain (2018) (B&E) Happell (2015) (B&E) Coblentz (2015) (B) Vancampfort (2019) (E) Mixed Mangurian (2019) (B&E) McBain (2016) (B&E) McBain (2018) (B&E) McDonnell (2011) (B&E) Vaez (2017) (B&E) Wright (2006) (B) T2D Education PCP Kahn (2009) (B) Mixed Chwastiak (2018) (E) McBain (2018) (E) T2D Weight Management Advice Mixed McBain (2018) (E)	When asked if RGNs should be employed in mental health to look after physical problems, 71% replied 'no' while 18% replied 'yes'. This indicates that mental health nurses would rather not abdicate responsibility for physical care to others, but instead engage in training and collaborative care. (Nash, 2009) The thing here is this side of the hospital vs in [other part of hospital trust] there's this culture, and if I've heard it once I've heard it 1000 times 'I'm not a general nurse' (Shannon, 2017)

	T2D Monitoring BP Mixed McBain (2018) (E) T2D Examining Feet Mixed McBain (2018) (E)	
Skills	Theme 1: Lacking in skills T2D Care Generally PCP McBain (2018) (B) Wright (2006) (B) MHP Aloudah (2021) (B) Coblentz (2015) (B) Hemmingway (2015) (B) Nash (2009) (B) McDonnell (2011) (B) McBain (2016) (B) McBain (2018) (B) Happell (2013) (B) Happell (2015) (B) Wright (2006) (B)* Papachristou Nadal (2019) (B) Papachristou Nadal (2022) (B) Mixed Wright (2006) (B) Xin Wang (2016) (B)	Respondents were asked to self-select from a list of areas related to diabetes care where they would like to receive specific training. This list was derived from a literature review of nursing care for people with diabetes and adapted by the author to a mental health context. Particular areas are illustrated in Figure 4. The sample expressed a need for training in all aspects of diabetes care. Most training requests were in areas that staff were currently providing care. (Nash, 2009)
	Theme 2: Skill Proficiency T2D Care Generally PCP Wright (2006) (E)* MHP Happell (2013) (E) Shannon (2017) (E) Wright (2006) (E) Mixed Kaufman (2012) (E)	GPs possess medical expertise in CHD screening and can provide appropriate management of results - CMHT & GP N=14 (Wright, 2006)
	Theme 3: Skill beyond T2D care T2D Care Generally PCP McBain (2018) (B) MHP Happell (2015) (E) Nash (2009) (B) Wright (2006) (E)* Mixed McBain (2016) (B) Vaez (2017) (B&E)	While 65% reported that they needed more training in diabetes in order to manage T2D in people with SMI, a third requested more training to improve their communication and negotiation skills. Physical health nurses were more likely to request training in communication and negotiation skills compared with psychiatrists ($P<0.001$) (McBain, 2018)
Memory, Attention, Decision Processes	Theme 1: Tailoring Care to the needs of the individual T2D Care Generally MHP Hultsjö (2013) (E) Shannon (2017) (E)	Really matching what program is appropriate for every client, right? So if that person is seeking the social aspect, matching them with a group (provider group 4). (Cimo, 2018)

	Mixed Coblentz (2015) (E) McBain (2016) (E) McBain (2018) (E) T2D Education PCP Kahn (2009) (E) Mixed Chwastiak (2018) (E) Cimo & Dewa (2019) (B&E)	
	Theme 2: Routine Care T2D Care Generally MHP Aloudah (2021) (B) Shannon (2017) (B&E) Mixed McBain (2016) (E) McBain (2018) (E) Vaez (2017) (B)	"Completely routine part of the job. As soon as you see somebody who has diabetes you begin that process of finding out what they're taking, when they're taking it, how well is it managed and who are they seeing" (McBain, 2016) Without systems to ensure routine assessment in some community teams, nurses might not be aware that service users have a condition like T2D, or that other problems might not be detected. I mean obviously through observation if somebody is putting on weight each time you see them you'd be able to notice that, but I think possibly things that are not visible to the eye I'm not sure how they would be picked up because if you're not monitoring it on a regular basis how would you know? [Community nurse] (Shannon, 2017)
Reinforcement	Theme 1: Absence and presence of incentives T2D Care Generally PCP McDonnell (2011) (B) McBain (2016) (E) McBain (2018) (B) MHP McBain (2018) (E) Mixed Xin Wang (2016) (B) Vaez (2017) (B) McBain (2016) (E) McBain (2018) (B&E) T2D Referral for Retinopathy Screening Mixed McBain (2018) (E)	There is no incentive mechanism to support such coordination. The absence of policies on performance evaluation and rewards in Hualong did not encourage or reward care coordination (Xin Wang, 2016) [...]All three GPs along with two consultant psychiatrists felt that incentives do or would encourage them to manage diabetes in people with SMI, these were primarily pay-for-performance schemes such as the Quality Outcomes Framework (QOF) [33] and Commissioning for Quality and Innovation (CQUIN) [34] targets. (McBain, 2016)
	Theme 2: Discipline T2D Care Generally MHP McBain (2018) (E) Mixed McBain (2016) (E) McBain (2018) (B&E)	I think I'd be disciplined if I'm found to be negligent (McBain, 2016)
Emotion	Theme 1: Negative emotion T2D Care Generally PCP McBain (2018) (B) McDonnell (2011) (B) Wright (2006) (B) MHP Papachristou Nadal (2019) (B) Mixed	Physical health nurses were, however, significantly more scared to work with someone with SMI compared with psychiatrists (P=0.002) (McBain, 2018)

	Coblentz (2015) (B) McBain (2016) (B) McBain (2018) (B) T2D Monitoring Cholesterol Mixed McBain (2018) (E)	
Beliefs about Consequences	Theme 1: Personal consequences T2D Care Generally MHP Wright (2006) (E) Shannon (2017) (E)	For example, participants described how inpatient nurses would complete physical health monitoring because there was the expectation that they would, therefore attitudes might not have changed but practice had. Or rather, people's beliefs about the their role in physical healthcare might not have changed, but they knew there would be personal consequences for failing to change their behaviour (Shannon, 2017)
	Theme 2: Service user consequences T2D Care Generally Mixed McBain (2016) (E) McBain (2018) (E) McDonnell (2011) (B) MHP Aloudah (2021) (E) Vancampfort (2019) (E)	Expecting negative physical and psychological outcomes in patients if diabetes was not effectively managed acted as an enabler to action (McBain et al., 2016) Denial of medical problems (2.88) (McDonnell, 2011)
Behavioural Regulation	Theme 1: Action plans T2D Care Generally PCP McBain (2018) (E) MHP Shannon (2017) (E) Mixed McBain (2016) (E)	Inpatient Nurse: You know about the admission checklist. So on there we've got a nurse's physical health assessment …we'll ask about height and weight, blood sugar and then it's got all the lifestyle questions around smoking and things like that as well, so I guess as soon as someone comes in we'll try to do that as soon as possible. (Shannon, 2017)
Optimism	Theme 1: Optimism about service user health T2D care Generally Mixed McBain (2016) (B) McBain (2018) (B) T2D Diet/ Nutrition Advice Mixed McBain (2018) (E)	Only a third of the sample were optimistic about the health of their clients with T2D (McBain, 2018)
	Theme 2: Optimism about ability to provide care T2D Care Generally Mixed McBain (2016) (E) McBain (2018) (E) T2D HbA1c Targets Set & Ongoing Reviews Mixed McBain (2018) (E)	A feeling of hope and optimism about being able to manage type 2 diabetes in people with SMI in the future was expressed by five mental health professionals and one GP (McBain, 2016)

Appendix 7: Study 2 - Content Analysis Extraction Table

Key:

Y = Identified

Blank = not identified

Identified intervention functions and policy categories

			Intervention Functions									Policy Categories							
Author	**Date**	**TOTAL**	Education	Persuasion	Enablement	Incentivisation	Coercion	Training	Restrictions	Environmental Restructuring	Modelling	Service Provision	Regulation	Environmental/Social Planning	Legislation	Fiscal Measures	Guidelines	Communication/Marketing	**TOTAL**
	TOTAL	8	6	0	1	0	0	4	0	4	0	3	0	1	0	0	0	6	
Hemingway	2013	2	Y					Y										Y	1
Hemingway	2015	2	Y					Y										Y	1
Happell	2015	1								Y		Y							1
Wynn	2011	2	Y					Y										Y	1
Cook	2021	2			Y					Y		Y						Y	2
Crang	2021	1	Y															Y	1
Patel	2022	2	Y							Y				Y				Y	2
Chwastiak	2018	3	Y					Y		Y		Y							1

Identified behaviour change techniques

			Goals and Planning									Feedback and Monitoring							Social Support			Shaping knowledge			
Author	**Date**	**Total Number of BCTs**	Goal setting (behaviour)	Problem solving	Goal setting (outcome)	Action planning	Review behaviour goal(s)	Discrepancy between current behaviour and goal	Review outcome goal(s)	Behavioural contract	Commitment	Monitoring of behaviour by others without feedback	Feedback on behaviour	Self-monitoring of behaviour	Self-monitoring of outcome(s) of behaviour	Monitoring of outcomes(s) of behaviour without feedback	Biofeedback	Feedback on outcome(s) of behaviour	Social support (unspecified)	Social support (practical)	Social support (emotional)	Instruction on how to perform the behaviour	Information about antecedents	Re-attribution	Behavioural experiments
Hemingway	2013	2																				Y			
Hemingway	2015	4																				Y			
Wynn	2011	4											Y									Y			
Happell	2015	1																							
Patel	2022	3																				Y			
Cook	2021	4																Y		Y					
Crang	2021	2																				Y			
Chwastiak	2018	3																				Y			

		Natural consequences						Comparison of behaviour			Associations								Repetition and Substitution							Comparison of outcomes		
Author	**Year**	Information about health consequences	Salience of consequences	Information about social and environmental consequences	Monitoring of emotional consequences	Anticipated regret	Information about emotional consequences	Demonstration of behaviour	Social comparison	Information about others' approval	Prompts/cues	Cue signalling reward	Reduce prompts/cues	Remove access to reward	Remove aversive stimulus	Satiation	Exposure	Associative learning	Behavioural practice/rehearsal	Behaviour substitution	Habit formation	Habit reversal	Overcorrection	Generalisation of target behaviour	Graded tasks	Credible source	Pros and cons	Comparative imagining of future outcomes
Hemingway	2013	Y																										
Hemingway	2015	Y						Y											Y									
Wynn	2011	Y																	Y									
Happell	2015																											
Patel	2022	Y									Y																	
Cook	2021										Y																	
Crang	2021	Y																										
Chwastiak	2018	Y																										

		Reward and Threat											Regulation				Antecedents						Identity				
Author	Year	Material incentive (behaviour)	Material reward (behaviour)	Non-specific reward	Social reward	Social incentive	Non-specific incentive	Self-incentive	Incentive (outcome)	Self-reward	Reward (outcome)	Future punishment	Pharmacological support	Reduce negative emotions	Conserving mental resources	Paradoxical instructions	Restructuring physical environment	Restructuring social environment	Avoidance/reducing exposure to cues for behaviour	Distraction	Adding objects to the environment	Body changes	Identification of self as role model	Framing/reframing	Incompatible beliefs	Valued self-identity	Identity associated with changed behaviour
Hemingway	2013																										
Hemingway	2015																										
Wynn	2011																										
Happell	2015																	Y									
Patel	2022																										
Cook	2021																	Y									
Crang	2021																										
Chwastiak	2018																	Y									

Author	Year	Scheduled consequences										Self-belief				Covert Learning		
		Behaviour cost	Punishment	Remove reward	Reward approximation	Rewarding completion	Situation-specific reward	Reward incompatible behaviour	Reward alternative behaviour	Reduce reward frequency	Remove punishment	Verbal persuasion about capability	Mental rehearsal of successful performance	Focus on past success	Self-talk	Imaginary punishment	Imaginary reward	Vicarious consequences
Hemingway	2013																	
Hemingway	2015																	
Wynn	2011																	
Happell	2015																	
Patel	2022																	
Cook	2021																	
Crang	2021																	
Chwastiak	2018																	

Appendix 8: Study 2 - Individual Study Critical Appraisal

Criteria	**Studies**						
	Chwastiak (2018)	**Happell (2014)**	**Wynn (2011)**	**Cook (2021)**	**Crang (2021)**	**Hemingway (2013)**	**Hemingway (2015)**
Randomised Controlled Trials							
2.1. Is randomization appropriately performed?	?	?	N/A	N/A	N/A	N/A	N/A
2.2. Are the groups comparable at baseline?	Y	?	N/A	N/A	N/A	N/A	N/A
2.3. Are there complete outcome data?	X	X	N/A	N/A	N/A	N/A	N/A
2.4. Are outcome assessors blinded to the intervention provided?	?	?	N/A	N/A	N/A	N/A	N/A
2.5 Did the participants adhere to the assigned intervention?	Y	?	N/A	N/A	N/A	N/A	N/A
Non-Randomised Controlled Trials							
3.1. Are the participants representative of the target population?	N/A	N/A	X	X	X	X	X
3.2. Are measurements appropriate regarding both the outcome and intervention (or exposure)?	N/A	N/A	Y	Y	Y	Y	Y
3.3. Are there complete outcome data?	N/A	N/A	Y	?	X	X	X
3.4. Are the confounders accounted for in the design and analysis?	N/A	N/A	X	?	?	X	X
3.5. During the study period, is the intervention administered (or exposure occurred) as intended?	N/A	N/A	Y	?	?	?	?
Qualitative Studies							
1.1. Is the qualitative approach appropriate to answer the research question?	N/A	N/A	N/A	N/A	N/A	N/A	Y
1.2. Are the qualitative data collection methods adequate to address the research question?	N/A	N/A	N/A	N/A	N/A	N/A	Y
1.3. Are the findings adequately derived from the data?	N/A	N/A	N/A	N/A	N/A	N/A	Y
1.4. Is the interpretation of results sufficiently substantiated by data?	N/A	N/A	N/A	N/A	N/A	N/A	Y
1.5. Is there coherence between qualitative data sources, collection, analysis and interpretation?	N/A	N/A	N/A	N/A	N/A	N/A	?
Mixed Methods Studies							
5.1. Is there an adequate rationale for using a mixed methods design to address the research question?	N/A	N/A	N/A	N/A	N/A	N/A	?

5.2. Are the different components of the study effectively integrated to answer the research question?	N/A	N/A	N/A	N/A	N/A	N/A	Y
5.3. Are the outputs of the integration of qualitative and quantitative components adequately interpreted?	N/A	N/A	N/A	N/A	N/A	N/A	Y
5.4. Are divergences and inconsistencies between quantitative and qualitative results adequately addressed?	N/A	N/A	N/A	N/A	N/A	N/A	Y
5.5. Do the different components of the study adhere to the quality criteria of each tradition of the methods involved?	N/A	N/A	N/A	N/A	N/A	N/A	N

Appendix 9: Study 3 (Prioritisation Delphi) – Participant Information Sheet and Informed Consent Form (Health Professional)

Phase 1 and Phase 3 – Participant Information Sheet (Healthcare Professional)

Chief Investigator: [redacted]

PhD Student: Tracey Dorey – [redacted]

The Supporting Diabetes Care Study:

Designing an Intervention to Support Mental and Physical Health Professionals to Deliver Type II Diabetes Mellitus Care for People with Severe Mental Illness

Online Expert Panel

Invitation

We would like to invite you to take part in a research study. Before you decide whether you would like to take part it is important that you understand why the research is being done and what it would involve for you. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. You will be given a copy of this information sheet to keep.

If anything is not clear and you would like some more information, please contact Tracey Dorey or the Chief Investigator on the above details.

What is the purpose of the study?

Individuals with a severe mental illness (SMI) have a two to threefold increased risk of developing type 2 diabetes (T2DM) and suffer greater risk of complications, as well as increased emergency appointments, hospitalisation and mortality.

Acknowledging this inequality, the study forms part of a PhD research project that aims to help us to provide better care by developing the approaches that healthcare professionals use to manage T2DM in people with an SMI.

What do we mean by SMI?

For this study we use the term SMI to include individuals who have been diagnosed with schizophrenia, schizoaffective disorder, bipolar disorder or other psychoses, such as depression with psychosis.

What does taking part involve?

You are invited to be a member of the Online Expert Panel. The panel will consist of 16 members, including health care professionals e.g. individuals from general, diabetes, and mental health specialities (*n=8*), service users (*n=4*) and carers (*n=4*).

As a member of the Online Expert Panel, we would like you to respond to two online questionnaires. Both questionnaires involve you contributing some ideas and subsequently considering how much you agree (or disagree) with the ideas of others on the panel. The first questionnaire will focus on ideas about what needs to be addressed, the second will be asking for your opinions on how these ideas could be brought to life in your context. All parts of the questionnaire are anonymous so nobody will be able to tell which responses belong to which panel member.

Both of these questionnaires can be completed individually at a time convenient to you on a PC, laptop, tablet or phone. Each questionnaire consists of between 2 and 3 rounds so there will be separate questionnaires, the first questionnaire should take you no longer than 25-minutes to complete and the second no longer than 20-minutes. Your responses do not have to be provided in one go; you can return to each questionnaire as many times as you wish for a two-week period before submitting it.

We will ask you for your ethnicity, this data is classed as Special Category Data. We ask for this information, alongside others such as your age etc, to provide a summary of the individuals who participate in the study.

Why have I been invited to take part?

You have been invited to take part as you have experiences and expertise that will be important in ensuring any ideas generated are suitable for the healthcare context.

Do I have to take part?

No, it is up to you to decide whether to take part. You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

If you choose to withdraw during the study, it would be greatly appreciated if you could nominate a suitable replacement, e.g. a fellow health care professional in the same role as you and provide Tracey's email contact to enable the nominated individual to arrange participation should they wish.

What are the possible benefits of taking part?

Participating in this study offers you the opportunity to provide your experience and expertise to supporting the development of approaches used by healthcare professionals. This study aims to contribute to the ongoing process of improving outcomes for people with T2DM and an SMI.

What are the possible disadvantages or risks of taking part?

There are no obvious disadvantages or risks to participating in this study, if however, you find participation difficult you are free to withdraw at any time.

Whilst it is hoped that the content of this study will not cause you upset should you find yourself experiencing distress during your participation there are a number or organisations you can contact including Samaritans. They can be contacted on 116 123 for free or you can write an email to jo@samaritans.org (they aim to respond to emails within 24-hours). You may also find it useful to identify someone you can speak to, prior to participation, should you become upset such as a friend, family member, colleague or mentor

How is the project being funded?

The study is part of a funded PhD studentship by East London NHS Foundation Trust.

Data Privacy

City, University of London is the data controller for the personal data collected for this research project. Your personal data will be processed for the purposes outlined in this notice. The legal basis for processing your personal data will be that this research is a task in the public interest, that is City, University of London considers the lawful basis for processing personal data to fall under Article 6(1)(e) of GDPR (public task) as the processing of research participant data is necessary for learning and teaching purposes and all research with human participants by staff and students has to be scrutinised and approved by one of City's Research Ethics Committees.

Further, City considers the processing of special category personal data will fall under Article 9(2)(g) of the GDPR as the processing of special category data has to be for the public interest in order to receive research ethics approval and occurs on the basis of law that is, inter alia, proportionate to the aim pursued and protects the rights of data subjects.

The rights you have under the data protection legislation are listed below, but not all of the rights will be apply to the personal data collected in each research project.

- right to be informed
- right of access
- right to rectification
- right to erasure
- right to restrict processing
- right to object to data processing
- right to data portability
- right to object
- rights in relation to automated decision making and profiling

For more information, please visit www.city.ac.uk/about/city-information/legal

What if I have concerns about how my personal data will be used after I have participated in the research?

In the first instance you should raise any concerns with the research team, but if you are dissatisfied with the response, you may contact the Information Compliance Team at [redacted], who will liaise with City's Data Protection Officer Dr William Jordan to answer your query.

If you are dissatisfied with City's response you may also complain to the Information Commissioner's Office at www.ico.org.uk

Will the information I give in this study be kept confidential?

Yes, confidentiality will be ensured as each participant will create a unique identifier. This will be used to identify your data. The personal information you provide, such as your age, gender and role, will be stored separately from the data you provide.

Your anonymous ideas will be presented to the rest of the panel for the second survey, however only your idea will be provided and there will be no way of identifying who generated this idea.

Your participation in the study will only be known to the research team. When any information is presented you will not be identifiable as the information you provide about yourself will be used only to provide a summary of the participants in the study. Any further data you provide, for example your ideas, will not be identifiable as they will be presented anonymously.

The electronic survey tool, Qualtrics, is being used to obtain and store the research data. City has put in place an agreement with Qualtrics, which sets out rights and responsibilities for both organisations with regards to personal data – how it is processed, who owns and has access to the data, security arrangements and where it is stored. City insists that the personal data is held within the European Economic Area (EEA) and not in the USA. Whilst the agreement has been set up to protect personal data, it also affords the information governance protection required for all research data.

There will be some free text options within the questionnaire; to ensure your anonymity please do not disclose any additional sensitive or personal data. Whilst I have a duty not to disclose confidential information, there are some circumstances where this may not be possible, such as if the information provided suggests misconduct or risk of harm to yourself or others. In these circumstances I may have to share this information with my supervisors and encourage you to disclose this to an appropriate third party.

All data will be stored electronically in a password protected file and only accessible to the research team. This information is stored within the OneDrive account, which is held on the City, University of London's IT system. City ensures that its IT systems meet the security requirements of the data protection legislation. It will be stored for 10 years after which it will be destroyed. Destruction will be completed following the procedures outlined by City, University of London.

What will happen to the results of the study?

The data collected will be written up as part of the PhD student’s thesis and may be presented at conferences and published in peer-reviewed journals. None of the data published will identify you.

Who has reviewed the study?

This study has been approved by City, University of London, School of Health Sciences Research Ethics Committee as well as The Health Research Authority.

What if there is a problem?

If you have any concerns or complaints about anything to do with this study, please speak to Tracey Dorey or the chief investigator and we will do our best to answer your questions. You can email us on the details above.

If you remain unhappy and wish to complain formally, you can do this through City’s complaints procedure. To complain about the study, you need to phone 020 7040 3040. You can then ask to speak to the Secretary to Senate Research Ethics Committee and inform them that the name of the project is The Supporting Diabetes Care Study.

You can also write to the Secretary at:

[redacted]

[redacted]

[redacted] [redacted]

Can I get more information?

If you are interested in taking part in this study but would like some more information before you decide, please contact Tracey Dorey on the above email address.

Other participation opportunities

As part of this project there is an opportunity to participate in a brief interview following your involvement as an online expert panel member.

If I decide to take part what do I do now?

If you do decide to take part in this study, thank you very much. A link has been sent to you which enables you to access and complete the consent form and the questionnaire. You need to answer yes to all statements in the consent form if you wish to participate. If you are not happy with any of the statements, please select no and this will exit the questionnaire. Once you have consented you will be asked a couple of quick questions about you and your professional role. Once this data is captured, you'll then be able to start answering the questions.

Thank you for taking the time to read this information sheet.

Informed Consent Form

(*Each statement will have a YES or NO in Qualtrics, which if NO is selected will enable the participant to exit the interview. Participants will not be able to continue until all boxes are selected as YES).*

Participants Statement of Informed Consent

- I confirm that I have read and understood the participant information dated [INSERT DATE AND VERSION NUMBER] for the above study

- I understand this will involve completing three questionnaires asking me about my ideas on how we can improve the approaches to diabetes care for people with severe mental illness

- This information will be held by City as data controller and processed for the following purposes:

  Public Task: The legal basis for processing your personal data will be that this research is a task in the public interest, that is City, University of London considers the lawful basis for processing personal data to fall under Article 6(1)(e) of GDPR (public task) as the processing of research participant data is necessary for learning and teaching purposes and all research with human participants by staff and students has to be scrutinised and approved by one of City's Research Ethics Committees.

  I understand that the following special category data will be collected and retained as part of this research study: ethnicity. City considers the processing of special category personal data will fall under: Article 9(2)(g) of the GDPR as the processing of special category data has to be for the public interest in order to receive research ethics approval and occurs on the basis of law that is, inter alia, proportionate to the aim pursued and protects the rights of data subjects and also under Article 9(2)(a) of the GDPR as the provision of these personal data is completely voluntary.

- I agree to City recording and processing this information about me. I understand that this information will be used only for the purpose(s) explained in the participant information and my consent is conditional on City complying with its duties and obligations under the General Data Protection Regulation (GDPR).

- I have had the opportunity to consider the information and ask questions, which have been answered satisfactorily

- I understand that my participation is voluntary and that I am free to withdraw without giving a reason without being penalised or disadvantaged

- I understand that any information I provide is confidential, and that no information that could lead to the identification of any individual will be disclosed in any reports on the project, or to any other party. No identifiable personal data will be published. The identifiable data will not be shared with any other organisation.

- I agree to the arrangements for data storage, archiving and sharing

- I understand that my responses, although anonymous, will be available through an online repository for Theses, it may also be published in peer-reviewed journals
- I have read and understand the above statements

- I agree to take part in this study

Appendix 10: Study 3 (Prioritisation Delphi) – Participant Questions

Round One: Idea Generation

Section 1: Initial Information

In this section, we're going to ask you a quick question about your tole to make sure you get access to the right questions.

I am a…

- Healthcare Professional (Radio Button)
- Service User (Radio Button)
- Carer (Radio Button)

This will appear for all participants, but branch logic will direct panel members to the appropriate set of questions outlined below

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Section 2: Eligibility

We have identified a few criteria that we need from our panel, to make sure that we have a spread of voices contributing, please can you confirm that the following apply to you:

Each question will be followed by a yes/no radio button. If no is selected the participant will be sent to the end of the survey and thanked for their interest but told that they did not meet the eligibility criteria.

Healthcare Professional

- I am a healthcare professional* providing care for people with a diagnosis of SMI and/or T2DM
- I am aged 18 years or over
- I work at East London Foundation Trust

Service User

- I am aged 18 years or over
- I have been diagnosed with schizophrenia, schizoaffective disorder, bipolar disorder or other psychoses
- I have been diagnosed with Type 2 diabetes
- I am able to read and write in English
- I am capable of providing online informed consent*

Carer

- I am aged 18 years or over
- I care for someone who has been diagnosed with Type 2 diabetes and a severe mental illness (schizophrenia, schizoaffective disorder, bipolar disorder or other psychoses)
- I am able to read and write in English

Section 3: Unique Identifier

All participants will complete this question

Please provide your unique identifier 5 characters (Comprising the last 3 digits of your phone number and your initials).

Example: 123AB

Please keep your unique identifier safe as you will need this if you want to withdraw from your data from the study.

Section 4: Demographics

All participants will complete this question

- Age (Free Text)
- Gender *(Guidance to be sought on appropriate categories)*
- Ethnicity (*Listed based on Government guided categories:* https://www.ethnicity-facts-figures.service.gov.uk/ethnic-groups)

Section 5: Panel Details

Branch logic will direct the panel to appropriate questions

Healthcare Professional Questions

Now we'd like to ask you a few details about your experiences as a healthcare professional.

- My current role is (*Free text*)
- I have worked in my current role for: (*<1 year, 1-5 years, >5 years, >10 years, >15 years*)
- I have worked as a healthcare professional for: (<1 year, 1-5 years, >5 years, >10 years, >15 years)
- I have undertaken relevant previous roles including (*Free text*)
- I worked in my previous role for: (*<1 year, 1-5 years, >5 years, >10 years, >15 years*)

Service User Questions

We'd now like to ask a few questions about your mental health and diabetes

- Please tell us about your mental health diagnosis and finish this sentence - I was diagnosed with…. *(Free text)*
- Could you tell us when you were diagnosed, to the best of your memory. If you struggle to remember exactly even the year would be helpful *(Date, Month, Year)*
- Can you now tell us when you were diagnosed with type 2 diabetes (again this is just to the best of your memory with any details helpful)

Carer Questions

Now we'd like to ask you a few details about your experiences as a carer

- Please tell us about who you provide care for by completing the sentence - I provide care for.....e.g. partner, child *(Free text)*
- Please tell us about their severe mental illness diagnosis – what were they diagnosed with?
- Please tell us when they were diagnosed with their severe mental illness. If you struggle to remember exactly even the year would be helpful
- Please tell us when they were diagnosed with their Type 2 diabetes. If you struggle to remember exactly even the year would be helpful

---

Section 6: Idea Generation

These questions will be presented to the appropriate stakeholder group using branch logic **(design note only, text not included in Qualtrics)**

Healthcare Professional

Your Questions

In this section, we'd like you to share your ideas with us from your perspective as a healthcare professional or working in the healthcare context.

We want your help to identify things that could be done to **improve outcomes** for people who have Type 2 diabetes and a severe mental illness.

In this round, we'd like to explore the current care offer with you, including the offer overall and/or your perceived ability to deliver it. We're looking specifically at when and where we could potentially make changes, so we encourage you to consider barriers to providing even better care than is currently available as well as opportunities to make additions to the current care offer which you think would add value.

To get started, we'd like you to think about the provision of Type 2 diabetes care overall. Try to consider how you would finish one/some/all of the following sentences. You'll have the opportunity to unpack your responses in the next section.

Things to consider:
In the development of this survey, we looked at some previous research and found some potential areas that could be a focus. Examples included:

- *The ability to better communicate with people with a severe mental Illness*
- *The ability to provide tailored lifestyle advice such as diet or exercise advice*
- *The ability to provide care when service users have recovered from an acute crisis*
- *The ability to provide care when service users has been discharged from inpatient services*

We are **not** looking for examples of things that could be done to **prevent** Type 2 diabetes but things that can be done **once an individual has been diagnosed**.

Questions

Please think about when you and/or other healthcare professional(s) provide care for some with Type 2 diabetes and/or an SMI when answering the following questions (*Each question will be followed by a free text box)*

- For people who have a severe mental illness, Type 2 diabetes care would be better if I could/had…..
- For people who have a severe mental illness, Type 2 diabetes care would be better if they (other healthcare professionals) could/had…..
- For people who have a severe mental illness, Type 2 diabetes care would be better if more time was spent on…..
- For people who have a severe mental illness, Type 2 diabetes care was provided when…..
- What other ideas do you have that perhaps fall outside the scope of these sentences?

Service User

Initial Information

In this section, we'd like you to share your ideas with us from your perspective as a service user.

Here are some examples that might help get you started. These are just examples, please say what YOU want to say.

- I wanted to talk to my mental health nurse about how hard I find it to eat the right foods for my diabetes, but they didn't ask me about it.

- I find it difficult to manage my diabetes when my mental health is suffering, I'd like some help with that.

We are **not** looking for examples of things that could have been done to **prevent** you getting diabetes. We'd really like your thoughts on things that can be done **after you received your diabetes diagnosis.**

Your Ideas

Please think about when you receive care for your diabetes when answering the following questions. (*Each question will be followed by a free text box)*

- What about the care for your diabetes works well?
- What could be done differently or better?
- Is there anything else you would like to tell us about you have received diabetes care or wanted to receive care?

Carer

Initial Information

In this section, we'd like you to share your ideas with us from your perspective as a carer.

We want your help to identify things that could be done to improve the care someone you care for receives for their diabetes.

Here are some examples that might help get you started. These are just examples, please say what YOU want to say.

- My son has schizophrenia and Type 2 diabetes but most of the time is spent talking about his mental health and not addressing his diabetes. If the mental health team would spend more time talking to him about his diabetes and helping him to access other services that could help him, that would make a difference.

We are **not** looking for examples of things that could have been done to **prevent** someone you care for getting diabetes. We'd really like your thoughts on things that can be done after **they received the diabetes diagnosis.**

Your Ideas

Please think about when someone you care for receives care for their diabetes when answering the following questions. (*Each question will be followed by a free text box)*

- What about their diabetes care works well?
- What could be done differently or better?
- Is there anything else you would like to tell us about when someone you care for has received diabetes care or wanted to receive care?

Round Two: Idea Ranking

Section 1. Your Role

To make sure you get the right questions, please tell me if you're a….

- Healthcare Professional
- Service User
- Carer

Section 2. Unique Identifier

Please enter your unique identifier so we can identify your data if you'd like to withdraw. This was created when you gave us your ideas. If you struggle to remember please create a new identifier, however you will need to keep this safe to ensure that you can withdraw your data in the future.

Section 3. Idea Ranking

Healthcare Professional

Initial Information

In this section, we’d like you to review the ideas submitted by all members of the panel and rank the ideas.

There were XX ideas generated from the first round. To avoid duplication, any similar ideas were combined which resulted in XX ideas.

For this round, have a look at the ideas below and rank them in order of your preference. Depending on the number of ideas, participants may be asked to only select their top 3.

When considering your ranking please think about the following:

- How much of an impact the idea will have on improving T2DM outcomes for people with an SMI
- How likely it is that the behaviour can be changed
- How likely it is that the idea will influence (either positively or negatively) other behaviour e.g. << provide an example>>.
- How easy it will be to measure a change happens

Questions

Please rank the following ideas, with your favourite idea at the top i.e. Number 1. And your least favourite at the bottom i.e. Number XX

The ideas will be provided in a ranking table that can be moved about by the participants. (Design Note)

Please tell us a little bit more about your rationale for the ranking of these ideas e.g. what did you particularly like/dislike about your favourite/least favourite ideas?

Service User

Initial Information

In this section we’d like you to review the ideas submitted by all members of the panel and rank them.
There were XX ideas suggested as ways to improve diabetes care from the first round. Some were similar so these have been grouped together, meaning there are XX ideas in total.

We now need your help to decide which idea will be the best to take forward.

Please read each of the ideas and think about the following:

- I think this idea will help my diabetes
- This seems possible
- I think doing this will change other parts of diabetes care. This might make things better or worse e.g. << provide an example>>.

- It will be obvious that this has happened

Questions

Please rank the following ideas, with your favourite idea at the top i.e. Number 1. And your least favourite at the bottom i.e. Number XX

The ideas will be provided in a ranking table that can be moved about by the participants. (Design Note)

Please tell us a little bit more about your rationale for the ranking of these ideas e.g. what did you particularly like/dislike about your favourite/least favourite ideas?

Carer

Initial Information

In this section we'd like you to review the ideas submitted by all members of the panel and rank them.

There were XX ideas suggested as ways to improve diabetes care from the first round. Some were similar so these have been grouped together, meaning there are XX ideas in total.

We now need your help to decide which idea will be the best to take forward.

Please read each of the ideas and think about the following:

- I think this idea will help someone I care about with their diabetes
- This seems possible
- I think doing this will change other parts of diabetes care. This might make things better or worse e.g. << provide an example>>.
- It will be obvious that this has happened

Questions

Please rank the following ideas, with your favourite idea at the top i.e. Number 1. And your least favourite at the bottom i.e. Number XX

The ideas will be provided in a ranking table that can be moved about by the participants. (Design Note)

Please tell us a little bit more about your rationale for the ranking of these ideas e.g. what did you particularly like/dislike about your favourite/least favourite ideas?

Appendix 11: Study 3 (Prioritisation Delphi) – Participant Information Sheet and Informed Consent Form (Service User and Carer)

Chief Investigator: Dr Kathleen Mulligan – [redacted]

PhD Student: Tracey Dorey – [redacted]

The Supporting Diabetes Care Study:

Designing an Intervention to Support Mental and Physical Health Professionals to Deliver Type II Diabetes Mellitus Care for People with Severe Mental Illness

Online Expert Panel

Invitation

We would like to invite you to take part in a research study. Before you decide whether you would like to take part it is important that you understand why the research is being done and what it would involve for you. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. You will be given a copy of this information sheet to keep.

If anything is not clear and you would like some more information, please contact Tracey Dorey or the Chief Investigator on the above details.

What is the purpose of the study?

Individuals with a severe mental illness (SMI) have a two to threefold increased risk of developing type 2 diabetes (T2DM) and suffer greater risk of complications, as well as increased emergency appointments, hospitalisation and mortality.

This study forms part of a PhD research project that aims to help us to provide better care by developing the approaches that healthcare professionals use to manage T2DM in people with an SMI.

What do we mean by SMI?

For this study we use the term SMI to include individuals who have been diagnosed with schizophrenia, schizoaffective disorder, bipolar disorder or other psychoses, such as depression with psychosis. If you want to discuss whether your diagnosis is included in this study please feel free to contact Tracey ([redacted]).

What does taking part involve?

You are invited to be a member of the **Online Expert Panel**. The panel will consist of 16 members, including health care professionals e.g. individuals from general, diabetes, and mental health specialities (*n=8*), people with a lived experience of severe mental illness and type 2 diabetes (*n=4*) and carers (*n=4*).

As a member of the Online Expert Panel, we would like you to respond to an online questionnaire to hear your experiences of your, or someone you care for, diabetes care. We would also like to know your ideas about what needs to be addressed in the current care process. We would also like you to then consider how much you agree (or disagree) with the ideas of others on the panel. All parts of the questionnaire are anonymous so nobody will be able to tell which responses belong to which panel member. We will then ask you to complete one final questionnaire which will ask for your help to provide some details about how we can bring the idea to life.

The questionnaires can be completed individually at a time convenient to you on a PC, laptop, tablet or phone. It is estimated that the total completion time will only be 25-minutes across the questionnaires. Your responses do not have to be provided in one go; you can return to the questionnaire as many times as you wish before the final closing date. The date will be provided when you complete the questionnaires.

We will ask you for your ethnicity and your health/health of the person you care for (delete as appropriate), this data is classed as Special Category Data. We ask for this information, alongside others such as your age etc, to provide a summary of the individuals who participate in the study.

Why have I been invited to take part?

For carers

You have been invited to take part because you have first-hand experience of caring for someone who has diabetes and mental illness.

For people with lived experience

You have been invited to take part because you have first-hand experience of receiving care for diabetes and mental illness.

*One of the above sentences will be deleted based on the recipient

Do I have to take part?

For carers

No, it is up to you to decide whether to take part. If you decide to participate you will be asked to complete a consent form. However, if you decide at any point during your participation that you wish to withdraw, you are free to withdraw at any time without giving a reason. Please be assured that deciding to withdraw at any time or choosing not to take part will not impact on the service that the person you care for receives currently or in the future. You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

For people with lived experience

No, it is up to you to decide whether to take part. If you decide to participate you will be asked to complete a consent form. However, if you decide at any point during your participation that you wish to withdraw, you are free to withdraw at any time without giving a reason. Please be assured that deciding to withdraw at any time or choosing not to take part will not impact on the care you receive currently or in the future. You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

*One of the above sentences will be deleted based on the recipient

What are the possible benefits of taking part?

We don’t expect there to be any personal benefits to you for taking part. However, we do hope that the information you submit will help us to understand how healthcare professionals can provide improved care for people with T2DM and an SMI.

What are the possible disadvantages or risks of taking part?

We do not believe that answering this online questionnaire will cause distress, however if you find that responding to or commenting on these questions is upsetting please stop at any point. It may be a good idea to identify someone you can talk to, should you become upset, prior to starting the survey. This could be a member of your family, a friend or a healthcare professional.

If you have concerns about your mental health and it is the day time please contact your GP or your Community Mental Health Team (CMHT) and ask for your care coordinator or the person on duty. If it is an evening, weekend or bank holiday, please contact your local crisis team, details can be found by calling NHS 111.

If you have more general questions about mental health please contact any of the charities below who will be able to provide specialist advice and resources:

Samaritans on Tel: 116123 or email jo@samaritans.org (they aim to respond to emails within 24-hours)

Mind on Tel. 0300 123 3393 or website http://www.mind.org.uk/
Rethink Mental Illness Tel. 0300 5000 927 or website http://www.rethink.org/
Bipolar UK Tel. 0207 931 6480 or website http://www.bipolaruk.org.uk/

If you have concerns about the care you receive you can contact the PALS (Patient and Advice and Liaison Service). PALS is a confidential service which supports patients, relatives, carers or members of the public to get advice and information about their service. PALS can help when you have concerns about the treatment and care we provide, when you need advice or do not know where to turn. PALS information can be obtained from your Trust’s website.

How is the project being funded?

The study is part of a funded PhD studentship by East London NHS Foundation Trust.

Data Privacy

City, University of London is the data controller for the personal data collected for this research project. Your personal data will be processed for the purposes outlined in this notice. The legal basis for processing your personal data will be that this research is a task in the public interest, that is City, University of London considers the lawful basis for processing personal data to fall under Article 6(1)(e) of GDPR (public task) as the processing of research participant data is necessary for learning and teaching purposes and all research with human participants by staff and students has to be scrutinised and approved by one of City's Research Ethics Committees.

Further, City considers the processing of special category personal data will fall under Article 9(2)(g) of the GDPR as the processing of special category data has to be for the public interest in order to receive research ethics approval and occurs on the basis of law that is, inter alia, proportionate to the aim pursued and protects the rights of data subjects.

The rights you have under the data protection legislation are listed below, but not all of the rights will be apply to the personal data collected in each research project.

- right to be informed
- right of access
- right to rectification
- right to erasure
- right to restrict processing
- right to object to data processing
- right to data portability
- right to object
- rights in relation to automated decision making and profiling

For more information, please visit www.city.ac.uk/about/city-information/legal

What if I have concerns about how my personal data will be used after I have participated in the research?

In the first instance you should raise any concerns with the research team, but if you are dissatisfied with the response, you may contact the Information Compliance Team at dataprotection@city.ac.uk or phone 0207 040 4000, who will liaise with City's Data Protection Officer Dr William Jordan to answer your query.

If you are dissatisfied with City's response you may also complain to the Information Commissioner's Office at www.ico.org.uk

Will the information I give in this study be kept confidential?

Yes, confidentiality will be ensured as each participant will be provided with a unique identifier. This will be used to identify your data. The personal information you provide, such as your age, gender and role, will be stored separately from the data you provide.

Your anonymous ideas will be presented to the rest of the panel for the second survey, however only your idea will be provided and there will be no way of identifying who generated this idea.

Your participation in the study will only be known to the research team. When any information is presented you will not be identifiable as the information you provide about yourself will be used only to provide a summary of the participants in the study. Any further data you provide, for example your ideas, will not be identifiable as they will be presented anonymously.

The electronic survey tool, Qualtrics, is being used to obtain and store the research data. City has put in place an agreement with Qualtrics, which sets out rights and responsibilities for both organisations with regards to personal data – how it is processed, who owns and has access to the data, security arrangements and where it is stored. City insists that the personal data is held within the European Economic Area (EEA) and not in the USA. Whilst the agreement has been set up to protect personal data, it also affords the information governance protection required for all research data.

There will be some free text options within the questionnaire; to ensure your anonymity please do not disclose any additional sensitive or personal data. Whilst I have a duty not to disclose confidential information, there are some circumstances where this may not be possible. For example, if the information disclosed suggests risk of harm to yourself and/or others. If this occurs, every effort will be made to discuss the importance of disclosure with you and encourage it.

All data will be stored electronically in a password protected file and only accessible to the research team. This information is stored within the OneDrive account, which is held on the City, University of London's IT system. City ensures that its IT systems meet the security requirements of the data protection legislation. It will be stored for 10 years after which it will be destroyed. Destruction will be completed following the procedures outlined by City, University of London.

What will happen to the results of the study?

The data collected will be written up as part of the PhD student's thesis and may be presented at conferences and published in peer-reviewed journals. None of the data published will identify you.

Who has reviewed the study?

This study has been approved by City, University of London, School of Health Sciences Research Ethics Committee as well as The Health Research Authority.

What if there is a problem?

If you have any concerns or complaints about anything to do with this study, please speak to Tracey Dorey or the chief investigator and we will do our best to answer your questions. You can email us on the details above.

If you remain unhappy and wish to complain formally, you can do this through City's complaints procedure. To complain about the study, you need to phone 020 7040 3040. You can then ask to speak to the Secretary to Senate Research Ethics Committee and inform them that the name of the project is The Supporting Diabetes Care Study.

You can also write to the Secretary at:

[redacted]

[redacted]

[redacted]

Can I get more information?

If you are interested in taking part in this study but would like some more information before you decide, please contact Tracey Dorey on the above email address.

If I decide to take part what do I do now?

If you do decide to take part in this study, thank you very much. You will first be asked to complete a consent form (click on the arrow at the bottom to access this). You need to answer yes to all statements if you wish to participate. If you are not happy with any of the statements, please select no and this will exit the questionnaire. Once you have consented we will ask a couple of quick questions about you. Once this data is captured, you'll then be able to start answering the questions.

Thank you for taking the time to read this information sheet.

Appendix F2

Phase 1 – Informed Consent Form (People with Lived Experience and Carer)

Informed Consent Form

The Supporting Diabetes Care Study

(*Each statement will have a YES or NO in Qualtrics, which if NO is selected will enable the participant to exit the interview. Participants will not be able to continue until all boxes are selected as YES).*

Participants Statement of Informed Consent

- I confirm that I have read and understood the participant information dated [INSERT DATE AND VERSION NUMBER] for the above study

- I understand this will involve completing three questionnaires asking me about my ideas on how we can improve the approaches to diabetes care for people with severe mental illness

- This information will be held by City as data controller and processed for the following purposes:

  Public Task: The legal basis for processing your personal data will be that this research is a task in the public interest, that is City, University of London considers the lawful basis for processing personal data to fall under Article 6(1)(e) of GDPR (public task) as the processing of research participant data is necessary for learning and teaching purposes and all research with human participants by staff and students has to be scrutinised and approved by one of City's Research Ethics Committees.

  I understand that the following special category data will be collected and retained as part of this research study: ethnicity and health data. City considers the processing of special category personal data will fall under: Article 9(2)(g) of the GDPR as the processing of special category data has to be for the public interest in order to receive research ethics approval and occurs on the basis of law that is, inter alia, proportionate to the aim pursued and protects the rights of data subjects and also under Article 9(2)(a) of the GDPR as the provision of these personal data is completely voluntary.

- I agree to City recording and processing this information about me. I understand that this information will be used only for the purpose(s) explained in the participant information and my consent is conditional on City complying with its duties and obligations under the General Data Protection Regulation (GDPR).

- I have had the opportunity to consider the information and ask questions, which have been answered satisfactorily

- I understand that my participation is voluntary and that I am free to withdraw without giving a reason without being penalised or disadvantaged

- I understand that any information I provide is confidential, and that no information that could lead to the identification of any individual will be disclosed in any reports on the project, or to any other party. No identifiable personal data will be published. The identifiable data will not be shared with any other organisation.

- I agree to the arrangements for data storage, archiving and sharing

- I understand that my responses, although anonymous, will be available through an online repository for Theses, it may also be published in peer-reviewed journals

- I am capable of providing online informed consent

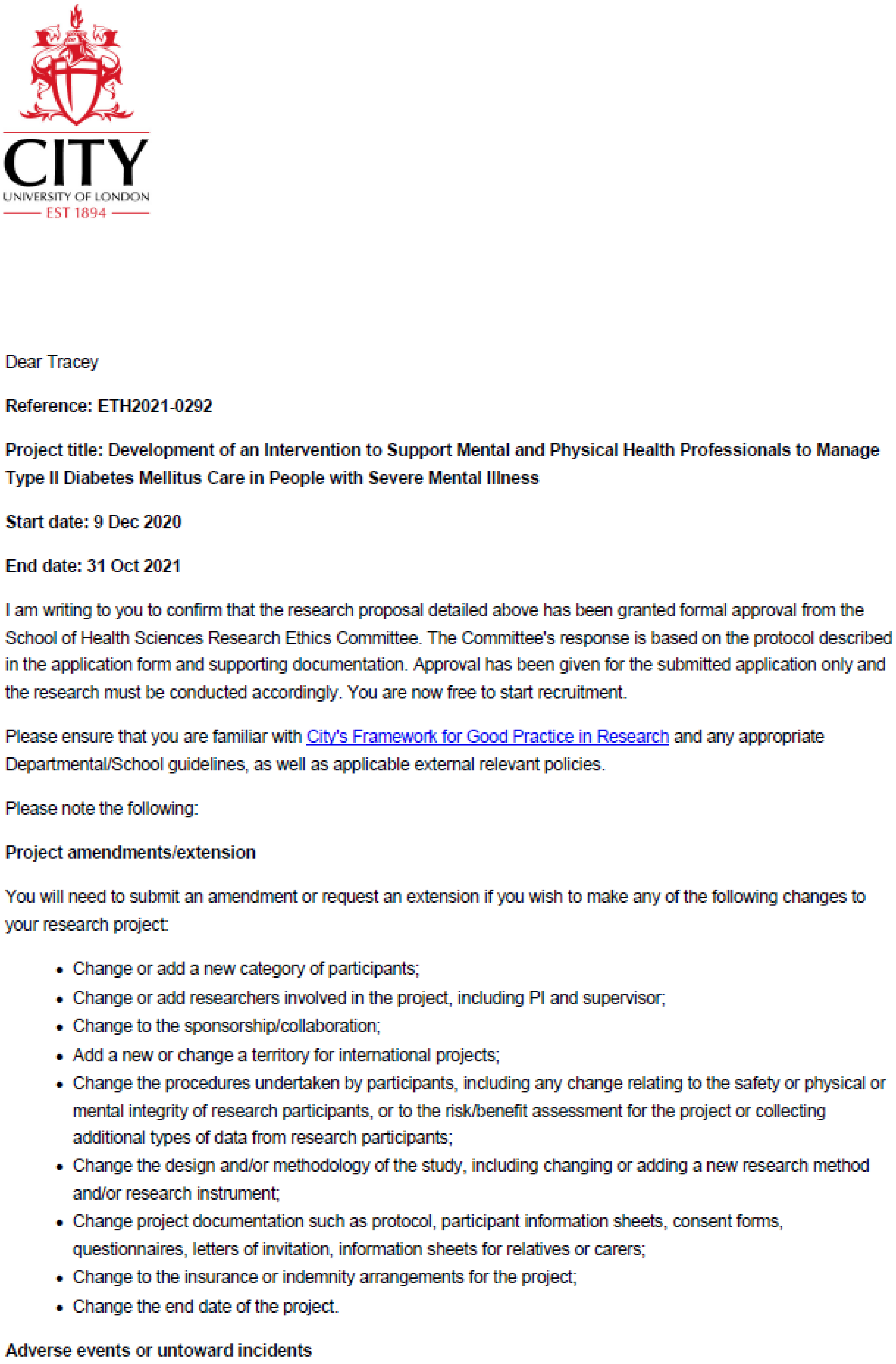
- I have read and understand the above statements

- I agree to take part in this study

Appendix 12: Study 3 (Prioritisation Delphi) Codebook

Themes	Codes
Appointments	Scheduling
Care process	Specific care process e.g., blood pressure, medication, cholesterol etc.
Collaborative care	Collaboration Liaison Communication Goals (professional behaviour focussed)
Dietary advice	Eating
Self-management provision	Education Empower Self-care
Relationships	Interaction Family Communication
Personalised care	Goals (service user) Accessibility Modification Individualised
Provision of care at different times	Relapse Diagnosis
Wellbeing	Emotion

Appendix 13: School of Health Sciences Ethics Approval



CITY
UNIVERSITY OF LONDON
EST 1894

Dear Tracey

Reference: ETH2021-0292

Project title: Development of an Intervention to Support Mental and Physical Health Professionals to Manage Type II Diabetes Mellitus Care in People with Severe Mental Illness

Start date: 9 Dec 2020

End date: 31 Oct 2021

I am writing to you to confirm that the research proposal detailed above has been granted formal approval from the School of Health Sciences Research Ethics Committee. The Committee's response is based on the protocol described in the application form and supporting documentation. Approval has been given for the submitted application only and the research must be conducted accordingly. You are now free to start recruitment.

Please ensure that you are familiar with City's Framework for Good Practice in Research and any appropriate Departmental/School guidelines, as well as applicable external relevant policies.

Please note the following:

Project amendments/extension

You will need to submit an amendment or request an extension if you wish to make any of the following changes to your research project:

- Change or add a new category of participants;
- Change or add researchers involved in the project, including PI and supervisor;
- Change to the sponsorship/collaboration;
- Add a new or change a territory for international projects;
- Change the procedures undertaken by participants, including any change relating to the safety or physical or mental integrity of research participants, or to the risk/benefit assessment for the project or collecting additional types of data from research participants;
- Change the design and/or methodology of the study, including changing or adding a new research method and/or research instrument;
- Change project documentation such as protocol, participant information sheets, consent forms, questionnaires, letters of invitation, information sheets for relatives or carers;
- Change to the insurance or indemnity arrangements for the project;
- Change the end date of the project.

Adverse events or untoward incidents

CITY
UNIVERSITY OF LONDON
EST 1894

You will need to submit an Adverse Events or Untoward Incidents report in the event of any of the following:

a) Adverse events

b) Breaches of confidentiality

c) Safeguarding issues relating to children or vulnerable adults

d) Incidents that affect the personal safety of a participant or researcher

Issues a) and b) should be reported as soon as possible and no later than five days after the event. Issues c) and d) should be reported immediately. Where appropriate, the researcher should also report adverse events to other relevant institutions, such as the police or social services.

Should you have any further queries relating to this matter, please do not hesitate to contact me. On behalf of the School of Health Sciences Research Ethics Committee, I do hope that the project meets with success.

Kind regards

Nicholas Drey

School of Health Sciences Research Ethics Committee

City, University of London

Appendix 14: HRA Approval

Ymchwil Iechyd
a Gofal Cymru
Health and Care
Research Wales

NHS
Health Research
Authority

[redacted]

Email: approvals@hra.nhs.uk

13 January 2021

Dear [redacted]

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title: **Development of an Intervention to Support Mental and Physical Health Professionals to Manage type 2 Diabetes Mellitus Care in People with Severe Mental Illness**
IRAS project ID: **280046**
Protocol number: **1.0**
REC reference: **20/HRA/6187**
Sponsor **City, University of London**

I am pleased to confirm that HRA and Health and Care Research Wales (HCRW) Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?

HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The *"After HRA Approval – guidance for sponsors and investigators"* document on the HRA website gives detailed guidance on reporting expectations for studies with HRA and HCRW Approval, including:

- Registration of Research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

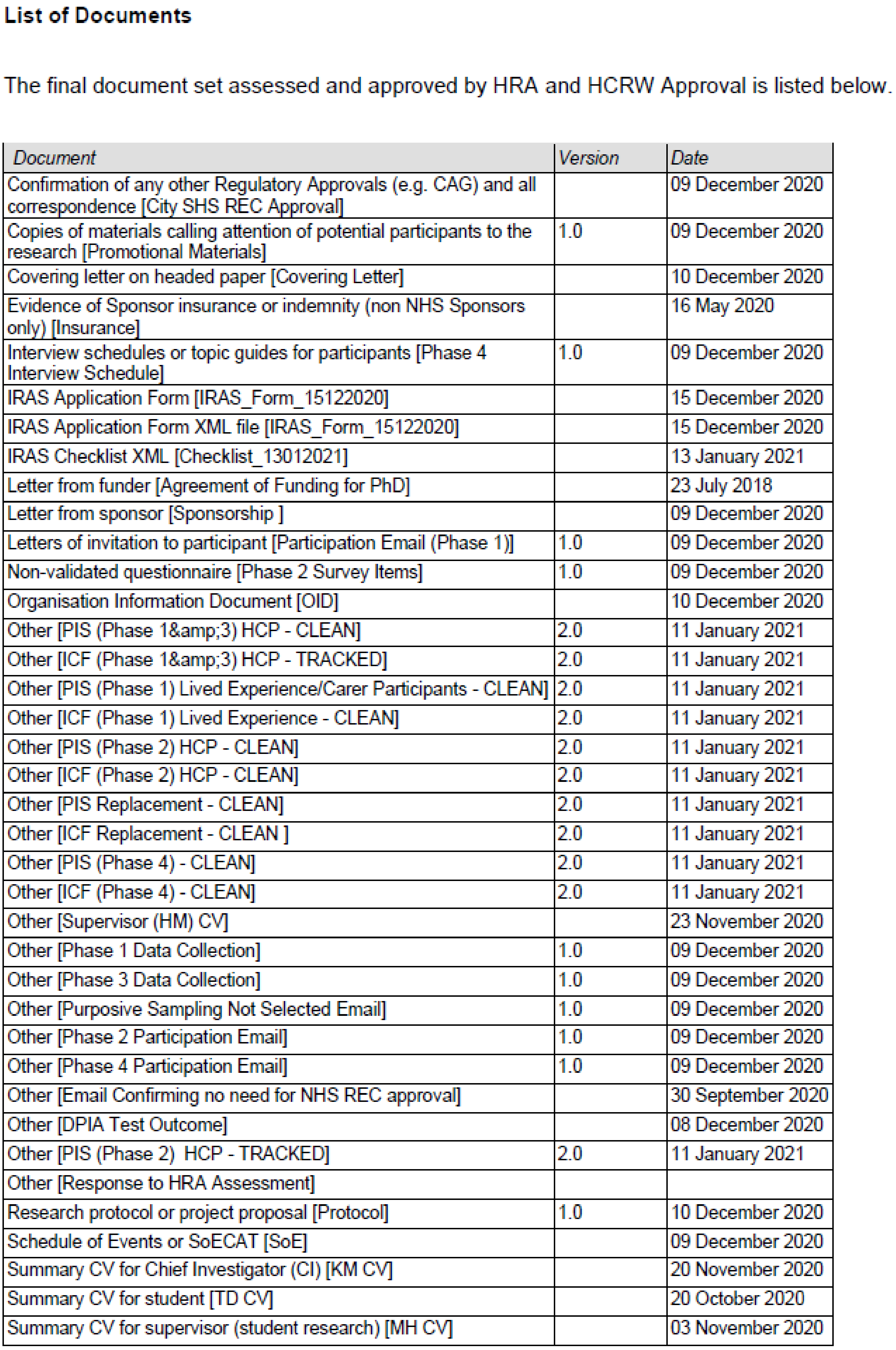
[redacted]

Yours sincerely,

[redacted]

Email: approvals@hra.nhs.uk

Copy to: [redacted]



List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
Confirmation of any other Regulatory Approvals (e.g. CAG) and all correspondence [City SHS REC Approval]		09 December 2020
Copies of materials calling attention of potential participants to the research [Promotional Materials]	1.0	09 December 2020
Covering letter on headed paper [Covering Letter]		10 December 2020
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance]		16 May 2020
Interview schedules or topic guides for participants [Phase 4 Interview Schedule]	1.0	09 December 2020
IRAS Application Form [IRAS_Form_15122020]		15 December 2020
IRAS Application Form XML file [IRAS_Form_15122020]		15 December 2020
IRAS Checklist XML [Checklist_13012021]		13 January 2021
Letter from funder [Agreement of Funding for PhD]		23 July 2018
Letter from sponsor [Sponsorship]		09 December 2020
Letters of invitation to participant [Participation Email (Phase 1)]	1.0	09 December 2020
Non-validated questionnaire [Phase 2 Survey Items]	1.0	09 December 2020
Organisation Information Document [OID]		10 December 2020
Other [PIS (Phase 1&3) HCP - CLEAN]	2.0	11 January 2021
Other [ICF (Phase 1&3) HCP - TRACKED]	2.0	11 January 2021
Other [PIS (Phase 1) Lived Experience/Carer Participants - CLEAN]	2.0	11 January 2021
Other [ICF (Phase 1) Lived Experience - CLEAN]	2.0	11 January 2021
Other [PIS (Phase 2) HCP - CLEAN]	2.0	11 January 2021
Other [ICF (Phase 2) HCP - CLEAN]	2.0	11 January 2021
Other [PIS Replacement - CLEAN]	2.0	11 January 2021
Other [ICF Replacement - CLEAN]	2.0	11 January 2021
Other [PIS (Phase 4) - CLEAN]	2.0	11 January 2021
Other [ICF (Phase 4) - CLEAN]	2.0	11 January 2021
Other [Supervisor (HM) CV]		23 November 2020
Other [Phase 1 Data Collection]	1.0	09 December 2020
Other [Phase 3 Data Collection]	1.0	09 December 2020
Other [Purposive Sampling Not Selected Email]	1.0	09 December 2020
Other [Phase 2 Participation Email]	1.0	09 December 2020
Other [Phase 4 Participation Email]	1.0	09 December 2020
Other [Email Confirming no need for NHS REC approval]		30 September 2020
Other [DPIA Test Outcome]		08 December 2020
Other [PIS (Phase 2) HCP - TRACKED]	2.0	11 January 2021
Other [Response to HRA Assessment]		
Research protocol or project proposal [Protocol]	1.0	10 December 2020
Schedule of Events or SoECAT [SoE]		09 December 2020
Summary CV for Chief Investigator (CI) [KM CV]		20 November 2020
Summary CV for student [TD CV]		20 October 2020
Summary CV for supervisor (student research) [MH CV]		03 November 2020

Appendix 15: Confirmation of Capacity and Capability

[redacted]

Appendix 16: Study 3 (Prioritisation Delphi) – Full list of ideas, themes and refinement for survey two

Ideas List	Theme 1	Theme 2	Refined for List	Category	Notes
Scheduling regular physicals	Appointments		Regularly schedule and monitor physical health	Healthcare Professional	
Improve of visits frequency to daily.	Appointments		Regularly schedule and monitor physical health	Healthcare Professional	
More regular care - physicals	Appointments		Regularly schedule and monitor physical health	Healthcare Professional	
deal with frustrations around poor engagement and not immediately discharge people	Attitudes		Ensure discharge of individuals is not related to frustrations around poor engagement	Healthcare Professional	
Pay close attention to your patients’ feet	Care Process		Ensure foot care is regularly and closely monitored	Healthcare Professional	
The weight management exercises to observe in the patients	Care Process		Offer weight management education and support	Healthcare Professional	
Keep your Cholesterols under check	Care Process		Regularly assess cholesterol, blood pressure and medication	Healthcare Professional	
Medication support	Care Process		Regularly assess cholesterol, blood pressure and medication	Healthcare Professional	
Medication management	Care Process		Regularly assess cholesterol, blood pressure and medication	Healthcare Professional	
creating a treatment plan with both the diabetic nurse and myself to ensure we both physical health and mental health issues	Collaborative Care		Create a treatment plan collaboratively with the diabetes and mental health teams to ensure a focus on both	Healthcare Professional	
liaise better with diabetic nurses	Collaborative Care		Improve liaison between mental health care team and diabetes nurses	Healthcare Professional	
Relationship between MDT	Collaborative Care		Improve liaison/communication between all members of the care team (i.e. physical and mental health professionals)	Healthcare Professional	

have a service which initiates the meeting of both professionals together	Collaborative Care		Proactive service which initiates meetings between all professionals involved in care	Healthcare Professional	
Treatment planning with whole care team	Collaborative Care	Goals	Set goals for the individual as a whole care team (i.e. physical and mental health professionals)	Healthcare Professional	
mental health support provided to address comfort eating	Diet/Nutrition		Offer mental health support to target comfort eating	Healthcare Professional	
work on distraction techniques away from eating	Diet/Nutrition		Provide guidance on distraction techniques to focus on eating	Healthcare Professional	
Set a diary of the foods they should eat less and come up with a healthy eating plan. Set timers of when they should take their next insulin injection.	Diet/Nutrition	Medication Management	Provide individualised healthy eating plans which cover foods which should eaten less frequently.	Healthcare Professional	Did not use the insulin timer suggestion as not a behaviour
Exercise is done according to the doctor's guidance program, which allows the patient to develop a schedule of life time.	Exercise		Provide a guided, personalised, exercises programme	Healthcare Professional	
Goals should be more aimed at the person More attention should be given to the person especially if they have a mental health problem. Points/stickers/rewards should be rewarded especially if the person has mental health problems.	Goals	Relationship	Set individual goals relevant to the service user	Healthcare professional	
Goal setting	Goals		Set individual goals relevant to the service user	Healthcare Professional	
changing lifestyle help	Lifestyle		Offer lifestyle modification education and support	Healthcare Professional	
Nothing overall very good. Possibly more follow ups if needed.	Miscellaneous		Regularly schedule and monitor physical health	Healthcare Professional	
Calculate the ideal weight according to the patient's gender, age and height, calculate the daily need for calories according to the ideal weight and working nature, children, pregnant women, nursing mothers, malnutrition and emasculation and accompanied by wasting disease should be increased as appropriate, obesity, appropriate reduction.	Miscellaneous		Set individual goals relevant to the service user	Healthcare Professional	

Love	Relationship		Focus on the interaction between service user and healthcare professional e.g. to improve the interaction to ensure it is friendly, not disregarding fears and communication	Healthcare Professional	
Friendly	Relationship		Focus on the interaction between service user and healthcare professional e.g. to improve the interaction to ensure it is friendly, not disregarding fears and communication	Healthcare Professional	
improve my communication with others to promote good health	Relationship		Focus on the interaction between service user and healthcare professional e.g. to improve the interaction to ensure it is friendly, not disregarding fears and communication	Healthcare Professional	
Treating patients with better care	Relationship		Focus on the interaction between service user and healthcare professional e.g. to improve the interaction to ensure it is friendly, not disregarding fears and communication	Healthcare Professional	
There should be love shown more compared to medicone	Relationship		Focus on the interaction between service user and healthcare professional e.g. to improve the interaction to ensure it is friendly, not disregarding fears and communication	Healthcare Professional	
The only care needed is to show love	Relationship		Focus on the interaction between service user and healthcare professional e.g. to improve the interaction to ensure it is friendly, not disregarding fears and communication	Healthcare Professional	
more local support groups. more physical training.	Self-Management	Social Support	Offer self-management education programmes and support	Healthcare Professional	
self-managing confidence	Self-Management		Provide consultations that empower the service user and make them feel confident in diabetes management	Healthcare Professional	

providing easy to understand information about diabetes	Tailoring		Ensure information provided in consultations is easy to understand and appropriate for the individual	Healthcare Professional	
Care provided at the time of diagnosis is a time to target	Time		Focus on the time of diagnosis as time to provide care	Healthcare Professional	
When there is continuous high blood sugar levels, and the client is not able to control it having a one-on-one support for a short duration does help a lot but due to shortage of nurses who specialise in diabetes its a challenge to achieve .	Time		Offer more intensive support at critical times of diabetes management - e.g. when continuous uncontrolled high blood sugar	Healthcare Professional	
Additional help when physical health affects mental health	Time		Provide additional support when physical health (diabetes) affects mental health	Healthcare Professional	
Individuals raised concerns on their mental health being affected by their physical health	Time		Provide consultations that empower the service user and make them feel confident in diabetes management	Healthcare Professional	
When it was my birthday there was cake and my parent really wanted some but it had too much sugar, my parent had a tantrum and whatever he could find would throw on the floor. I was alone and felt I needed support so I calmed them down and told them that they could help me open presents	Time		Use a proactive approach to diabetes care focussing on difficult times such as mental health breakdown	Healthcare Professional	Covered by critical time list item
Care provided at the time of mental health breakdown	Time		Use a proactive approach to diabetes care focussing on difficult times such as mental health breakdown	Healthcare Professional	
When they were lonely	Time		Use a proactive approach to diabetes care focussing on difficult times such as mental health breakdown	Healthcare Professional	Covered by critical time list item
when food choices went out of control because of a mental health breakdown. Other carers were very scared to address this issue.	Time		Use a proactive approach to diabetes care focussing on difficult times such as mental health breakdown	Healthcare Professional	
A time immediately after my diagnosis.. I needed provision of sufficient information to help me be aware and overcome it	Time		Use time of diagnosis as time to provide care	Healthcare Professional	

A time when I was diagnosed with Diabetes. I wasn't properly informed of the risks involved and I feel they should have done better	Time		Use time of diagnosis as time to provide care	Healthcare Professional	
Immediately after their diagnosis.. I felt they needed more support.	Time		Use time of diagnosis as time to provide care	Healthcare Professional	
Emotional Wellbeing	Wellbeing		Offer advice and guidance on emotional wellbeing	Healthcare Professional	
Maintain contact	Wellbeing		Regularly schedule and monitor physical health	Healthcare Professional	
continue to assess risk	Wellbeing		Regularly schedule and monitor physical health	Healthcare Professional	
liaise with mental health			Proactive service which initiates meetings between all professionals involved in care	Healthcare Professional	
Scheduling regular physicals	Appointments		Regularly schedule and monitor physical health	Healthcare Professional	
Not really. I think the healthcare visits frequency is far low.	Appointments		Regularly schedule and monitor physical health	Healthcare Professional	
Scheduling regular physicals and eye exams	Appointments		Regularly schedule and monitor physical health including eye exams	Healthcare Professional	
They should be constant communication between the patient and the medical personnel. A regular program for weight management should be given.	Diet/Nutrition	Weight Management	Offer weight management education and support	Healthcare Professional	
monitor their blood glucose , continuous education around healthy eating and understanding of what increases their blood sugar levels and could cause a drop in their blood sugar levels	Knowledge		Offer self-management education programmes and support	Healthcare Professional	BG monitoring covered in care processes
Mostly its the one on one information giving , having regular checks with a diabetic nurse Sometimes due to the waiting times, generally clients who have a severe mental illness find it a challenge to attend appointments so the longer the waiting time the more likely they would not attend the appointments .	Relationship	Service Provision	Conduct consultations which provide one on one information giving	Healthcare Professional	

Relationship between provider and service user	Relationship		Focus on the interaction between service user and healthcare professional e.g. to improve the interaction to ensure it is friendly, not disregarding fears and communication	Healthcare Professional	
Not disregarding clients fears not matter how silly it maybe	Relationship		Focus on the interaction between service user and healthcare professional e.g. to improve the interaction to ensure it is friendly, not disregarding fears and communication	Healthcare Professional	
Being closer to the patients and understanding them	Relationship		Focus on the interaction between service user and healthcare professional e.g. to improve the interaction to ensure it is friendly, not disregarding fears and communication	Healthcare Professional	
Talk positively to patients	Relationship		Healthcare professionals talk positively to service users	Healthcare Professional	
Self-management support	Self-Management		Offer self-management education programmes and support	Healthcare Professional	
The first step is to make the patient more confident that they can treat the disease and cooperate with the diet plan formulated by the doctor. Moreover, it is necessary to pay attention to the reasonable arrangement of work and rest time for patients, and to supervise and encourage them.	Self-Management		Provide consultations that empower the service user and make them feel confident in diabetes management	Healthcare Professional	
Attention should be paid to diabetes patients in daily life to avoid factors that increase blood sugar. Daily life, study, eating, activities, rest, sleep and other daily life should be regular, reasonable arrangement, timing and quantity.	Self-Management		Provide consultations which promote self-care and self-management focussing on the daily life of the individual	Healthcare Professional	
Promoting self-care. Keep your blood pressure in check often Scheduling regular physicals and eye exam	Self-Management		Provide consultations which promote self-care and self-management focussing on the daily life of the individual	Healthcare Professional	

For other Healthcare Professionals to understand deterioration in their clients . Be able to understand the basics of diabetes , also educate their clients about it	Self-management		Offer self-management education programmes and support	Healthcare Professional	Other aspects are underlying causes
Family	Social Support		Provide consultations which engage family members to support diabetes management	Healthcare Professional	
The family members of the patients should know as much as possible about the knowledge of diabetes, so as to help the patients better implement the treatment plan of diabetes.	Social Support		Provide consultations which engage family members to support diabetes management	Healthcare Professional	
Support from family	Social Support		Provide consultations which engage family members to support diabetes management	Healthcare Professional	
During The First treatment phase. I felt my family should have been closer to me	Time		Focus on the time of diagnosis as time to provide care	Healthcare Professional	
I felt psychologically disturbed and my family should have been closer than ever	Time		Use a proactive approach to care focussing on difficult times such as mental health breakdown	Healthcare Professional	
It was when her blood pressure shot too high and her eyes were having impaired vision.	Time		Use a proactive approach to diabetes care focussing on difficult times	Healthcare Professional	Covered by critical time list item
Nursing staff in the home should supervise the patient to carry on the regular daily life, the standard exercise and pay attention to personal hygiene, pay attention to keep warm, sleep enough.	Wellbeing		Regularly schedule and monitor physical health	Healthcare Professional	
making appointments on their own	Appointments		Make and attend appointments	Service User	
medication adherence	Care Process		Take medication as prescribed	Service User	
Keep your blood pressure and cholesterol under control	Care Process		Self-management	Service User	Not used as focussed on the individual (service user) ensuring their behaviours keep BP/C under control - not HCP behaviour
Avoid sugar sweetened beverages	Diet/Nutrition		Eat Healthily	Service User	
Eat healthy foods	Diet/Nutrition		Eat Healthily	Service User	
Avoid sugar sweetening	Diet/Nutrition		Eat Healthily	Service User	
Eating Habits	Diet/Nutrition		Eat Healthily	Service User	

Avoiding sugar sweetened beverages.	Diet/Nutrition		Eat Healthily	Service user	
Daily exercises	Exercise		Ensure frequent exercise	Service User	
Having physical exercise	Exercise		Ensure frequent exercise	Service User	
increase activity levels through private trainers	Exercise		Exercise regularly	Service User	Not included as addition to provision and not a specific behaviour
Do daily physicals and exercises	Exercise		Ensure frequent exercise	Service User	
Make a commitment to managing your diabetes	Goals		Make a commitment to self-management	Service User	
Meditation	Miscellaneous		Engage in self-management strategies	Service User	
Use hypoglycaemic drugs strictly according to the doctor's instructions and pay attention to the usage and incompatibility of the drugs. Sulfonylureas should be taken before meals, and metguanidines should be taken at meal time or after meals.	Miscellaneous		Take medication as prescribed	Service User	
Seek help	Seek Help		Seek help	Service User	
self-care	Self-Management		Engage in self-care	Service User	
attending appointments	Appointments		Make and attend appointments	Service User	
managing sugar intake i.e.. limiting sugar intake during the time they are well	Diet/Nutrition		Eat Healthily	Service User	
Engage with diabetes team	Relationship		Engage with diabetes team	Service User	
question do I have negative attitudes about mental illness, can I change them?	Attitudes				Not included as not a behaviour but an underlying cause - i.e. stigma
Educate yourself.	Knowledge				Not included as not a behaviour but an underlying cause - i.e. a lack of knowledge
better planning around treatment more awareness of diabetes and how this affects ones mental health more awareness in general	Knowledge				Not included as not a behaviour but an underlying cause - i.e. a lack of knowledge
Medical	Miscellaneous				Not included as not a behaviour
Timed resting moments	Miscellaneous				Not included as not a behaviour
Coming up with a routine to develop speech for mental patients	Miscellaneous				Not included as not relevant to T2D
Keep vaccines and medicines up to date	Miscellaneous				Not included as not relevant to T2D
Take your vaccines on time	Miscellaneous				Not included as not relevant to T2D

sticking to a plan	Miscellaneous				Not included as not clear what behaviour this relates to
Generally, improved care	Miscellaneous				Not included as not a behaviour
Practical	Miscellaneous				Not included as not a behaviour
Consistent	Miscellaneous				Not included as not a behaviour
Be persistent	Miscellaneous				Not included as not a behaviour
he got an accident on a bike and had severe cuts on the leg and bleeding could not stop.	Miscellaneous				Not included as not a behaviour
The care should be more serious to avoid stress to the victims	Miscellaneous				Not included as not a behaviour
Sleep	Miscellaneous				Not included as not relevant to T2D
No	N/A				N/A
No	N/A				N/A
No	N/A				N/A
Be willing to work ‘outside the box’.	Roles				Not included as not a behaviour but an underlying cause - i.e. roles/responsibilities
Making the services accessible and affordable.	Service Provision				Not included as not a behaviour
I think the care received in insufficient, much on visits frequency and emergency response. Need to improve on that.	Time		Regularly schedule and monitor physical health/ Use a proactive approach to care focussing on difficult times such as mental health breakdown		

Appendix 17: Study 3 (Prioritisation Delphi) – Responses to survey two

Service User/Carer Responses							
Behaviour	**Idea 1**	**Idea 2**	**Idea 3**	**Total Score**	**Total number of times selected**	**Percentage of participants with a top 3 ranking**	**Percentage of participants with a top 1 ranking**
Create a treatment plan collaboratively with the diabetes and mental health teams to ensure a focus on both	2	1	1	9	4	33.3%	16.7%
Provide individualised healthy eating plans which cover foods which should be eaten less frequently	1	2	1	8	4	33.3%	8.3%
Use a proactive approach to diabetes care focussing on difficult times such as mental health breakdown	1	2	1	8	4	33.3%	8.3%
Provide consultations which empower the service user and make them feel confident in diabetes management	1	1	1	6	3	25.0%	8.3%
Provide a guided, personalised exercise programme	1	0	2	5	3	25.0%	8.3%
Offer weight management education and support	0	1	1	3	2	16.7%	0.0%
Healthcare professionals talk positively to service users	1	0	0	3	1	8.3%	8.3%
Regularly assess cholesterol, blood pressure and medication	1	0	0	3	1	8.3%	8.3%
Focus on the time of diagnosis of diabetes to provide more intensive support	1	0	0	3	1	8.3%	8.3%
Ensure information provided in consultations is easy to understand and appropriate for the individual	1	0	0	3	1	8.3%	8.3%

Offer self-management education programmes and support	0	1	1	3	2	16.7%	0.0%
Provide consultations which provide one on one information giving	1	0	0	3	1	8.3%	8.3%
Regularly schedule and monitor physical health	1	0	0	3	1	8.3%	8.3%
Offer lifestyle modification education and support	0	0	2	2	2	16.7%	0.0%
Improve liaison/communication between all members of the care team	0	1	0	2	1	8.3%	0.0%
Set individual goals relevant to the service user	0	1	0	2	1	8.3%	0.0%
Offer mental health support to target comfort eating	0	1	0	2	1	8.3%	0.0%
Ensure discharge of individuals is not related to frustrations around poor engagement	0	1	0	2	1	8.3%	0.0%
Offer advice and guidance on emotional wellbeing	0	0	1	1	1	8.3%	0.0%
Provide consultations which engage family members to support diabetes management	0	0	1	1	1	8.3%	0.0%
Improve liaison between mental health care team and diabetes nurse	0	0	0	0	0	0.0%	0.0%
Ensure foot care is regularly and closely monitored	0	0	0	0	0	0.0%	0.0%
Healthcare professionals talk positively to service users	0	0	0	0	0	0.0%	0.0%
Provide consultations which promote self-care and self-management focussing on the daily life of the individual	0	0	0	0	0	0.0%	0.0%
Offer more intensive support at critical times of diabetes management - e.g. when continuous uncontrolled high blood sugar	0	0	0	0	0	0.0%	0.0%

Provide individualised healthy eating plans which cover foods which should be eaten less frequently	0	0	0	0	0	0.0%	0.0%
Total Check	**12**	**12**	**12**				
Number of individual ideas chosen	**19**	**63.3%**					
Number of individual ideas selected per participant	**1.6**						

Healthcare Professional							
Behaviour	**Idea 1**	**Idea 2**	**Idea 3**	**Total Score**	**Total number of times selected**	**Percentage of participants with a top 3 ranking**	**Percentage of participants with a top 1 ranking**
Improve liaison between mental health care team and diabetes nurse	2	0	0	6	2	29%	29%
Create a treatment plan collaboratively with the diabetes and mental health teams to ensure a focus on both	0	2	0	4	2	29%	0%
Use a proactive approach to diabetes care focussing on difficult times such as mental health breakdown	1	0	0	3	1	14%	14%
Focus on the time of diagnosis of diabetes to provide more intensive support	1	0	0	3	1	14%	14%
Offer lifestyle modification education and support	1	0	0	3	1	14%	14%
Set individual goals relevant to the service user	1	0	0	3	1	14%	14%
Provide consultations which promote self-care and self-management focussing on the daily life of the individual	0	1	1	3	2	29%	0%
Offer weight management education and support	0	1	0	2	1	14%	0%

Ensure information provided in consultations is easy to understand and appropriate for the individual	0	1	0	2	1	14%	0%
Ensure foot care is regularly and closely monitored	0	1	0	2	1	14%	0%
Provide consultations which empower the service user and make them feel confident in diabetes management	0	0	2	2	2	29%	0%
Provide consultations which engage family members to support diabetes management	0	0	1	1	1	14%	0%
Healthcare professionals talk positively to service users	0	0	1	1	1	14%	0%
Regularly schedule and monitor physical health	0	0	1	1	1	14%	0%
Offer more intensive support at critical times of diabetes management - e.g. when continuous uncontrolled high blood sugar	0	0	1	1	1	14%	0%
Provide individualised healthy eating plans which cover foods which should be eaten less frequently	0	0	0	0	0	0%	0%
Provide a guided, personalised exercise programme	0	0	0	0	0	0%	0%
Healthcare professionals talk positively to service users	0	0	0	0	0	0%	0%
Regularly assess cholesterol, blood pressure and medication	0	0	0	0	0	0%	0%
Improve liaison/communication between all members of the care team	0	0	0	0	0	0%	0%
Provide individualised healthy eating plans which cover foods which should be eaten less frequently	0	0	0	0	0	0%	0%
Offer self-management education programmes and support	0	0	0	0	0	0%	0%
Offer mental health support to target comfort eating	0	0	0	0	0	0%	0%

Offer advice and guidance on emotional wellbeing	0	0	0	0	0	0%	0%
Provide consultations which provide one on one information giving	0	0	0	0	0	0%	0%
Ensure discharge of individuals is not related to frustrations around poor engagement	0	0	0	0	0	0%	0%
Set goals for the individual as a whole care team (i.e., physical, and mental health professionals)	1	0	0	3	1	14%	14%
Improve liaison/communication between all members of the care team (i.e., physical and mental health professionals	0	1	0	2	1	14%	0%
Total Check	**7**	**7**	**7**				
Number of individual ideas chosen	**15**	**50%**					
Number of individual ideas selected per participant	**2.14**						

TOTAL							
Behaviour	**Idea 1**	**Idea 2**	**Idea 3**	**Total Score**	**Total number of times selected**	**Percentage of participants with a top 3 ranking**	**Percentage of participants with a top 1 ranking**
Create a treatment plan collaboratively with the diabetes and mental health teams to ensure a focus on both	2	3	1	13	6	31.6%	33.3%
Use a proactive approach to diabetes care focussing on difficult times such as mental health breakdown	2	2	1	11	5	26.3%	40.0%

Provide individualised healthy eating plans which cover foods which should be eaten less frequently	1	2	1	8	4	21.1%	25.0%
Provide consultations which empower the service user and make them feel confident in diabetes management	1	1	3	8	5	26.3%	20.0%
Focus on the time of diagnosis of diabetes to provide more intensive support	2	0	0	6	2	10.5%	100.0%
Improve liaison between mental health care team and diabetes nurse	2	0	0	6	2	10.5%	100.0%
Provide a guided, personalised exercise programme	1	0	2	5	3	15.8%	33.3%
Offer weight management education and support	0	2	1	5	3	15.8%	0.0%
Ensure information provided in consultations is easy to understand and appropriate for the individual	1	1	0	5	2	10.5%	50.0%
Offer lifestyle modification education and support	1	0	2	5	3	15.8%	33.3%
Set individual goals relevant to the service user	1	1	0	5	2	10.5%	50.0%
Regularly schedule and monitor physical health	1	0	1	4	2	10.5%	50.0%
Healthcare professionals talk positively to service users	1	0	0	3	1	5.3%	100.0%
Regularly assess cholesterol, blood pressure and medication	1	0	0	3	1	5.3%	100.0%
Offer self-management education programmes and support	0	1	1	3	2	10.5%	0.0%
Provide consultations which provide one on one information giving	1	0	0	3	1	5.3%	100.0%
Provide consultations which promote self-care and self-management focussing on the daily life of the individual	0	1	1	3	2	10.5%	0.0%

Improve liaison/communication between all members of the care team	0	1	0	2	1	5.3%	0.0%
Offer mental health support to target comfort eating	0	1	0	2	1	5.3%	0.0%
Provide consultations which engage family members to support diabetes management	0	0	2	2	2	10.5%	0.0%
Ensure foot care is regularly and closely monitored	0	1	0	2	1	5.3%	0.0%
Ensure discharge of individuals is not related to frustrations around poor engagement	0	1	0	2	1	5.3%	0.0%
Offer advice and guidance on emotional wellbeing	0	0	1	1	1	5.3%	0.0%
Healthcare professionals talk positively to service users	0	0	1	1	1	5.3%	0.0%
Offer more intensive support at critical times of diabetes management - e.g., when continuous uncontrolled high blood sugar	0	0	1	1	1	5.3%	0.0%
Set goals for the individual as a whole care team (i.e., physical, and mental health professionals)	1	0	0	3	1	5.3%	100.0%
Improve liaison/communication between all members of the care team (i.e. physical and mental health professionals	0	1	0	2	1	5.3%	0.0%
Total	**19**	**19**	**19**				
Number of Individual Ideas	**27**	**90%**					
Number of individual ideas selected per participant	**1.4**						
Number one ideas	**15**						

Appendix 18: Study 4 (Interview Study) – Participant Information Sheet and Informed Consent Form

Chief Investigator: [redacted]

PhD Student: Tracey Dorey –[redacted]k

The Supporting Diabetes Care Study:

Designing an Intervention to Support Mental and Physical Health Professionals to Deliver Type II Diabetes Mellitus Care for People with Severe Mental Illness

Exploring the barriers and enablers of Type 2 diabetes care for people experiencing a relapse of their severe mental illness

Invitation

We would like to invite you to take part in a research study. Before you decide whether you would like to take part it is important that you understand why the research is being done and what it would involve for you. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. You will be given a copy of this information sheet to keep.

If anything is not clear and you would like some more information, please contact the PhD Student Researcher Tracey Dorey or Chief Investigator on the above details.

What is the purpose of the study?

Individuals with a severe mental illness have a two to threefold increased risk of developing Type 2 diabetes mellitus (T2DM) and suffer greater risk of complications, as well as increased emergency appointments, hospitalisation, and mortality.

Acknowledging this inequality, the study forms part of a PhD research project that aims to help us to provide better care by developing the approaches that healthcare professionals use to manage T2DM in people with a severe mental illness (SMI).

Managing T2DM at times of mental health breakdown has been identified by the Online Expert Panel. The panel consists of both service users and service providers. They believe that targeting T2DM at this challenging time is one approach to reducing the inequalities faced by people with T2DM and an SMI.

We would like to better understand factors that impact T2DM care when people are also facing a mental health breakdown.

What do we mean by SMI?

For this study we use the term SMI to include individuals who have been diagnosed with schizophrenia, bipolar or other psychoses, such as depression with psychosis.

What does taking part involve?

You are invited to participate in an interview, which should take no longer than 20 - 45 minutes to complete. The interview will be undertaken remotely using Microsoft Teams and at a time convenient for you.

You will be asked about your experience of providing care, or the provision of care by others, for people with an SMI who are experiencing a relapse of their SMI. Please be assured, there are no right or wrong answers, we really want to hear about your experience and opinions.

We will ask you for your ethnicity, this data is classed as Special Category Data. We ask for this information, alongside others such as your age etc, to provide a summary of the individuals who participate in the study.

Why have I been invited to take part?

You have been invited to participate as you are a professional working within, or who has worked in, the NHS who has experience of providing care to individuals who have an SMI and may also have T2DM.

Do I have to take part?

No, it is up to you to decide whether to take part. You can stop being part of the study at any time. You are free to ask for withdrawal of your data at any time up to 1 month after your interview is completed.

What are the possible benefits of taking part?

There are no direct benefits to healthcare professionals in the participating in this study, however it offers you the opportunity to provide your experience and expertise to supporting the development of approaches used by healthcare professionals. This study aims to contribute to the ongoing process of improving outcomes for people with T2DM and an SMI.

What are the possible disadvantages or risks of taking part?

There are no obvious disadvantages or risks to participating in this study, if however, you find participation difficult please stop and withdraw at any time.

How is the project being funded?

The study is part of a funded PhD studentship by East London NHS Foundation Trust.

Data Privacy

City, University of London is the data controller for the personal data collected for this research project. Your personal data will be processed for the purposes outlined in this notice. The legal basis for processing your personal data will be that this research is a task in the public interest, that is City, University of London considers the lawful basis for processing personal data to fall under Article 6(1)(e) of GDPR (public task) as the processing of research participant data is necessary for learning and teaching purposes and all research with human participants by staff and students has to be scrutinised and approved by one of City's Research Ethics Committees.

Further, City considers the processing of special category personal data will fall under Article 9(2)(g) of the GDPR as the processing of special category data has to be for the public interest in order to receive research ethics approval and occurs on the basis of law that is, inter alia, proportionate to the aim pursued and protects the rights of data subjects.

The rights you have under the data protection legislation are listed below, but not all of the rights will be apply to the personal data collected in each research project.

- right to be informed
- right of access
- right to rectification
- right to erasure
- right to restrict processing
- right to object to data processing
- right to data portability
- right to object
- rights in relation to automated decision making and profiling

For more information, please visit www.city.ac.uk/about/city-information/legal

What if I have concerns about how my personal data will be used after I have participated in the research?

In the first instance you should raise any concerns with the research team, but if you are dissatisfied with the response, you may contact the Information Compliance Team at dataprotection@city.ac.uk or phone 0207 040 4000, who will liaise with City's Data Protection Officer Dr William Jordan to answer your query.

If you are dissatisfied with City's response you may also complain to the Information Commissioner's Office at www.ico.org.uk

Will the information I give in this study be kept confidential?

Yes, confidentiality will be ensured as each participant will be provided with a unique identifier. This will be used to identify your data. The personal information you provide, such as your age, gender and role, will be stored separately from the data you provide.

Your participation in the study will only be known to the research team. When any information is presented you will not be identifiable as the information you provide about yourself will be used only to provide a summary of the participants in the study. Any further data you provide will not be identifiable as they will be presented anonymously

Whilst I have a duty not to disclose confidential information, there are some circumstances where this may not be possible. For example, if the information disclosed suggests risk of harm to yourself and/or others. If this occurs, every effort will be made to discuss the importance of disclosure with you and encourage it.

Personal data (the audio-file) will be accessible to the PhD student, supervisors and a third party (Essential Secretary) for transcription. City, acting as the data controllers have a GDPR compliant contract with Essential Secretary as they may process personal data, depending on what is discussed within the interviews. Transfer of the files is subject to protected and encrypted transfer system; all files are password protected and upon completion of transcription all files are removed from the third-party system.

The transcripts will be reviewed and any identifiable data removed. Anonymised verbatim quotes from the interview will be used as part of the research findings in the final written thesis and may be published, however these will not be identifiable to you.

The audio files and interview transcripts will be retained by the PhD student and stored on a password protected folder in the OneDrive storage system. City ensures that its IT systems and those of approved third parties met the security requirements of the data protection legislation.

All data will be stored electronically in a password protected file and only accessible to the research team. This information is stored within the OneDrive account, which is held on the City, University of London's IT system. City ensures that its IT systems meet the security requirements of the data protection legislation. It will be stored for 10 years after which it will be destroyed. Destruction will be completed following the procedures outlined by City, University of London.

What if there is a problem?

If you have any concerns or complaints about anything to do with this study, please speak to the researcher or chief investigator and we will do our best to answer your questions. You can email us on the details above.

What will happen to the results of the study?

The information you provide will support the development of approaches that healthcare professionals use to manage T2DM in people with an SMI. The data collected will be written up as part of the PhD student's thesis and may presented at conferences of published in peer-reviewed journals. None of the data published will be identifiable.

Who has reviewed the study?

This study has been approved by City, University of London School of Health Sciences Research Ethics Committee as well as The Health Research Authority.

What if there is a problem?

If you have any concerns or complaints about anything to do with this study, please speak to Tracey Dorey or the chief investigator and we will do our best to answer your questions. You can email us on the details above.

If you remain unhappy and wish to complain formally, you can do this through City's complaints procedure. To complain about the study, you can either phone 020 7040 3040 and ask to speak to the Secretary to Senate Research Ethics Committee or email SenateREC@city.ac.uk and inform them that the name of the project is The Supporting Diabetes Care Study.

Can I get more information?

If you are interested in taking part in this study but would like some more information before you decide, please contact me on the above email address.

If I decide to take part what do I do now?

If you do decide to take part in this study, thank you very much. To participate you need to complete the following Informed Consent Form. You need to initial all the statements if you wish to participate and return this to Tracey Dorey ([redacted].

Following this a convenient date and time for the interview will be arranged. If you have any questions about any of the statements on the Informed Consent Form, or any aspect of the study, please contact Tracey Dorey.

Thank you for taking the time to read this information sheet.

The Supporting Diabetes Care Study

Exploring the barriers and enablers of Type 2 diabetes care for people experiencing a relapse of their severe mental illness

Name of Principal Investigator/Researcher: Dr Kathleen Mulligan & Mrs Tracey Dorey

[redacted]

Initial Here

1	I confirm that I have read and understood the participant information dated 4.0 (August 2022) for the above study	
2	This information will be held by City as data controller and processed for the purposes explained in the end note*	
3	I agree to City recording and processing this information about me. I understand that this information will be used only for the purpose(s) explained in the	

	participant information and my consent is conditional on City complying with its duties and obligations under the General Data Protection Regulation (GDPR).	
4	I have had the opportunity to consider the information and ask questions, which have been answered satisfactorily	
5	I understand that my participation is voluntary and that I am free to withdraw without giving a reason without being penalised or disadvantaged	
6	I understand that any information I provide is confidential, and that no information that could lead to the identification of any individual will be disclosed in any reports on the project, or to any other party. No identifiable personal data will be published. The identifiable data will not be shared with any other organisation.	
7	I agree to the arrangements for data storage, archiving and sharing	
8	I understand that my responses, although anonymous, will be available through an online repository for Theses, it may also be published in peer-reviewed journals	
9	I agree to the interview being audio recorded	
10	I understand that the interview will be transcribed by an external company (Essential Secretary	
11	I understand that my anonymous data will be made open access in the form of direct quotes	
12	I have read and understand the above statements	
13	I agree to take part in this study	

______________________ ______________________________ ______________

Name of Participant Signature Date

______________________ ______________________________ ______________

Name of Researcher Signature Date

When completed, 1 copy for the participant, 1 copy for the researcher file (Stored electronically)

**Public Task: The legal basis for processing your personal data will be that this research is a task in the public interest, that is City, University of London considers the lawful basis for processing personal data to fall under Article 6(1)(e) of GDPR (public task) as the processing of research participant data is necessary for learning and teaching purposes and all research with human participants by staff and students has to be scrutinised and approved by one of City's Research Ethics Committees*

I understand that the following special category data will be collected and retained as part of this research study: ethnicity. City considers the processing of special category personal data will fall under: Article 9(2)(g) of the GDPR as the processing of special category data has to be for the public interest in order to receive research ethics approval and occurs on the basis of law that is, inter alia, proportionate to the aim pursued and protects the rights of data subjects and also under Article 9(2)(a) of the GDPR as the provision of these personal data is completely voluntary.

Appendix 19: Study 4 (Interview Study) – Interview Schedule

Introduction: Thank you for agreeing to take part in this interview. I am conducting this study to help us understand how diabetes is managed in people with severe mental illness when experiencing mental health relapse. By this I mean an exacerbation of mental health symptoms that have been reported, in previous studies, to make management of diabetes more challenging - all questions are referring specifically to this timepoint.

I'm interviewing health professionals across several different specialties so while you may care for many other groups of patients, I'd like to focus on the care of people who have both diabetes and SMI. I'll start by asking some general questions before focussing on more specific aspects of T2D care. Are you happy to get started?

Questions:

1. I'd like to start by asking how much of your work involves looking after people with diabetes and SMI?
2. How many of your patients do you think have diabetes and an SMI?
3. Have you supported service users who have experienced a relapse which has impacted their T2D? Can you tell me about what happened? If not, do you think relapse could impact T2D in your patients?

The following questions are asking more specifically about HbA1C monitoring, lifestyle (diet/exercise, alcohol, smoking) advice and goals, and referrals to appropriate other services (GP/Diabetes Team) where needed. When answering these consider them either as something you do or hypothetically…

1. Are these specific tasks something you carry out at a time of relapse? If not, who does/would?
2. Is continued management of T2D considered when you're supporting someone with a relapse? If so, what happens? If not, why?
3. Is this something you do personally or is it part of routine care? If not, should it be?
4. When a service user comes to you when beginning to experience a relapse is continued management of T2D important to you? Why?

5. Are aspects of monitoring and managing this more challenging? Is there something about these tasks or relapse in particular that you think affects this, or a combination of these particular tasks and relapse i.e. would other tasks or at another time make a difference?
6. How would you/do you approach these tasks when supporting someone experiencing relapse?
7. What does/would help you to undertake these tasks? Tell me more about…..
   PROMPT: Discuss each task separately/consider the TDF domains when prompting
8. What does/would make it more difficult? Tell me more about….

Close: That's all the questions I have for you, has anything occurred to you about this topic during the interview that we haven't discussed?

Thank you for taking part.

Appendix 20: Study 4 (Interview Study) – Deductive Codebook

Domain names and constructs taken from Cane et al. 2012

Domains ***Constructs***	**Coding Rules**
Knowledge: awareness of the existence of something *Knowledge of condition/scientific rationale, procedural knowledge and knowledge of task environment*	• Knowledge of interconnection between T2D/SMI - generally but also relapse and the impact on T2D • Relapse and impact on T2D (including self-management) and the need for • Awareness of guidance for lifestyle advice (NICE) • BGM level knowledge • Knowledge of referral services • Conflict between guidance and practice • Procedural knowledge "We do X then Y" • Training being mentioned without details of how and the transfer of knowledge shouldn't be coded as "knowledge" • Descriptions of hypothetical behaviour should be considered for coding as "Intentions"
Skills: ability or proficiency acquired through practice *Skill development, competence, ability, interpersonal skills, practice and skill assessment*	• The need for *special/additional* skills to provide T2D care to people with SMI • Additional training need specifically outlining skill development/assessment • Competence and ability regarding T2D care – blood glucose monitoring, lifestyle advice • Repeated practicing of skills (where saying "I am good at blood taking" consider if "Belief about Capabilities" as about confidence not necessarily skill development • Skills for motivation/language etc. (interpersonal skills) and the ability to support engagement with lifestyle services
Social professional role and identity: a coherent set of behaviours and displayed personal qualities of an individual in a social or work setting	• Feelings of professional responsibility for diabetes care (outcomes) and/or mental health – either jointly or separate • Belief about certain aspects of care belonging to different professions • Boundaries around specific aspects of T2D care • Shared care with other providers

Professional identity, professional role, social identity, identity, professional boundaries, professional confidence, group identity, leadership, organisational commitment	- Not about relationships, more specific about *what* someone is doing - Organisational commitment to physical health monitoring
Beliefs about capabilities: acceptance of the truth/reality about or validity of an ability, talent or facility that a person can put to constructive use *Self-confidence, perceived confidence, self-efficacy, perceived behavioural control, beliefs, self-esteem, empowerment, professional confidence*	- HCPs having confidence in their ability to provide T2D lifestyle advice, take bloods, blood glucose monitoring - Description of how easy/difficult it would be to carry out the behaviours - Capabilities of the professional and not the service user – consider Beliefs about Consequences or Social Influence
Optimism: confidence that things will happen for the best or that desired goals will be attained Optimism, pessimism, unrealistic optimism, identity	- Optimism about T2D health outcomes of those with SMI - Optimism that the interventions (lifestyle, BGM, referrals) are of benefit/will work
Beliefs about consequences*:* acceptance of the truth/reality about or validity of outcomes of a behaviour in a given situation *Beliefs, outcome expectancies, characteristics of outcome expectancies, anticipated regret, consequents*	- Consequences of not providing T2D care during relapse – for self or service user - Impact of relapse on T2D management or vice versa - Both positive and negative consequences - Providing advice at the right time to garner positive and realistic outcomes - Relapse intensity and impact on behaviour – outcome expectancies? - Consequence of medication for mental illness impacting diabetes (enabler of care- monitoring, not intervention) is not a target behaviour (I.e. medication management) so code as ECR

Reinforcement: *increasing the probability of a response by arranging a dependent relationship, or contingency, between the response and a given stimulus* *Rewards (proximal/distal, valued/not valued, probable/improbable), incentives, punishment, consequents, reinforcement, contingencies, sanctions*	• Expectation of discipline if not managing T2D in those with SMI, or reward if done so • Can include verbal praise from colleagues, senior management etc (social reward)
Intentions: conscious decision to perform a behaviour or a resolve to act in a certain way *Stability of intentions, stages of change, TTM*	• Intention to provide T2D care during relapse, specifically take bloods, act on blood results, refer to services, provide lifestyle advice and goals • Use of I will, I would or I always • Must have explicit description of personal intent, motivation or inclination. • Not about an "end point" which would be more goals
Goals*:* mental representation of outcomes or end states that an individual wants to achieve *Distal/Proximal goals, goal priority, goal/target setting, autonomous controlled goals, action planning, implementation intention*	• Importance of managing T2D during relapse (prioritisation) • Reaching an end point (goal) with the behaviours I.e. avoiding crisis, becoming mentally well, going back to green, avoiding diabetes complications, stability with diabetes • Goal conflict – mental health outcomes versus diabetes – must be outcome or end point focussed
Memory attention decision processes*:* ability to retain information, focus selectively on aspects of the environment and choose between two or more alternatives	• When/why behaviours are easy to forget • Decisions related to behaviours • T2D care during relapse is part of my routine • Tailoring of lifestyle interventions during relapse – to the individual • Focussing attention on specific behaviours – not exercise • Cognitive overload making decisions difficult or affecting ability to retain information - i.e. so much to think about can't remember

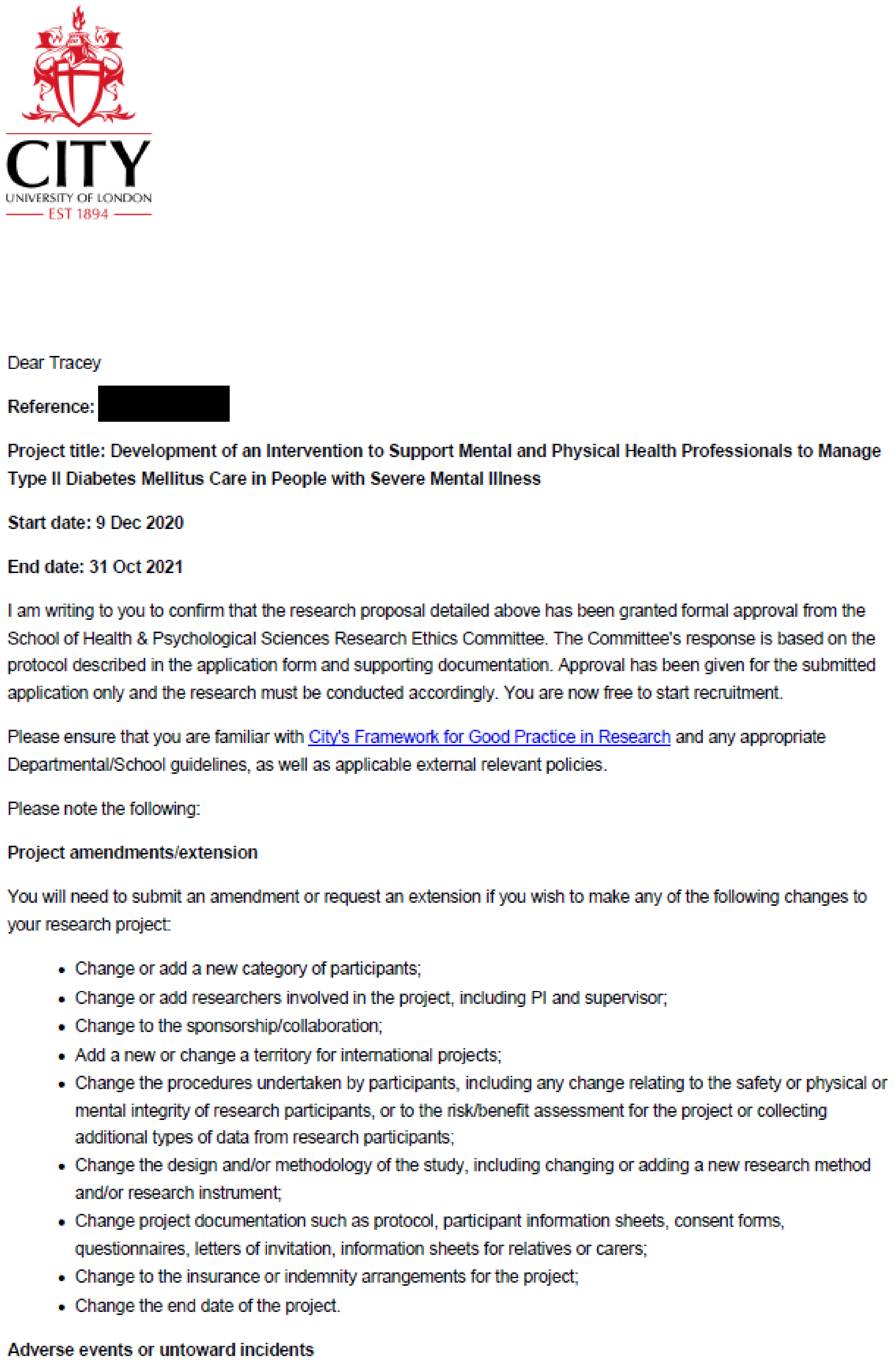
Memory, attention, attention control, decision making, cognitive overload,	- Consideration of other options and impact on decisions is important
Environmental context and resources: any circumstances of a person's situation or environment that discourages or encourages the development of skills and abilities, independence, social competence, and adaptive behaviour *Environmental stressors, Resources/material resources, organisation culture/climate, salient events/critical incidents, person x environment interaction, barriers and facilitators*	- IT system integration to improve ability to provide care – access to other staff and sharing of information - Having access to other professions to support care (used as a resource) - must be explicit in how this impacts behaviour not just role description/boundaries which more likely is Social/Professional Role and Identity - Insufficient time (resource) to carry out behaviours affected by workload for example - Availability of training (resource) - not available to them to develop skills (must be explicit in the discussion of availability of training or lack of it) - Availability of equipment to carry out behaviours – clinic space, scales etc. - Aspects of relapse (I.e. intensity) that influence whether behaviours are carried out (may also be Beliefs about Consequences) - If focus is more on how environmental factors affect decision making (explicit) then code at Memory, Attention and Decision Making. If not explicit then code at ECR
Social influences: interpersonal processes that can cause an individual to change their thoughts, feeling or behaviours. *Social pressure, social norms, group conformity, social comparison, group norms, social support, power, intergroup conflict, alienation group identity, modelling*	- Access to diabetes care team and their support in providing support for these behaviours during relapse – must be state how the social interaction affects behaviour. - Input from family/friends/carers (I.e. discussions about relapse or diabetes management) that influence behaviours - Team wide patterns of thought related to the behaviour (social norm) - Need to focus on the *interaction* between people and not merely presence/absence of a person (resource so more likely ECR) or role requirements (SPRI) affecting behaviour
Emotion: *a complex reaction pattern, involving experiential, behavioural and physiological elements, by which the individual attempts to deal with a personally significant matter or event*	- Negative emotions e.g. worry, fear, apprehension, frustration or positive e.g. joy, happiness etc. which affects behaviours at times of relapse - *Intense* verbal responses "No" to questions about behaviours - Must be professional emotion and not service user emotion and the effect on behaviours (SPRI) - unless explicit that the emotion of service user affects emotional state of professional which in turn affects behaviour

Fear, anxiety, affect, stress, depression, positive/negative affect, burn-out	
Behavioural regulation: anything aimed at managing or changing objectively observed or measured actions *Self-monitoring, breaking habit, action planning*	• Specific plans (Care Plan) or measures to guide management of T2D care at times of relapse • Must be clear that the outcome of plan/self-monitoring etc results in measurable (objective) outcomes for behaviours. If not explicit in how plans/strategies will lead to measurable outcomes, then consider Intentions and/or Beliefs about Consequences

Appendix 21: Study 4 (Interview Study) – Inductive Codebook

Theme	Codes
T2D is serious but it's never my problem	Awareness Causation Empowerment of service users Physical health generally Contracts Disconnection

Appendix 22: Study 4 (Interview Study) – Amendment 1 School of Health Sciences Ethical Approval



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Dear Tracey

Reference: [redacted]

Project title: Development of an Intervention to Support Mental and Physical Health Professionals to Manage Type II Diabetes Mellitus Care in People with Severe Mental Illness

Start date: 9 Dec 2020

End date: 31 Oct 2021

I am writing to you to confirm that the research proposal detailed above has been granted formal approval from the School of Health & Psychological Sciences Research Ethics Committee. The Committee's response is based on the protocol described in the application form and supporting documentation. Approval has been given for the submitted application only and the research must be conducted accordingly. You are now free to start recruitment.

Please ensure that you are familiar with City's Framework for Good Practice in Research and any appropriate Departmental/School guidelines, as well as applicable external relevant policies.

Please note the following:

Project amendments/extension

You will need to submit an amendment or request an extension if you wish to make any of the following changes to your research project:

- Change or add a new category of participants;
- Change or add researchers involved in the project, including PI and supervisor;
- Change to the sponsorship/collaboration;
- Add a new or change a territory for international projects;
- Change the procedures undertaken by participants, including any change relating to the safety or physical or mental integrity of research participants, or to the risk/benefit assessment for the project or collecting additional types of data from research participants;
- Change the design and/or methodology of the study, including changing or adding a new research method and/or research instrument;
- Change project documentation such as protocol, participant information sheets, consent forms, questionnaires, letters of invitation, information sheets for relatives or carers;
- Change to the insurance or indemnity arrangements for the project;
- Change the end date of the project.

Adverse events or untoward incidents

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You will need to submit an Adverse Events or Untoward Incidents report in the event of any of the following:

a) Adverse events

b) Breaches of confidentiality

c) Safeguarding issues relating to children or vulnerable adults

d) Incidents that affect the personal safety of a participant or researcher

Issues a) and b) should be reported as soon as possible and no later than five days after the event. Issues c) and d) should be reported immediately. Where appropriate, the researcher should also report adverse events to other relevant institutions, such as the police or social services.

Should you have any further queries relating to this matter, please do not hesitate to contact me. On behalf of the School of Health & Psychological Sciences Research Ethics Committee, I do hope that the project meets with success.

Kind regards

Alison Welton

School of Health & Psychological Sciences Research Ethics Committee

City, University of London

Appendix 23: Study 4 (Interview Study) – Amendment 1 HRA Approval

[redacted]

Appendix 24: Study 4 (Interview Study) – Amendment 1 Confirmation ongoing Capability and Capability

[redacted]

Appendix 25: Study 4 (Interview Study) Analysis of domains identified as of low importance

Beliefs about capabilities

Confidence in abilities was described at the team level, having confidence in discussing T2D with service users, but also generally in terms of confidence in working with individuals who have an SMI. This was referenced when discussing taking bloods which was impacted by experience:

> Oh easier, it's all about having the confidence and putting your mind to it, [yes] I don't think there's anything difficult in it, [brilliant] anybody can do it, [yes] you have to have passion for it, [got you] to be able to do it, [yes]. Especially the bloods, taking the blood can be very challenging for some people, because I've been in care for about 11 to 12 years now that I've been doing care, so I'm used to it, so for somebody coming new, [yes] they may find the blood challenging. (Participant no)

Optimism

Exercise, for some service users, was described as "*something individuals would not be able to do*" (Participant 01) during relapse and therefore this lack of optimism about the ability of service user's ability created a barrier to provision. If however there was a clear statement of the need for exercise during relapse in the care plan, or exercise was a known part of their lifestyle e.g. getting back to a known form of exercise, then a lack of optimism was less of a barrier to provision.

Intention

Intention to ask about T2D was only explicitly discussed by one participant (P03) with the main intention being to understand what problems in lifestyle reflect in the mental illness.

How is this an outward reflection on their mental state and not with the intention of addressing the lifestyle issue.

Emotion

The perceived limited control that health professionals have for creating lifestyle change, even with the provision of appropriate advice, can be exasperating creating a barrier to provision. During relapse this can be manifested through the negative symptoms of psychosis (e.g. low mood, motivation) that can impact ability to change but also the involvement of others in food provision:

> *INT: So, yeah, they're. I imagine. Do you feel? There's not a lot you can do in that situation is there?*
>
> *RES: No.*
>
> *INT: It's like that food is being provided by someone else and it's, that's, yeah, that's.*
>
> *RES: Or they can't afford food. So, I've got a lot of people going to food banks and having, just eating what they're given.*

Behavioural regulation

Care plans and NICE guidance are utilised as forms of behavioural regulation, providing guidance and observable behaviour guidance. If T2D care (including exercise) is detailed in the care plan it was an enabler of provision, even during relapse.

Appendix 26: Study 5 (Intervention Design Delphi) – Participant Information Sheet and Informed Consent Form

Chief Investigator: Dr Kathleen Mulligan – [redacted]

PhD Student: Tracey Dorey – [redacted]

The Supporting Diabetes Care Study:

Designing an Intervention to Support Mental and Physical Health Professionals to Deliver Type II Diabetes Mellitus Care for People with Severe Mental Illness

Online Expert Panel

Invitation

We would like to invite you to take part in a research study. Before you decide whether you would like to take part it is important that you understand why the research is being done and what it would involve for you. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is Not clear or if you would like more information. You will be given a copy of this information sheet to keep.

If anything is Not clear and you would like some more information, please contact Tracey Dorey or the Chief Investigator on the above details.

What is the purpose of the study?

Individuals with a severe mental illness (SMI) have a two to threefold increased risk of developing type 2 diabetes (T2DM) and suffer greater risk of complications, as well as increased emergency appointments, hospitalisation and mortality

Acknowledging this inequality, the study forms part of a PhD research project that aims to help us to provide better care by developing the approaches that healthcare professionals use to manage T2DM in people with an SMI.

What do we mean by SMI?

For this study we use the term SMI to include individuals who have been diagnosed with schizophrenia, bipolar or other psychoses, such as depression with psychosis.

What does taking part involve?

You are invited to be a member of the **Online Expert Panel**. The panel for this questionnaire will consist of 8 health care professionals e.g. individuals from general, diabetes, and mental health specialities.

As a member of the Online Expert Panel, we would like you to respond to an online questionnaire. The questionnaire is split in two and will involve you contributing some ideas and subsequently considering how much you agree (or disagree) with the ideas of others on the panel. The questionnaire will focus how we can take the ideas generated by the Online Expert Panel previously and bring them to life in your context. All parts of the questionnaire are anonymous so nobody will be able to tell which responses belong to which panel member.

The questionnaires can be completed individually at a time convenient to you on a PC, laptop, tablet or phone. The first questionnaire should take you X longer than 15-minutes to complete and the second X longer than 10-minutes. Your responses do Not have to be provided in one go; you can return to each questionnaire as many times as you wish for a two-week period before submitting it.

We will ask you for your ethnicity, this data is classed as Special Category Data. We ask for this information, alongside others such as your age etc, to provide a summary of the individuals who participate in the study.

Why have I been invited to take part?

You have been invited to take part as you have experiences and expertise that will be important in ensuring any ideas generated are suitable for the healthcare context.

Do I have to take part?

X, it is up to you to decide whether to take part. If you decide to participate you will be asked to complete a consent form. You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

If you choose to withdraw during the study, it would be greatly appreciated if you could provide a suitable replacement e.g. a fellow health care professional in the same role as you.

What are the possible benefits of taking part?

Participating in this study offers you the opportunity to provide your experience and expertise to supporting the development of approaches used by healthcare professionals. This study aims to contribute to the ongoing process of improving outcomes for people with T2DM and an SMI.

What are the possible disadvantages or risks of taking part?

There are X obvious disadvantages or risks to participating in this study, if however, you find participation difficult you are free to withdraw at any time.

Whilst it is hoped that the content of this study will Not cause you upset should you find yourself experiencing distress during your participation there are a number or organisations you can contact including Samaritans. They can be contacted on 116 123 for free or you can write an email to jo@samaritans.org (they aim to respond to emails within 24-hours). You may also find it useful to identify someone you can speak to, prior to participation, should you become upset such as a friend, family member, colleague or mentor.

How is the project being funded?

The study is part of a funded PhD studentship by East London NHS Foundation Trust.

Data Privacy

.

City, University of London is the data controller for the personal data collected for this research project. Your personal data will be processed for the purposes outlined in this Notice. The legal basis for processing your personal data will be that this research is a task in the public interest, that is City, University of London considers the lawful basis for processing personal data to fall under Article 6(1)(e) of GDPR (public task) as the processing of research participant data is necessary for learning and teaching purposes and all research with human participants by staff and students has to be scrutinised and approved by one of City's Research Ethics Committees.

Further, City considers the processing of special category personal data will fall under Article 9(2)(g) of the GDPR as the processing of special category data has to be for the public interest in order to receive research ethics approval and occurs on the basis of law that is, inter alia, proportionate to the aim pursued and protects the rights of data subjects.

The rights you have under the data protection legislation are listed below, but Not all of the rights will be apply to the personal data collected in each research project.

- right to be informed
- right of access
- right to rectification
- right to erasure
- right to restrict processing
- right to object to data processing
- right to data portability
- right to object
- rights in relation to automated decision making and profiling

For more information, please visit www.city.ac.uk/about/city-information/legal

What if I have concerns about how my personal data will be used after I have participated in the research?

In the first instance you should raise any concerns with the research team, but if you are dissatisfied with the response, you may contact the Information Compliance Team at dataprotection@city.ac.uk or phone 0207 040 4000, who will liaise with City's Data Protection Officer Dr William Jordan to answer your query.

If you are dissatisfied with City's response you may also complain to the Information Commissioner's Office at www.ico.org.uk

Will the information I give in this study be kept confidential?

P, confidentiality will be ensured as be provided with a unique identifier. This will be used to identify your data. The personal information you provide, such as your age, gender and role, will be stored separately from the data you provide.

Your participation in the study will only be known to the research team. When any information is presented you will Not be identifiable as the information you provide about yourself will be used only to provide a summary of the participants in the study. Any further data you provide, for example your ideas, will Not be identifiable as they will be presented anonymously.

The electronic survey tool, Qualtrics, is being used to obtain and store the research data. City has put in place an agreement with Qualtrics, which sets out rights and responsibilities for both organisations with regards to personal data – how it is processed, who owns and has access to the data, security arrangements and where it is stored. City insists that the personal data is held within the European Economic Area (EEA) and Not in the USA. Whilst the agreement has been set up to protect personal data, it also affords the information governance protection required for all research data.

There will be some free text options within the questionnaire; to ensure your anonymity please do Not disclose any additional sensitive or personal data. Whilst I have a duty Not to disclose confidential information, there are some circumstances where this may Not be possible. For example, if the information disclosed suggests risk of harm to yourself and/or others. If this occurs, every effort will be made to discuss the importance of disclosure with you and encourage it.

All data will be stored electronically in a password protected file and only accessible to the research team. This information is stored within the OneDrive account, which is held on the City, University of London's IT system. City ensures that its IT systems meet the security requirements of the data protection legislation. It will be stored for 10 years after which it will be destroyed. Destruction will be completed following the procedures outlined by City, University of London.

What will happen to the results of the study?

The data collected will be written up as part of the PhD student's thesis and may be presented at conferences and published in peer-reviewed journals. None of the data published will identify you.

Who has reviewed the study?

This study has been approved by City, University of London, School of Health Sciences Research Ethics Committee as well as The Health Research Authority.

What if there is a problem?

If you have any concerns or complaints about anything to do with this study, please speak to Tracey Dorey or the chief investigator and we will do our best to answer your questions. You can email us on the details above.

If you remain unhappy and wish to complain formally, you can do this through City's complaints procedure. To complain about the study, you need to phone 020 7040 3040. You can then ask to speak to the Secretary to Senate Research Ethics Committee and inform them that the name of the project is The Supporting Diabetes Care Study.

You can also write to the Secretary at:

[redacted]

[redacted]

[redacted]

Can I get more information?

If you are interested in taking part in this study but would like some more information before you decide, please contact Tracey Dorey on the above email address.

Other participation opportunities

As part of this project there is an opportunity to participate in a brief interview following your involvement as an online expert panel member.

If I decide to take part what do I do now?

If you do decide to take part in this study, thank you very much. To participate you need to send an email to Tracey ([redacted]) to confirm that you'd like to take part. A link will then be sent to questionnaire. You will first be asked to complete a consent form (click on the arrow at the bottom to access this). You need to answer P to all statements if you wish to participate. If you are

Not happy with any of the statements, please select X and this will exit the questionnaire. Once you have consented we will ask a couple of quick questions on demographics and your professional role. Once this data is captured, you'll then be able to start answering the questions.

Thank you for taking the time to read this information sheet.

Informed Consent Form

The Supporting Diabetes Care Study

(*Each statement will have a P or X in Qualtrics, which if X is selected will enable the participant to exit the interview. Participants will Not be able to continue until all boxes are selected as P).*

Participants Statement of Informed Consent

- I confirm that I have read and understood the participant information dated [INSERT DATE AND VERSION NUMBER] for the above study

- I understand this will involve completing three questionnaires asking me about my ideas on how we can improve the approaches to diabetes care for people with severe mental illness

- This information will be held by City as data controller and processed for the following purposes:

  Public Task: The legal basis for processing your personal data will be that this research is a task in the public interest, that is City, University of London considers the lawful basis for processing personal data to fall under Article 6(1)(e) of GDPR (public task) as the processing of research participant data is necessary for learning and teaching purposes and all research with human participants by staff and students has to be scrutinised and approved by one of City's Research Ethics Committees.

  I understand that the following special category data will be collected and retained as part of this research study: ethnicity. City considers the processing of special category personal data will fall under: Article 9(2)(g) of the GDPR as the processing of special category data has to be for the public interest in order to receive research ethics approval and occurs on the basis of law that is, inter alia, proportionate to the aim pursued and protects the rights of data subjects and also under Article 9(2)(a) of the GDPR as the provision of these personal data is completely voluntary.

- I agree to City recording and processing this information about me. I understand that this information will be used only for the purpose(s) explained in the participant information and my consent is conditional on City complying with its duties and obligations under the General Data Protection Regulation (GDPR).

- I have had the opportunity to consider the information and ask questions, which have been answered satisfactorily

- I understand that my participation is voluntary and that I am free to withdraw without giving a reason without being penalised or disadvantaged

- I understand that any information I provide is confidential, and that X information that could lead to the identification of any individual will be disclosed in any reports on the project, or to any other party. X identifiable personal data will be published. The identifiable data will Not be shared with any other organisation.

- I agree to the arrangements for data storage, archiving and sharing

- I understand that my responses, although anonymous, will be available through an online repository for Theses, it may also be published in peer-reviewed journals

- I have read and understand the above statements

- I agree to take part in this study

Appendix 27: Study 5 (Intervention Design Delphi) – Strategy Information Pack (Version 1.0, Dec 22)

The Supporting Diabetes Care Study

Phase 3 Study: Proposed Strategy Pack

Behaviour Change Technique Strategy Tables

To provide context some example barrier and enablers are provided to demonstrate how the BCTs could be used to either overcome a barrier or utilise an enabler. The list of barriers and/or enablers is not exhaustive, many more were identified; so, you may find some may not be relevant to you. Even where this is the case, please consider the BCT and how it can be applied in the NHS setting.

Nº.	**Example beliefs from interviews reflecting barriers and enablers**	**Behaviour Change Technique (BCT)**	**Description of BCT**	**Example delivery of BCTs**
1	Knowledge of lifestyle advice generally is very good but less so more specialised knowledge of T2D specific advice, particularly dietary advice that is appropriate during relapse (Barrier)	Information on health consequences	Provide information about health consequences of performing the behaviour	**Could be provided in a continued support for T2D during relapse workshop:** 1. Provide information about the possible health consequences of monitoring and providing T2D care during relapse - positive and negative 2. Provide information about the health consequences of suboptimal/optimal management of T2D and how this could be exacerbated during a relapse – positive/negative
1b		Instructions on how to perform behaviour	Advise or agree on how to	**Could be provided in a continued support for T2D during relapse workshop:**

			perform the behaviour	1. Provide guidance on how to amend generic lifestyle advice for more tailored T2D advice
2	Identified professional role is believed to dictate what aspects of T2D care are the responsibility of the professionals (Enabler)	Social Support & Encouragement	Advise on, arrange, or provide social support, praise, or reward for performance of the behaviour.	**Could be provided in work setting:** 1. Identify a T2D/relapse "champion" or "lead" within teams (MHN role) who will act as mentor/educator to peers and champion/encourage/support T2D management during relapse. The role can also act as a link between the Diabetes Nurse Specialist and MH team as needed.
3a	Providing T2D care (at the wrong time) during relapse is believed to have the potential for harmful consequences for service users. (Barrier)	Salience of consequences	Use methods specifically designed to **emphasise** the consequences of performing the behaviour with the aim of making them more memorable (goes beyond informing about consequences)	**Could be provided in a continued support for T2D during relapse workshop:** 1. Show videos of service users speaking about the negative/positive consequences of not providing T2D lifestyle guidance during a relapse on their health and wellbeing. Describing the impact of this support on their experience and engagement with mental health services and on their SMI

3b		Comparative imagining of future outcomes	Prompt people to imagine and compare future outcomes of changed versus unchanged behaviour.	**Could be provided in a continued support for T2D during relapse workshop:** 1. Ask staff to think about and compare possible or likely outcomes of providing versus not providing T2D care during a relapse
4a	The priority during a relapse is the mental health of the service user (Barrier)	Goal setting (Behaviour)	Set or agree on a goal defined in terms of the behaviour to be achieved	**Could be provided in a continued support for T2D during relapse workshop:** 1. Create goal(s) using "If...then" statements which are focussed on provision of T2D care during relape
4b		Review goals (behaviour)	Review behaviour goal(s) jointly with the person and consider modifying goal(s) or behaviour change strategy in light of achievement. This may lead to re-setting the same goal, a small change in that goal or	**Could be enacted during work:** 1. As part of mentoring/yearly reviews with line managers(?) review goals set regarding provision of T2D care. Discuss impact of these goals and decide on whether the goals should be re-set, changed slightly or overhauled. The aim of the goal (whether slightly changed or overhauled) should still meet the aim of T2D care provision during relapse

			setting a new goal instead of (or in addition to) the first, or no change	
5	Having access to colleagues in diabetes services, or diabetic nurses within the service, is believed to be important for providing guidance in action when an individual is experiencing a relapse of their SMI (Enabler)	Restructuring social environment	Change the social environment to facilitate performance of the wanted behaviour or create barriers to the unwanted behaviour.	**Could be enacted during work:** 1. Use clinical cases during morning huddle (?)/frequent team meeting as a stimulus for discussion around provision of T2D care during relapse
6	Access to staff in the MDT who have knowledge/experience in physical health and/or T2D is believed to support T2D care (Enabler)	Social reward	Arrange verbal or non-verbal reward if there has been effort and/or progress in performing the behaviour includes Positive reinforcement.	**Could be enacted during work:** 1. Champion/lead to provide positive reinforcement/praise when discussing/raising issues of T2D care during relapse

7	Access to colleagues in diabetes services, or diabetic nurses within the service, is believed to be important for providing guidance in action when an individual is experiencing a relapse of their SMI (Enabler)	Information about others' approval	Provide information about what other people think about the behaviour. The information clarifies whether others will like, approve, or disapprove of what the person is doing or will do.	**Could be enacted during work:** 1. Ask service users to provide information/feedback on the collaborative care process during relapse (this could be before or after) paying particular attention to the support provided for their T2D. **Could be provided in a continued support for T2D during relapse workshop:** 1. Show video clip of other MHNs/senior staff/colleagues describing their approval of T2D care (lifestyle advice) during relapse.
8	Lifestyle should be discussed during a relapse but this should be a check for general wellbeing rather than a focused on T2D specific advice (Barrier)	Action Planning (G)	Prompt detailed planning of performance of the behaviour (must include at least one of the following: when, where, how often, and for how long, the behaviour should be performed).	**Could be provided in a continued support for T2D during relapse workshop:** 1. Ask staff to consider cues that could help them to provide more detailed T2D advice. Staff then asked to produce "if…then" statements linking a cue to the provision of T2D care. *This will be linked to the goal setting (behaviour) and review goals (behaviour)*

9a	Decisions have to be/will be made, during relapse, as to when is the best time to provide exercise advice, take bloods and provide general lifestyle advice (Barrier)	Action Planning (MADP)	Prompt detailed planning of performance of the behaviour (must include at least one of the following: when, where, how often, and for how long, the behaviour should be performed).	**Could be provided in a continued support for T2D during relapse workshop:** 1. Ask staff to consider cues that help them to decide to intervene in T2D management during a relapse. Staff then asked to produce "if…then" statements linking a cue to the provision of T2D care. These statements will be laminated and provided to staff
9b		Commitment	Ask the person to make a statement indicating a commitment to change behaviour.	**Could be provided in a continued support for T2D during relapse workshop:** 1. Ask staff to make a commitment using an "I will" statement as part of the action planning. The statement will relate to the provision of T2D care during relapse. The statement will be either written on a post it note or a laminated sheet. (Not about an intention but about commitment to the decision to provide T2D care during a relapse)
9c		Prompts/cues	Introduce an item into the environment that will prompt or	**Could be enacted during work:** 1. Use of laminated cue card/sticky notes that provide the if...then statements created during workshop. These should be attached to or included with a

			cue the behaviour. The prompt or cue would normally occur at the time or place that the behaviour is performed.	diary/notebook etc. That the staff member will use when supporting individuals during a relapse.
10	Some MHNs believe that their skills in relationship building and maintaining rapport are essential for blood glucose monitoring (taking bloods specifically)	Behavioural practice/rehearsal	Prompt practice or rehearsal of the performance of the behaviour one or more times in a context or at a time when the performance may not be necessary, in order to increase habit and skill	**Could be provided in a continued support for T2D during relapse workshop:** 1. As part of workshop have staff practice the discussion and approach to blood taking for blood glucose monitoring. Focus on ensuring that relationship and rapport are maintained during this aspect of care.
11	Some MHNs believe that having access to colleagues in diabetes services, or diabetic nurses within	Social support (practical)	Advise on, arrange, or provide	**Could be enacted during work:**

	the service, is important for providing guidance in action (related to T2D care) when an individual is experiencing a relapse of their SMI (Enabler)		practical help (e.g. from friends, relatives, colleagues, 'buddies' or staff) for performance of the behaviour	1. Is there anything practical that an individual (either T2D lead/champion or other staff) could do to support T2D care (specifically blood glucose monitoring, referrals or T2D lifestyle advice)?
12	The intensity of relapse is believed to affect the provision of T2D care, specifically blood glucose monitoring. (Barrier)	Add object to the environment	Add objects to the environment in order to facilitate performance of the behaviour	**Could be enacted during work:** 1. The addition of prompts/checklists as a pop up on a computer system to facilitate T2D specific checks 2. Is there anything that could be added to the environment that could make monitoring of blood glucose simpler? Any technology or equipment that you think would help? 3. Similarly, is there anything that could be added that would make referrals easier (i.e. mobile phone/iPad etc)?

Appendix 28: Study 5 (Intervention Design Delphi) – Strategy Information Pack (Version 2.0, May 23)

The Supporting Diabetes Care Study

Phase 3 Study: Proposed Strategy Pack

Behaviour Change Technique Strategy Table

To provide context some example barrier and enablers are provided to demonstrate how the BCTs could be used to either overcome a barrier or utilise an enabler. The list of barriers and/or enablers is not exhaustive, many more were identified; so, you may find some may not be relevant to you. Even where this is the case, please consider the BCT and how it can be applied in the NHS setting.

#.	**Example beliefs from interviews reflecting barriers and enablers**	**Behaviour Change Technique (BCT)**	**Description of BCT**	**Proposed delivery of BCTs**
Intervention Strategy: Appointment of a T2D/relapse champion				
A	Identified professional role is believed to dictate what aspects of T2D care are the responsibility of the professionals (Enabler) Having access to colleagues in diabetes	Social Support & Encouragement (3.1)	Advise on, arrange, or provide social support, praise, or reward for performance of the behaviour.	1. Identify a T2D/relapse "champion" or "lead" within teams (MHN role) who will act as mentor/educator to peers and champion/encourage/support T2D management during relapse. The role can also act as a link between the Diabetes Nurse Specialist and MH team as needed.

B	services, or diabetic nurses within the service, is believed to be important for providing guidance in action when an individual is experiencing a relapse of their SMI (Enabler)	Restructuring social environment (12.2)	Change the social environment to facilitate performance of the wanted behaviour or create barriers to the unwanted behaviour.	1. Use clinical cases during morning huddle (?)/frequent team meeting as a stimulus for discussion around provision of T2D care during relapse
C	Access to staff in the MDT who have knowledge/experience in physical health and/or T2D is believed to support T2D care (Enabler)	Social reward (10.4)	Arrange verbal or non-verbal reward if there has been effort and/or progress in performing the behaviour includes Positive reinforcement.	1. Champion/lead to provide positive reinforcement/praise when discussing/raising issues of T2D care during relapse
Intervention Strategy: Targets and Feedback				
D	The priority during a relapse is the mental health of the service user (Barrier)	Goal setting - behaviour (1.1)	Set or agree on a goal defined in terms of the behaviour to be achieved	1. Set compliance rate with appropriate senior management (e.g. 95% compliance rating with recording provision of lifestyle information)
		Review goal – behaviour (1.5)	Review behaviour goal(s) jointly with the person and consider modifying goal(s) or behaviour change strategy in light of achievement. This may lead to re-setting the same goal, a small change in that goal or setting a new	2. As part of mentoring/yearly reviews with line managers(?) review goals set regarding provision of lifestyle advice. Discuss impact of these goals and decide on whether the goals should be re-set, changed slightly or overhauled. The aim of the goal (whether slightly changed or overhauled) should still meet the aim of T2D care provision during relapse

			goal instead of (or in addition to) the first, or no change	
E	Lifestyle should be discussed during a relapse, but this should be a check for general wellbeing rather than a focused on T2D specific advice (Barrier)	Information about others' approval (6.3)	Provide information about what other people think about the behaviour. The information clarifies whether others will like, approve, or disapprove of what the person is doing or will do.	1. Ask service users to provide information/feedback on provision of T2D lifestyle advice during relapse as part of feedback questionnaire
Intervention Strategy: Changes to care planning and environment				
F	Lifestyle should be discussed during a relapse, but this should be a check for general wellbeing rather than a focused on T2D specific advice (Barrier) Some MHNs believe that having access to colleagues in diabetes services, or diabetic nurses within the service, is important for providing guidance in	Action Planning (1.4)	Prompt detailed planning of performance of the behaviour (must include at least one of the following: when, where, how often, and for how long, the behaviour should be performed).	1. Amendment or addendum appropriate Care Plan document to add a specific focus provision of the amended T2D lifestyle advice during relapse and HbA1c measurement. Discussed in collaboration with service users/carer
G		Prompts/cues (7.1)	Introduce an item into the environment that will prompt or cue the behaviour. The prompt	1. Relapse is a naturally occurring prompt/cue but amended Care Process document would act as cue to action

	action (related to T2D care) when an individual is experiencing a relapse of their SMI (Enabler)		or cue would normally occur at the time or place that the behaviour is performed.	
H		Add object to the environment (12.5)	Add objects to the environment in order to facilitate performance of the behaviour	1. Add prompts to computer system relating to provision of T2D care during relapse
I		Social support (practical)(3.2)	Advise on, arrange, or provide practical help (e.g. from friends, relatives, colleagues, 'buddies' or staff) for performance of the behaviour	1. During care planning meeting the involvement of service users/carers will focus on any practical help that could be provided when the plan is enacted during relapse
Intervention Strategy: Training session				
J	Knowledge of lifestyle advice generally is very good but less so more specialised knowledge of T2D specific advice, particularly dietary advice that is appropriate during relapse (Barrier)	Information on health consequences (5.1)	Provide information about health consequences of performing the behaviour	1. Provide information about the possible health consequences of monitoring and providing T2D care during relapse - positive and negative 2. Provide information about the health consequences of suboptimal/optimal management of T2D and how this could be exacerbated during a relapse – positive/negative
K		Instructions on how to perform behaviour (4.1)	Advise or agree on how to perform the behaviour	1. Provide an amended lifestyle advice guidance session by diabetic nurse specialist to guide more tailored T2D advice during relapse 2. Provide blood taking training where required

L	Providing T2D care (at the wrong time) during relapse is believed to have the potential for harmful consequences for service users. (Barrier)	Salience of consequences (5.2)	Use methods specifically designed to **emphasise** the consequences of performing the behaviour with the aim of making them more memorable (goes beyond informing about consequences)	1. Show videos of service users speaking about the negative/positive consequences of not providing T2D lifestyle guidance during a relapse on their health and wellbeing. Describing the impact of this support on their experience and engagement with mental health services and on their SMI. If not possible regarding GDPR etc. then alternative could be a written case study or a PPIE member to provide their experiences.
M	Access to colleagues in diabetes services, or diabetic nurses within the service, is believed to be important for providing guidance in action when an individual is experiencing a relapse of their SMI (Enabler) Lifestyle should be discussed during a relapse, but this should be a check for general wellbeing rather than a focused on T2D specific advice (Barrier)	Information about others' approval (6.3)	Provide information about what other people think about the behaviour. The information clarifies whether others will like, approve, or disapprove of what the person is doing or will do.	1. Show video clip of other MHNs/senior staff/colleagues describing their approval of T2D care (lifestyle advice) during relapse.
N	Some MHNs believe that their skills in relationship building and maintaining	Behavioural practice/rehearsal (8.1)	Prompt practice or rehearsal of the performance of the behaviour one or more times	1. As part of workshop have staff practice the discussion and approach to blood taking for blood glucose

	rapport are essential for blood glucose monitoring (taking bloods specifically) (Enabler)		in a context or at a time when the performance may not be necessary, in order to increase habit and skill	monitoring. Focus on ensuring that relationship and rapport are maintained during this aspect of care.
O	Some MHNs believe that having access to colleagues in diabetes services, or diabetic nurses within the service, is important for providing guidance in action (related to T2D care) when an individual is experiencing a relapse of their SMI (Enabler)	Social support (practical) (3.2)	Advise on, arrange, or provide practical help (e.g. from friends, relatives, colleagues, 'buddies' or staff) for performance of the behaviour	1. Diabetic nurse specialist to lead session – will provide opportunities for practical support when undergoing training. 2. Opportunity with T2D/relapse champion to identify any practical support opportunities

Appendix 29: Study 5 (Intervention Design Delphi) – Mapping exercise and shortlisting outcomes

Identified candidate intervention functions mapped to each important domain (Adapted from P.92 of The Behaviour Change Wheel)

Target			**Domain**	**Intervention Functions**								
Lifestyle advice	HbA1c monitoring	Referrals		Education	Persuasion	Incentivisation	Coercion	Training	Restriction	Environmental Restructuring	Modelling	Enablement
🟩	🟦	🟨	Knowledge	✓								
🟩	🟦	🟨	Environmental Context & Resources					✓	✓	✓		✓
🟩	🟦	🟨	Social/Professional Role & Identity	✓	✓						✓	
	🟪	🟨	Skill					✓				
🟩	🟦		Memory, Attention & Decision Process	✓						✓	✓	
🟩			Goals	✓	✓	✓	✓				✓	
🟩			Beliefs about Consequences	✓	✓						✓	
🟩			Social Influence						✓	✓	✓	✓
Number of domains targeted by each function				5	3	1	1	2	2	3	5	2

Potential policy categories available to support the delivery of intervention functions (Adapted from P114. of The Behaviour Change Wheel[112])

Target			**Intervention Functions**	**Policy Categories**						
Lifestyle advice	HbA1C monitoring	Referrals		Communication/Marketing	Guidelines	Fiscal Measures	Regulation	Legislation	Environmental/social planning	Service provision
🟩	🟦	🟨	Education	✓	✓		✓	✓		✓
🟩	🟦	🟨	Persuasion	✓	✓		✓	✓		✓
🟩	🟦	🟨	Training		✓	✓	✓	✓		✓
🟩	🟦	🟨	Environmental Restructuring		✓	✓	✓	✓	✓	
🟩	🟦	🟨	Modelling	✓						✓
🟩	🟦	🟨	Enablement		✓	✓	✓	✓	✓	✓

APEASE assessment outcomes for candidate intervention functions

Candidate intervention functions	**Does the intervention function meet the APEASE criteria in the context of the three target behaviours?**
Education	Yes – through the use of the training workshop – increases in knowledge are necessary
Persuasion	Yes – through the training workshop and the champion – positive feelings towards providing T2D care
Incentivisation	No, unlikely to be practicable or appropriate to promote change in the NHS environment –i.e., incentives (outside of those like CQUIN, QoF etc) are not appropriate and should be declared. Sign documentation “model of agreement and declaration” with any incentives declined – seems to go against ethics of care provision
Coercion	No, unlikely to be acceptable to use these measures to promote change in the NHS environment – just not appropriate to provide punishment/cost in care giving environment
Training	Yes – training workshop to upskill where necessary and identified by professional
Restriction	No not appropriate as will not use rules to create change – training and social norms more appropriate – more sensitive changes to care provision (more ethically appropriate)
Environmental restructuring	Yes – introduction of champion = social context change
Modelling	Yes – champion and discussion during huddles will provide opportunities for modelling
Enablement	Yes – targeted through social influence so social norms (champion) and targeting support of decision-making as to when to provide T2D care during tricky time of relapse
Shortlisted candidate intervention functions	Education, persuasion, training, environmental restructuring, modelling, and enablement

Policy category APEASE assessments

Candidate policy categories	Does the policy category meet the APEASE criteria in the context of the three target behaviours?
Communication/marketing	Possibly? Outside the scope of this project currently but could explore the use of this in the longer term (e.g. post-doctoral work/feasibility). Undertake some work to see whether a campaign to support T2D care during relapse could be promoted in NHS environment? Again, seems to be a wider campaign e.g. public health (stop smoking campaigns as an example) therefore appropriateness in NHS environment is questionable.
Guidelines	Possibly? Treatment protocols can be produced as part of the intervention (I know of the physical health treatment protocol in ELFT) – could simply add intervention into the document as a treatment recommendation to support implementation.
Fiscal measures	No. Not relevant for NHS environment
Regulation	No. Not appropriate for NHS environment nor intervention. This is a step on from guidelines which seem appropriate at a local NHS level. Wider regulation outside of scope of this project?
Legislation	No. Not appropriate for NHS environment nor intervention. Additionally, outside of resources/scope of this project
Environmental/social planning	No. Larger control of physical or social environment not appropriate for this intervention as focussed on NHS

	environment not public health. Additionally outside of resources/scope of this project
Service provision	Yes. Changes to provision including the explicit focus on T2D during relapse care behaviours plus support of champion
Shortlisted candidate policy categories	Service provision in current project with Guidelines and Communication/marketing possible for later inclusion? N.B – *Guidelines was subsequently included following input for the panel*

Behaviour change techniques, domains, sources and decisions - initial mapping

#	Behaviour Change Technique	Domain	Identified in the TDF/BCT Matrix[112]	Theory and Technique Tool [303]	Practicability	Acceptability	TD Decision	MH Decision
1	Information on health consequences	Knowledge	✓	Link	✓	✓	✓	✓
		Beliefs about consequences	X	Link	✓	✓		
2	Instructions on how to perform a behaviour	Knowledge	✓	Inconclusive	✓	✓	✓	✓
		Skill	X	Link	✓	✓		
3	Social support and encouragement (Social Support - Unspecified)	Social/professional role and identity	✓	Inconclusive	✓	✓	✓	✓
		Social influence	✓	Link	✓	✓		
4	Salience of consequences	Beliefs about consequences	✓	Link	✓	?	?	✓
5	Comparative imagining of future outcomes	Beliefs about consequences	✓	Link	?	?	?	?
6	Goal setting (behaviour)	Goals	✓	Link	✓	✓	✓	✓
7	Review of behaviour goals	Goals	✓	Link	✓	?	?	?
8	Restructuring the social environment	Environmental context and resources	✓	Link	✓	✓	✓	✓
		Social influence	✓	Inconclusive	✓	✓		
9	Social reward	Social influence	✓	Link	✓	✓	✓	✓

10	Information about others' approval	Social influence	X	Link	?	?	?	?
11	Action planning	Goals	✓	Absence	✓	?	?	X
		Memory, attention and decision process	X	Absence	?	?	?	?
12	Commitment	Memory, attention and decision process	X	Inconclusive	?	?	?	?
13	Prompts/cues	Memory, attention and decision process	X	Link	✓	?	?	✓
		Environmental context and resources	✓	Link				
14	Behavioural practice/rehearsal	Skill	✓	Link	?	?	?	X
15	Social support (practical)	Environmental context and resources	X	Link	✓	✓	✓	✓
		Social influence	✓	Link	✓	✓		
16	Adding objects to the environment	Environmental context and resources	X	Link	?	?	?	?

Key: ✓ = Yes; X = No;? = Unsure.

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Appendix 30: Study 5 (Intervention Design Delphi) – Behaviour change technique assessments

Key: ✓ = Yes, X = No, ? = Unsure

	APEASE		*Application Proposal Information*			*TD Assessment*		*MH Assessment*	
BCT	***Practicability***	***Acceptability***	**Belief statements reflecting potential barriers or enablers**	**Potential Application**	**Source**	**Decision**	**Notes**	**Decision**	**Notes**
TDF DOMAIN: Knowledge									
Information on health consequences	✓	✓	1. MHNs have knowledge of healthy lifestyle advice but this is not T2D specific (general plus diet particularly) (Barrier) 2. MHNs do/do not have knowledge of optimal blood glucose levels (Barrier) 3. MHNs are aware of the interaction between	1. Provide information about the possible health consequences of monitoring and providing T2D care during relapse - positive and negative 2. Provide information about the health consequences of suboptimal/optimal management of T2D and how this can be exacerbated during a relapse	Michie et al. 2013	✓		✓	This is feasible and likely to be acceptable; there are a good resources that can be used/ adapted e.g. https://www.diabetes.org.uk/professionals/resources/shared-practice/psychological-care/emotional-health-professionals-guide

Biofeedback	X	X	T2D/SMI and the specific impact of relapse (Enabler) 4. MHNs have an awareness of external services appropriate for referral (Enabler)	*Provide feedback about the body (e.g. physiological or biochemical state) using an external monitoring device as part of a behaviour change strategy*	Michie et al. 2013	X	Inappropriate for beliefs/target behaviours	X	Inappropriate for this setting/ staff group, Not feasible. Has potential for specialist medical/ community practice https://www.diabetes.co.uk/alternative-treatment/Diabetes-and-Biofeedback.html
Antecedents	X	X		*Provide information about antecedents (e.g. social and environmental situations and events, emotions, cognitions) that reliably predict performance of the behaviour*	Michie et al. 2013	X	Inappropriate for beliefs/target behaviours	X	On balance = No; Not relevant to staff behaviour/clincial activity.
Feedback on behaviour	?	?		*Monitor and provide informative or evaluative feedback on performance of the behaviour (e.g. form, frequency, duration, intensity)*	Michie et al. 2013	X	During relapse challenge to provide this feedback by suitable individual - query who this could be and how?	X	On balance = X; could be possible if e.g. a T2D lead/ clinical lead routinely reviewed relevant aspects (T2D relevant) aspects of support/ care / monitoring - and provided feedback. But this does not appear feasible/ acceptable.
Instructions on how to perform a behaviour	✓	✓		1. Provide guidance on how to amend generic lifestyle advice for more tailored T2D advice	Michie et al. 2013	✓		✓	e.g. metabolic syndrome features monitoring (waist circumference - where appropriate); diet / exercise guidance/ support. How to (practical demonstration) of signposting/ liaison with relevant services.

Information about social and environmental consequences	✓	✓		1. Provide information (e.g. written, verbal, visual) about the impact of providing T2D monitoring, referrals and lifestyle advice during relapse from a service user perspective	Michie et al. 2013	✓		?	Seems to overlap with previous = health consequences; socal and environmental seem less relevant/ pertinent.
TDF DOMAIN: Skill									
Graded Task	X	X	1. MHNs believe that their skills in relationship building/rapport are important for supporting management of T2D during relapse. (General, blood glucose and Referral engagement)(Enabler)	*Set easy-to-perform tasks, making them increasingly difficult, but achievable, until behavior is performed*	Michie et al. 2013	X	Inappropriate for beliefs/target behaviours	X	
Behavioural practice/rehearsal	?	?		Skill-based practise focussing on maintaining relationship/rapport whilst blood taking/intervention referral	Michie et al. 2013	?	Seems tough to fit into this BCT - Not sure it is appropriate but none of the others work either??	X	Feasibility and acceptability for this and above (and below) seem very limited. Would be appropriate for HEI initial training or CPD courses to use these approaches, but very unlikely to fit with activity and priorities of clinical services/ teams.
Habit reversal	X	X		*Prompt rehearsal and repetition of an alternative behavior to replace an unwanted habitual behavior*	Michie et al. 2013	X	Inappropriate for beliefs/target behaviours	X	As above (in the 'old days' staff used to smoke with patients! - which would have been relevant)
Body Changes	X	X		*Alter body structure, functioning or support* ***directly*** *to facilitate behavior change*	Michie et al. 2013	X	Inappropriate for beliefs/target behaviours	X	

Habit formation	X	X		*Prompt rehearsal and repetition of the behavior in the same context repeatedly so that the context elicits the behavior*	Michie et al. 2013	X	Inappropriate for beliefs/target behaviours	?	This could ? be relevant - there are some clinical activities, like putting on gloves for injection, or checking for medication s/e, or measuring BP.. That might be appropriate to be conducted at all relevant encounters. But - Not sure whether this fits (? some basic things like checking concordance with T2D meds/ appts/ diet.. activity plan - could/should be routine part of all clinical encounters..)
Instructions on how to perform a behaviour	X	X		*Provide instructions on how to perform the behaviour*	Michie et al. 2013	X	Inappropriate for beliefs/target behaviours	X	On balance probably X - there might be some odd things where this relevant. e.g. for staff training sessions on physical health/ SMI - I show how to measure waist circumference and demonstrate use of specific cardiac risk tools (though likely that these would be used/ applied in primary/ medical care .) e.g. https://www.ucl.ac.uk/primrose-risk-score/ and https://qrisk.org/three/
TDF DOMAIN: Social/Professional Role and Identity									

Social support and encouragement (Social Support - Unspecified)	✓	✓	1. During relapse the aim of the MHN role is management of mental health and Not T2D care (General, diet and exercise) (Barrier) 2. It is Not the responsibility of MHNs to provide T2D interventions, it is the remit of the GP/DNS (General) (Barrier) 3. It is Not the responsibility of MHNs to provide T2D specific lifestyle advice but general health promotion (Barrier) 4. Professional responsibility ends for T2D when referrals are made to external providers (Barrier) 5. MHNs' professional responsibility is to general physical health or ailments that are caused by side effects of mental health medication, such as weight gain but Not subsequent T2D diagnoses (Barrier) 6. MHNs believe that identified professional role defines role responsibilities (Enabler)	**1. Identify a T2D/relapse "champion" or "lead" within teams (MHN role) who will act as mentor/educator to peers and champion/encourage/support the behaviours**	Smith et al. 2022	✓		✓	P - physical health (? Not specific to T2D) lead seems most feasible and acceptable approach for support provision. ? in-house training/ support sessions timetabled.
TDF DOMAIN: Beliefs about consequences									
Emotional consequences	✓	?	1. Provision of lifestyle advice is affected by the limited perceived impact or harmful impact of providing the advice (Lifestyle) (Barrier) 2. MHNs believe providing	1. Provide information (e.g. written, verbal, visual) about emotional consequences (e.g.) of providing lifestyle interventions during relapse from a service user perspective	Michie et al. 2013	?		X	does Not seem particularly feasible/ likely to be associated with impacts/ changes

Salience of consequences	✓	?	T2D care (Lifestyle advice, blood glucose monitoring) has the potential for harmful consequences for service users (Barrier)	1. Show videos of service users speaking about the consequences of Not providing/providing T2D lifestyle advice (T2D monitoring)	Byrne-Davis, Bull and Hart, 2019	?		✓	Of this group = beliefs/ consequences - this seems the most suitable/ applicable. T2D consequences are multiple and potentially severe/ life changing. There are likely to be simple/ feasible approaches to extending awareness.
Anticipated regret	✓	?		1. Ask MHN to consider the degree of regret they may feel if they didn't provide the advice and the service user came to harm i.e. exacerbation of T2D symptoms/outcomes	Michie et al. 2013	?		X	
Social and environmental consequences	?	?		1. Service users provide information about the social/environmental consequences of Not managing their T2D during relapse	Michie et al. 2013	?	Could be part of the information provided about health consequences - both Consequences & Knowledge	X	
Comparative imaging of future outcomes	?	?		**1. Prompt MHNs to imagine and compare likely or possible outcomes of providing versus Not providing advice**	Michie et al. 2013	?		?	I see this as incorporated/ part of/ very closely related to promoting awareness =30 salience - 30,33,39 seem deliverable together/ aspects of same intervention/approach.
Pros and cons	?	?		1. Ask MHN to consider pros and cons of lifestyle delivery	Michie et al. 2013	?	Would require delivery outside of care - Not currently feasible	X	
Vicarious reinforcement* (Vicarious Consequence)	✓	?		*Prompt observation of the consequences (including rewards and punishments) for others when they perform the behaviour*	Michie et al. 2013	?	Would require delivery outside of care - Not currently feasible	X	

Threat	X	X		*Inform that future punishment or removal of reward will be a consequence of performance of an unwanted behavior*	Michie et al. 2013	X	Inappropriate for beliefs/target behaviours	X	
Covert conditioning*	✓	?		1. Ask MHNs to imagine providing the advice during relapse and it being received well and positive outcomes	Michie et al. 2013	?		X	
Covert sensitisation*	?	?		*Advise to imagine performing the unwanted behavior in a real-life situation followed by imagining an unpleasant consequence*	Michie et al. 2013	X	Behaviour Not wanted as acting as a barrier	X	
Information about health consequences	✓	✓		**1. Provide information about the health consequences of Not providing T2D care during relapse**	Michie et al. 2013	✓		✓	I see this as incorporated/ part / closely related to promoting awareness = 30 =salience (30+33+39)?
Material incentive (behaviour)	✓	X		*Inform that money, vouchers or other valued objects will be delivered if and only if there has been effort and/or progress in performing the behavior*	Michie et al. 2013	X	Inappropriate for beliefs/target behaviours	X	

Incentive (outcome)	X	X		*Inform that a reward will be delivered if and only if there has been effort and/or progress in achieving the behavioural outcome*	Michie et al. 2013	X	Inappropriate for beliefs/target behaviours	X	
Reward (outcome)	X	X		*Arrange for the delivery of a reward if and only if there has been effort and/or progress in achieving the behavioural outcome*	Michie et al. 2013	X	Inappropriate for beliefs/target behaviours	X	
TDF DOMAIN: Goals									
Goal setting (outcome)	?	?	1. MHN prioritise management of mental health over physical health (T2D) during relapse (General) 2. MHNs believe that the priority of lifestyle advice is a "back to basics" to support mental wellness rather than advice for management of T2D (Lifestyle)	*Set or agree on a goal defined in terms of a positive outcome of wanted behaviour*	Michie et al. 2013	X	Challenge as outcome is service user focussed and impacted by many factors - focus on behaviour goal	X	
Goal setting (behaviour)	✓	✓		1. Ask MHN to set SMART goals that include provision of T2D lifestyle advice during relapse. Working with service user to ascertain when, where and how to best to this for the individual	Michie et al. 2013	✓		✓	I am a bit stuck - are these focused on staff/ nurse behaviours - i.e. approaches to modify the approaches staff/ team use (thought so) - rather than ways to change patient behaviour? If goal-setting for staff, then- P - and this might focus on specific monitoring behaviours - with target to enact these at every encounter.

Review of outcome goal(s)	?	?		*Review outcome goal(s) jointly with the person and consider modifying goal(s) in light of achievement. This may lead to re-setting the same goal, a small change in that goal or setting a new goal instead of, or in addition to the first*	Michie et al. 2013	?	As above for outcome	?	As above - ? could be goal like ensuring all physical health/ screening checks completed by.., or all GP/ specialist contact details updated/ checked.. or all patients and families have received patient education leaflet..
Review of behaviour goals	✓	?		*Review behavior goal(s) jointly with the person and consider modifying goal(s) or behavior change strategy in light of achievement. This may lead to re-setting the same goal, a small change in that goal or setting a new goal instead of (or in addition to) the first, or no change*	Michie et al. 2013	?		?	Not sure if above best fits with outcome goals - or behaviour goals?
Action planning (Implementation intentions)	✓	?		Prompt detailed planning of performance of the behavior (must include at least one of context, frequency, duration and intensity). Context may be environmental (physical or social) or internal (physical, emotional or cognitive) (includes '**Implementation Intentions**')	Michie et al. 2013	?		X	

Discrepancy between current behaviour and goal	✓	?		1. When discussing goal setting ask MHN to consider current behaviour (form, frequency, intensity) of T2D care/lifestyle advice and how this compares to goal	Michie et al. 2013	?		X	
TDF DOMAIN: Memory, attention and decision processes									
Prompts/cues	✓	?	1. MHN have to decide when is best to intervene to take bloods and provide T2D lifestyle advice (Blood glucose and lifestyle advice) 2. MHN have to frequently consider multiple demands when deciding where to focus their attention (General)	**1. Prompt MHNs to imagine and compare likely or possible outcomes of providing versus Not providing advice**	Michie et al. 2013	?		✓	These are cost-effective/ generally easily implementable. I am thinking about setting alerts for e.g. screening/ checking whenever new meds prescribed or dose changed.. Or if BMI over certain parameter.. Or.. Maybe there's potential for prompts to be added/ modified in electronic patient record system... Lot of focus now on mobile delivery for prompts https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9014231/
Self-monitoring of behaviour	✓	?		1. Ask MHNs to create opportunities for reflection on how provision of these behaviours is going/being achieved perhaps with self or with champion/lead	Michie et al. 2013	?	Might be challenging to find the time either for self or with champion/lead	X	
Action planning (Implementation intentions)	✓	?		**1. Develop "If...then" statements that cue assessment of when the delivery of T2D lifestyle advice and blood glucose monitoring would feel appropriate**	Michie et al. 2013	?		X	

TDF DOMAIN: Environmental context and resources									
Restructuring the physical environment	✓	?	1. MHNs believe that the intensity of the relapse can affect T2D provision (General) 2. MHNs believe that blood glucose monitoring is challenging owing to psychosis symptoms experienced during a relapse (Blood glucose monitoring) 3. MHNs believe training (resource) is limited in T2D management 4. MHNs believe workload demands across all staff hinder ability, including MHNs ability to provide physical health care (including T2D) and building relationships for referral (General and referral)	*Change, or advise to change the physical environment in order to facilitate performance of the wanted behaviour or create barriers to the unwanted behaviour (other than prompts/cues, rewards and punishments)*	Michie et al. 2013	?	Unsure on what object could be added? Like the thought of Not needing a	X	If this was e.g. in-patient unit and there was poor food options.. Or drinks machines with high sugar drinks.. But seems unlikely/ limited relevance for CMHT setting/ practice.
Prompts/cues	✓	?		**1. Prompt MHNs to imagine and compare likely or possible outcomes of providing versus Not providing T2D care**	Michie et al. 2013	?		X	Prompts/ cues seem - for CMHT care - more relevant to previous domain = memory/ attention - than to environment / setting.
Restructuring the social environment	✓	✓		1, Use clinical cases during morning huddle as a stimulus for discussion around provision of T2D care during relapse	Michie et al. 2013; Smith et al. 2022	?		✓	P- I like your example. Lot of attention/ use of huddles .. - This (as =bold I think) does fit within 27 = Social/ Professional Role/ Identity
Avoidance/changing exposure cues for the behaviour	X	X		*Advise on how to avoid exposure to specific social and contextual/physical cues for the behaviour, including changing daily or weekly routines*	Michie et al. 2013	X	Not appropriate for target behaviours	X	

Discriminative (learned) cue*	X	X		*Identify an environmental stimulus that reliably predicts that reward will follow the behavior*	Michie et al. 2013	X	Not appropriate for target behaviours	X	
Social support (practical)	✓	✓		**1. Identify a T2D/relapse "champion" or "lead" within teams (MHN role) who will act as mentor/educator to peers and champion/encourage/support the behaviours**	Michie et al. 2013; Smith et al. 2022	✓		✓	P - and - as above this overlaps/ involves same intervention as 27 - Professional Role/ Identity
Remove aversive stimulus	X	X		*Advise or arrange for the removal of an aversive stimulus to facilitate behaviour change*	Michie et al. 2013	X	Not appropriate for target behaviours		
Adding objects to the environment	?	?		*Add objects to the environment in order to facilitate performance of the behaviour*	Michie et al. 2013	?	As above - like the idea of additions - maybe computer-based prompts?	?	Often clinics will have things as basic as patient education leaflets, health eating posters.. I know of (depot injection) clinics where the weighing scales have become a focus for 'weight watchers' type groups..
TDF DOMAIN: Social Influence									
Social comparison	X	X	1. MHNs believe that having access to colleagues in diabetes services, or diabetic nurses within the service, is important for providing guidance in action	*Draw attention to others' performance to allow comparison with the person's own performance*	Michie et al. 2013	X	Not appropriate for target behaviours		

Social support (Unspecified)	✓	✓	when an individual is experiencing a relapse of their SMI (general and diet specific)Advice from diabetes clinic supports decision making during relapse (general) (Enabler)	**1. Identify a T2D/relapse "champion" or "lead" within teams (MHN role) who will act as mentor/educator to peers and champion/encourage/support the behaviours**	Smith et al. 2020	✓		✓	P - having a Physical Health / T2D Lead seems to link to/ involve quite a lot of mechanisms.
Social support (practical)	✓	✓		**1. Identify a T2D/relapse "champion" or "lead" within teams (MHN role) who will act as mentor/educator to peers and champion/encourage/support the behaviours**	Smith et al. 2020	✓		✓	As above
Social reward	✓	✓		1. Champion/lead to provide positive reinforcement/praise when discussing/raising issues of T2D care during relapse	Michie et al. 2013; Smith et al. 2022	✓		✓	These seem most obviously linked to Lead/ Champion role
Restructuring the social environment	✓	✓		**1. Use clinical cases during morning huddle as a stimulus for discussion around provision of T2D care during relapse**	Michie et al. 2013; Smith et al. 2022	✓		✓	As above

Modelling or demonstrating behaviour	X	X		*Provide an observable sample of the performance of the behaviour, directly in person or indirectly e.g. via film, pictures, for the person to aspire to or imitate*	Michie et al. 2013	X	Not appropriate for the belief statement	?	It is possible e.g. in-house teaching that demonstrating 'expert' assessment practice or approaches to encourage/ motivate - could be relevant/ effective.. Maybe feasible?
Identification of self as role model	?	?		*Inform that one's own behavior may be an example to others*	Michie et al. 2013	X		X	In some environments (in-patient) staff wellbeing/ or smoking cessation activities are undertaken and can have a planned positive effect for patients.. But does Not seem relevant here
Vicarious reinforcement	X	X		*Prompt observation of the consequences (including rewards and punishments) for others when they perform the behaviour*	Michie et al. 2013	X	Inappropriate for beliefs/target behaviours	X	
Information about others' approval	?	?		1. Ask service users to provide information/feedback on the collaborative care process during relapse - whether this is beneficial or not and why	Michie et al. 2013	?		?	I am bit out of touch - but seems likely that some of these behaviours/ goals/ achievements might map on to CQUIN targets (external approval/quality rating) - this was previously Pd = https://www.rcpsych.ac.uk/docs/default-source/improving-care/ccqi/national-clinical-audits/ncap-library/improving-physical-health-in-smi---introductory-slides-cquin-1912.pdf?sfvrsn=93649804_4 - but can't see in most recent https://www.england.nhs.uk/wp-content/uploads/2022/01/B1477-i-cquin-22-23-march-2022.pdf But CQC = https://www.cqc.org.uk/sites/default/files/20191125_900852_briefguide-physical_healthcare_mental_health_settings_v4.pdf

Appendix 31: Completed GUIDED Reporting Checklist

GUIDED – a guideline for reporting for intervention development studies.

Supplementary File 1: Blank Checklist

Item description	Explanation	Page in manuscript where item is located	Other*
1. Report the context for which the intervention was developed.	Understanding the context in which an intervention was developed informs readers about the suitability and transferability of the intervention to the context in which they are considering evaluating, adapting or using the intervention. Context here can include place, organisational and wider socio-political factors that may influence the development and/or delivery of the intervention (15).	Chapter 5	
2. Report the purpose of the intervention development process.	Clearly describing the purpose of the intervention specifies what it sets out to achieve. The purpose may be informed by research priorities, for example those identified in systematic reviews, evidence gaps set out in practice guidance such as The National Institute for Health and Care Excellence or specific prioritisation exercises such as those undertaken with patients and practitioners through the James Lind Alliance.	Chapter 1	
3. Report the target population for the intervention development process.	The target population is the population that will potentially benefit from the intervention – this may include patients, clinicians, and/or members of the public. If the target population is clearly described then readers will be able to understand the relevance of the intervention to their own research or practice. Health inequalities, gender and ethnicity are features of the target population that may be relevant to intervention development processes.	Chapter 5	
4. Report how any published intervention development approach contributed to the development process	Many formal intervention development approaches exist and are used to guide the intervention development process (e.g. 6Squid (16) or The Person Based Approach to Intervention Development (17)). Where a formal intervention development approach is used, it is helpful to describe the process that was followed, including any deviations. More general approaches to intervention development also exist and have been categorised as follows (3):- Target Population-centred intervention development; evidence and theory-based intervention development; partnership intervention development; implementation-based intervention development; efficacy-based intervention development; step or phased-based intervention development; and intervention-specific intervention development (3). These approaches do not always have specific guidance that describe their use. Nevertheless, it is helpful to give a rich description of how any published approach was operationalised	Chapter 2	
5. Report how evidence from different sources informed the intervention development process.	Intervention development is often based on published evidence and/or primary data that has been collected to inform the intervention development process. It is useful to describe and reference all forms of evidence and data that have informed the development of the intervention because evidence bases can change rapidly, and to explain the manner in which the evidence and/or data was used. Understanding what evidence was and was not available at the time of intervention development can help readers to assess transferability to their current situation.	Chapter 5, 6 and 7	
6. Report how/if published theory informed the intervention development process.	Reporting whether and how theory informed the intervention development process aids the reader's understanding of the theoretical rationale that underpins the intervention. Though not mentioned in the e-Delphi or consensus meeting, it became increasingly apparent through the development of our guidance that this theory item could relate to either existing published theory or programme theory	Chapter 2-7	
7. Report any use of components from an existing intervention in the current intervention development process.	Some interventions are developed with components that have been adopted from existing interventions. Clearly identifying components that have been adopted or adapted and acknowledging their original source helps the reader to understand and distinguish between the novel and adopted components of the new intervention.	Chapter 4 and 7	
8. Report any guiding principles, people or factors that were prioritised when making decisions during the intervention development process.	Reporting any guiding principles that governed the development of the application helps the reader to understand the authors' reasoning behind the decisions that were made. These could include the examples of particular populations who views are being considered when designing the intervention, the modality that is viewed as being most appropriate, design features considered important for the target population, or the potential for the intervention to be scaled up.	Chapter 2	

Item description	Explanation	Page in manuscript where item is located	Other*
9. Report how stakeholders contributed to the intervention development process.	Potential stakeholders can include patient and community representatives, local and national policy makers, health care providers and those paying for or commissioning health care. Each of these groups may influence the intervention development process in different ways. Specifying how differing groups of stakeholders contributed to the intervention development process helps the reader to understand how stakeholders were involved and the degree of influence they had on the overall process. Further detail on how to integrate stakeholder contributions within intervention reporting are available (19).	Chapter 2, 5 and 7	
10. Report how the intervention changed in content and format from the start of the intervention development process.	Intervention development is frequently an iterative process. The conclusion of the initial phase of intervention development does not necessarily mean that all uncertainties have been addressed. It is helpful to list remaining uncertainties such as the intervention intensity, mode of delivery, materials, procedures, or type of location that the intervention is most suitable for. This can guide other researchers to potential future areas of research and practitioners about uncertainties relevant to their healthcare context.	Chapter 7	
11. Report any changes to interventions required or likely to be required for subgroups.	Specifying any changes that the intervention development team perceive are required for the intervention to be delivered or tailored to specific sub groups enables readers to understand the applicability of the intervention to their target population or context. These changes could include changes to personnel delivering the intervention, to the content of the intervention, or to the mode of delivery of the intervention.	Chapter 7 and 8	
12. Report important uncertainties at the end of the intervention development process.	Intervention development is frequently an iterative process. The conclusion of the initial phase of intervention development does not necessarily mean that all uncertainties have been addressed. It is helpful to list remaining uncertainties such as the intervention intensity, mode of delivery, materials, procedures, or type of location that the intervention is most suitable for. This can guide other researchers to potential future areas of research and practitioners about uncertainties relevant to their healthcare context.	Chapter 7 and 8	
13. Follow TIDieR guidance when describing the developed intervention.	Interventions have been poorly reported for a number of years. In response to this, internationally recognized guidance has been published to support the high quality reporting of health care? interventions[3]and public health interventions[14]. This guidance should therefore be followed when describing a developed intervention.	To be completed for forthcoming manuscript	
14. Report the intervention development process in an open access format.	Unless reports of intervention development are available people considering using an intervention cannot understand the process that was undertaken and make a judgement about its appropriateness to their context. It also limits cumulative learning about intervention development methodology and observed consequences at later evaluation, translation and implementation stages. Reporting intervention development in an open access (Gold or Green) publishing format increases the accessibility and visibility of intervention development research and makes it more likely to be read and used. Potential platforms for open access publication of intervention development include open access journal publications, freely accessible funder reports or a study web-page that details the intervention development process.	To be completed for forthcoming manuscript	

*e.g. if item is reported elsewhere, then the location of this information can be stated here.