Exploring the Barriers and Facilitators of Following a Meal Plan for Type 2 Diabetes: A Survey Using the Theoretical Domains Framework

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ABSTRACT

Background: Type 2 Diabetes Mellitus (T2DM) is a critical health topic in Newfoundland and Labrador (NL). In 2016, the Canadian Diabetes Association estimates that 179,000 residents in NL are living with diabetes or pre-diabetes, which is approximately 35% of our population and the highest prevalence within Canada. Patients with this disease find it challenging to make health-related choices to reduce the negative impacts associated with diabetes on their long-term well-being and to improve their lifestyles. Using a Theoretical Domains Framework (TDF), we will identify what domains play a significant role in creating barriers and facilitators for the self-management of T2DM. As the global prevalence of diabetes continues to grow and technology continues to develop, there is an obvious potential for technology to help support individuals self-manage T2DM.

Purpose: The primary objective of the study is to identify which behavioral domains of the TDF (e.g., knowledge, social influence, skills) will predict the intention to follow a meal plan for the self-management of diabetes for subsequent intervention development. The secondary objective is to explore if patients in a Remote Monitoring Program (RMP) for diabetes would use technology to help manage their diabetes and whether they perceive technology as an effective tool for self-management.

Methods: Patients enrolled in the RMP for T2DM through the Eastern Regional Health Authority, NL (n=300) received a questionnaire via mail as part of a cross-sectional study to assess their experience with following a meal plan for diabetes self-management. The questionnaire also included an open-ended question to evaluate the attitudes of NL residents regarding the effectiveness of technology as a self-management tool.

Results: The Regression model (n=54) indicated only two significant predictors of meal plan intention, Emotions (β=-0.648, p=0.003) and Social Influences (β=0.475, p=0.0026), accounting for three quarters of the variance.

Conclusions: Now that the influence of others in one's social environment and one's emotional health have been identified as the significant predictors of the self-management of T2DM, these domains will be the focus for the creation of intervention content in a subsequent project.

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List of Abbreviations

ACRE	Accelerated Chest Pain Risk Evaluation
BCT	Behaviour Change Techniques
BCW	Behaviour Change Wheel
BMI	Body Mass Index
COM-B	Capability, Opportunity, Motivation model of behaviour
DPA	Daily Physical Activity
IDF	International Diabetes Federation
kg	Kilograms
lbs	Pounds
NL	Newfoundland and Labrador
RMP	Remote Monitoring Program
SD	Standard Deviation
SPSS	Statistical Package for Social Science
SSS	Stop Smoking Services
T2DM	Type 2 Diabetes Mellitus
TDF	Theoretical Domains Framework
US	United States
WHO	World Health Organization

Chapter 1 : Introduction

1.1 Background and Study Rationale

1.1.1 Diabetes – A Growing Public Health Issue

Diabetes Mellitus, a chronic disease, is marked by the body's inability to regulate levels of glucose (sugar), which can result in an excess or a deficiency of sugar in the blood (BC, 2014). There are three types of diabetes: Type 1, Type 2 and Gestational diabetes, and there is also impaired glucose tolerance (prediabetes). Prediabetes is defined as higher than normal glucose levels and is the precursor to T2DM. Prediabetes can be reversed with weight reduction, proper diet, and physical activity (BC, 2014). T2DM, the most common diabetes diagnosis (roughly 90%), occurs when the body does not respond properly to the insulin it produces, thus increasing the glucose in the blood (Canada, Diabetes, 2019). T2DM is most commonly developed in adulthood; however, over the past three decades, the prevalence of T2DM has risen dramatically across all age groups (World Health Organization, 2019).

The number of people with diabetes has increased from 108 million in 1980 to 422 million in 2014 (World Health Organization, 2019). In 2016, an estimated 1.6 million deaths were directly caused by diabetes and another 2.2 million deaths were attributable to high blood glucose in 2012 (World Health Organization, 2019). T2DM is an especially critical health challenge in NL, given the province has the highest prevalence within Canada. In 2016, the Canadian Diabetes Association estimated that 179,000 residents in NL were living with diabetes or pre-diabetes, approximately 35% of the population (Canadian Diabetes Association , 2016). NL continues to have some of the highest rates of chronic disease in Canada and as the population continues to age, the prevalence of chronic disease is expected to grow, including T2DM (Health and Community Service Government of Newfoundland and Labrador, 2017).

1.1.2 The Value of Self-Management

Having high blood sugar can cause diabetes-related complications such as kidney disease, foot and leg problems, eye disease (retinopathy) that can lead to blindness, heart attack and stroke, anxiety, nerve damage amputation and erectile dysfunction (Canadian Diabetes

Association , 2016). Preventing, or delaying, the complications associated with T2DM is possible. Genetic susceptibility and environmental influences seem to be the most important factors responsible for the development of T2DM (Asif, 2014). Fortunately, because environmental factors are modifiable, disease manifestation from these factors is largely preventable with self-management (Asif, 2014). Self-management refers to an individual's confidence and ability to manage their chronic conditions (Services, 2015). Daily self-management regimens for T2DM range from intensive (frequent glucose monitoring, intensive dietary behaviors, and medication regimens) to relatively less complex regimens (primarily diet and exercise) (Mulvaney, et al., 2009). To maintain good diabetes control and thus reduce the risk of complications and hospital visits, patients are advised to change their behaviors related to exercise, diet, smoking, and glucose monitoring. There is considerable value in the self-management of diabetes. Diabetes complications are common and almost triple the annual cost of managing diabetes (Bate, et al., 2003). Individuals can learn the skills to manage their own health and well-being through self-management education and support. T2DM management efforts may be individual or population-based and can occur in a variety of settings such as at home, in schools and workplaces, and within local communities (Services, 2015).

Unfortunately, difficulties with diabetes self-management tasks are found across all age groups, and changing behaviors related to dietary and physical activity choices is challenging for most individuals (Asif, 2014). Newfoundlanders and Labradoreans continue to report low rates of fruit and vegetable consumption (e.g., 76% do not eat enough fruit and vegetables); further, 20% smoke and 5% are physically inactive (Services, 2015). Evidence clearly shows that these challenges have a negative impact on health outcomes, result in poorer quality of life, increase the cost of delivering health care services, and negatively affect economic growth (Services, 2015).

1.1.3 Changing Self-Management Behaviors

Changing behavior related to health can be difficult. "The role of health behaviours in the origin of the current epidemic of non-communicable disease is observed to have driven attempts to change behaviour. It is noted that most efforts to change health behaviours have had limited success" (Kelly, et al., 2016). A recent study identified six errors policy makers typically make when discussing behavior change: assuming it is just common sense, it is about getting the

message across, knowledge and information drive behavior, people act rationally, people act irrationally, and it is possible to predict accurately (Kelly, et al., 2016). The study concluded that addressing behavior change in a healthcare setting requires careful, thoughtful science that leads to a deep understanding of the nature of what motivates people and the social and economic pressures that act upon them; once this is understood, we can better support behavior change (Kelly, et al., 2016).

Current support for people living with diabetes in NL includes the province's Remote Patient Monitoring Program (RMP) offered through the Eastern Regional Health Authority. At the time of this project, 300 patients had enrolled in the RMP for diabetes support. The RMP was originally set up as a pilot project that focuses on improving patient care and outcomes for people with chronic diseases, including diabetes and heart disease. It has been led by Eastern Health and is an innovative approach to providing self-management guidance with nurse monitoring and contact for patients with diabetes in remote areas of NL. Every patient in the program receives an IPad for one year which is monitored daily by nurses at Eastern Health. After the one year monitoring period, these patients are required to return the IPads and continue the self-management of their condition (Services, 2015). Conversations with RMP nurses over the course of this project suggested that the program was helping patients manage their disease; however, after completing the RMP, patients can regress to old regimens regarding self-management (e.g., see verbatim notes from patients enrolled in RMP in the Patient Engagement section of the Appendices).

1.1.4 A Rigorous Approach to Changing Behavior

‘’Implementation research is the scientific inquiry into questions concerning implementation—the act of carrying an intention into effect, which in health research can refer to policies, programs, or individual practices (collectively called interventions)’’ (Peters, et al., 2013). Implementation research seeks to understand and identify the factors that influence a specific audience in their real-world living conditions. Evidence demonstrates that behavior change interventions based on theory are more effective than those without a theoretical base

(Glanz, et al., 2010). Despite evidence to support implementation research, there is a well-recognized failure to translate research into practice and policy (McIssac, et al., 2018).

1.1.5 The Theoretical Domains Framework

The TDF is an integrative framework that was rigorously developed from various psychological theories to help apply theoretical approaches to interventions aimed at behavior change (Atkins, et al., 2017). In other words, the TDF provides a systematic approach for the exploration of implementation issues, the necessary steps for designing an implementation intervention to enhance that issue, and a simpler understanding of behavior change processes while carrying out evidence-based care. (Francis, et al., 2012). While the framework was originally developed to help identify the determinants of healthcare professionals' behavior (Atkins, et al., 2017), it has also been extended as a framework for understanding the underlying factors that influence changing health-related behaviors in patient populations. The final framework resulted in 14 domains (e.g., behavioural determinants such as knowledge, skills, and social influences) with various constructs falling under each domain (Atkins, et al., 2017). It has been successfully applied to investigating the determinants for smoking cessation, implementing dietary guidelines in early childcare education centres and for implementing sepsis-care (Roberts, et al., 2017) (Campbell, et al., 2018) (Grady, et al., 2017).The TDF represents a rigorous theoretical approach, but also a practical framework, to implementation research and can be used to capture the challenges with self-managing T2DM.

1.1.6 Approach to The Study

There is a lack of understanding about the barriers to successful self-management behaviors for patients with Type 2 diabetics in NL and there are few supporting studies for an evidence-based intervention for diabetes self-management. Investigating the domains of the TDF that make behavior and behavior change for self-managing diabetes challenging is needed for successful intervention development. Using the TDF prevents the oversight of factors that may be important determinants of behavior which can lead to an ineffective intervention. Using a theoretical framework to identify barriers to, and facilitators of, diabetes self-management behaviors would assist the development of theory-informed patient interventions. With the rise of technology-supported healthcare and the completion of the RMP, conceivably a mobile

application, that is theory informed and evidence-based, can offer support for self-management to patients in all areas of NL with the chronic disease.

1.2 Purpose

T2DM is prevalent throughout NL and diagnoses are increasing (Diabetes Canada, 2019). It is critical that patients in NL receive help in mitigating the adverse consequences associated with their disease. Therefore, this project will provide the groundwork for systematically moving forward in the creation of a diabetes self-management mobile application for individuals in the province suffering from the unfavorable effects associated with poor self-management of T2DM. A necessary first step is to identify the key domains of the TDF that are preventing healthy self-management behavior. Once patients have identified the key domains of behavior and behavior-change, then these barriers can be addressed by a theory driven approach using specific techniques employed for that domain.

This project is phase 1 of a 2-phase project. The first objective of this study, phase 1, is to investigate the predictors towards T2DM self-care management in a theoretically guided approach. The study employed an anonymous cross-sectional questionnaire, following the termination of the Eastern Health Remote Monitoring Pilot Project, to address T2DM self-management implementation problem in NL. These data can then be used to inform phase 2, the creation of content for an evidence-based mobile application. Phase 2 will be the focus of a subsequent research project.

The secondary objective is to explore if patients in the RMP would use technology to help manage their diabetes and whether they perceive technology as an effective tool for self-management as guidance for the direction of phase 2 of this project.
The next chapter will discuss in more detail the growing epidemic of diabetes at the global, national, and local level, how to properly manage diabetes, the challenges associated with the self-management of diabetes, current diabetes interventions, and the TDF Framework and how it can be used to create content for an evidence-based intervention.

Chapter 2 : Literature Review

The purpose of this literature review is to review and summarize the gaps in clinical literature on the self-management of T2DM and the challenges associated with it. The literature review includes four sections. The first will be the epidemiology of T2DM from a global, national, and local perspective. The second section summarizes the Canadian guidelines for diabetes management. The third takes a closer look at diabetes management including adherence, resources, and facilitators/barriers associated with diabetes that make management difficult. The last section introduces implementation research, including the TDF, the benefits of implementation research and the applicability of implementation research for diabetes self-management.

2.1 T2DM and Epidemiology

T2DM is a progressive, life-long chronic disease that is increasingly affecting the population worldwide (Government of Canada, 2017). The International Diabetes Federation (IDF) has identified diabetes as one of the largest global health emergencies of the 21st century (International Diabetes Federation, 2015). Normally, when the human body ingests food, the body breaks down all the sugars and starches into glucose. When glucose becomes present in the blood, the pancreas releases a hormone called insulin, which attaches to the glucose and moves that glucose from the blood into the human cells. Diabetes Canada defines T2DM as a disease in which the pancreas does not produce enough insulin, or the body does not properly use the insulin it makes; as a result, sugar (glucose) builds up in the blood instead of being used for energy (Association). Prediabetes, a precursor to T2DM, refers to blood sugar levels that are higher than normal, but not yet high enough to be diagnosed as T2DM (Diabetes Canada, 2018). See Table 1 for the World Health Organization (WHO) diagnostic guidelines for diabetes (Punthakee, et al., 2018).

Table 2-1 WHO Diabetes Guidelines for Diagnosing

Hemoglobin A1C level	Diagnosis
42 [mmol/mol] (6%)	Normal
42-47 [mmol/mol] (6.0%-6.4%)	Pre-Diabetes
48[mmol/mol] (6.5%)	T2DM

There are several risk factors for developing T2DM, which can be broken down in two categories: modifiable risk factors and non-modifiable risk factors (Kogan, et al., 2001). Modifiable risk factors include physical inactivity (< 3 times per week), diets that are rich in saturated fats and simple carbohydrates, and obesity (the result of an imbalance in the consumption of calories relative to their expenditure) (Castro, et al., 2009). Non-modifiable risk factors include age, genetics, ethnicity, and family history (Diabetes Canada, 2018). Research shows that 90% of T2DM cases can be primarily attributable to the recent upsurge in obesity due to poor lifestyle factors such as meal plan adherence and insufficient levels of exercise (Hossain, et al., 2007). It is now widely accepted that the growing obesity rates are largely responsible for the rising prevalence of T2DM (Sharma, et al., 2013).

Living with uncontrolled diabetes can cause many complications such as stroke, kidney failure, blindness, cardiovascular disease, strokes, lower limb amputations and early death (Diabetes Canada, 2018). However, with proper self-management, people living with T2DM can live a long and healthy life by keeping their blood sugar levels within a healthy range. Self-management regimes include, but are not limited to, eating healthy meals and snacks, enjoying regular physical activity, monitoring blood sugar levels at home, aiming for a healthy body weight, adhering to medications prescribed by a physician, and managing stress effectively. T2DM complications can be avoided if, again, sugar levels are kept within their target range, smoking is avoided, cholesterol and other blood fats are within a healthy range, blood pressure is healthy, foot care is ongoing, and regular visits with healthcare providers are maintained (Diabetes Canada, 2018).

2.1.1 Global Scale. Diabetes comprises a high portion of the population globally and may be the greatest chronic disease epidemic in the history of human existence; globally, 11.3% of deaths are due to diabetes (IDF Diabetes Atlas , 2019). In 2014, the WHO reported 422 million cases of diabetes, a meteoric rise of 3.8% since 1980 (Mathers, et al., 2006). Today, about one in eleven adults (age 20-79) worldwide are now living with diabetes (463 million people), with almost 90% of diagnoses being T2DM ((NCD-RisC)*, 2016).

In 2010, the global projection for diabetes in 2025 was 438 million; a decade later, that prediction has already been surpassed by 25 million people. The IDF estimates that there will be 578 million adults with diabetes by 2030, and 700 million by 2045. The IDF also estimates that approximately 4.2 million adults will die because of diabetes and its complications in 2019. (IDF Diabetes Atlas , 2019)

In 2017, it was estimated that diabetes healthcare expenditures including their diagnoses and complications, was approximately USD 727 billion dollars worldwide (2019). Two years later, in 2019, the IDF reported annual estimates of USD 760 billion and predicted an increase of costs to USD 825 billion by 2030 and USD 845 billion by 2045 (IDF Diabetes Atlas , 2019).

2.1.2 National Scale. In 2009, the Public Health Agency of Canada reported that diabetes was one of the most common chronic diseases in the country. At the time of that report, close to 2.4 million people were diagnosed with diabetes, or about 6.8 % of the entire population (Public Health Agency of Canada, 2011). Of that 6.8% of diagnoses, 6.4% were females over the age of one and 7.2% were males over the age of one (Public Health Agency of Canada, 2011). In 2013, approximately three million Canadians (an increase of 600,000) were living with diagnosed diabetes, representing 1 in 300 youth (1-19 years) and 1 in 10 adults (20 years and older) (Government of Canada, 2017). Of the three million diagnosed, 8.7% were males and 7.6% were females. The incidence of diabetes in 2013 was 200,000 Canadians, which represented 5.9 new cases per 1,000 people (Government of Canada, 2017). The prevalence is estimated to increase to 12.1% of the population by 2025 (Diabetes Canada).

The prevalence of diabetes varies across Canada. In 2009, NL, Nova Scotia, and Ontario had the highest prevalence in Canada, while Nunavut, Alberta, and Quebec had the lowest prevalence (Public Health Agency of Canada, 2011).

2.1.3 Local Scale. T2DM is a critical health topic in NL. In 2019, the Canadian Diabetes Association estimated that 67,000 people in the province (12%) were living with diabetes, which remains the highest prevalence within Canada. Another 21% of Newfoundlanders and

Labradoreans are living with pre-diabetes, bringing the total number of people experiencing the adverse consequences of diabetes to 182,000 (33%). (Diabetes Canada, 2018)

NL faces many unique challenges for preventing/managing T2DM. Residents in Newfoundland have a median age of 45.7 years, which is the highest among the provinces in Canada. About 16% of the population are above the age of 65 or older (Diabetes Canada, 2018). Approximately 67% of adults and 47% of youth are overweight or obese. Almost three quarters of residents do not eat enough fruit and vegetables daily, and 52% are physically inactive (Diabetes Canada, 2018). Additionally, many residents have challenges with accessing healthcare, as Newfoundland has a rural population that is higher than the national average (Diabetes Canada, 2018).The number of people affected by diabetes and pre-diabetes are estimated to increase to 209,000 (37%) by 2029 (Diabetes Canada, 2018). In 2010, the cumulative costs were $254 million and are estimated to reach $322 million by 2020 (Government of Canada, 2017).

2.2 Canadian Guidelines for T2DM

Every five years, Diabetes Canada releases Clinical Practice Guidelines for the prevention and management of diabetes. The guidelines are meant to improve health outcomes for Canadians and reduce the risk of complications. The most recent guidelines, released in 2018, provide summarizations of key research findings and the most effective treatments. The intended users are all health-care professionals that are involved in the management of people with diabetes and those at risk of developing diabetes, with a focus on primary care or "usual care" providers. The guidelines provide information related to foot care, pharmacologic glycemic control, physical activity and nutritional therapy. The guidelines are also meant to reduce inappropriate variation in practice, promote efficient use of healthcare resources, empower people living with diabetes, identify gaps in knowledge, prioritize research activities, inform public policy, and support quality control activities, including audits of practice (Diabetes Canada, 2018).

Many other countries also provide similar guidelines for diabetes prevention and management. Some countries have written their guidelines targeted for healthcare professionals

who are supporting type 2 diabetics and others, like Canada, have written their guidelines for professionals and patients. Guidelines in the United States (US) are intended for healthcare professionals to better patient care. The guidelines are called ‘’Standards of Medical Care in Diabetes – 2018’’ and were released by the American Diabetes Association (Association, American Diabetes, 2018). The UK provides more specific guidelines called ‘’Type 2 diabetes in adults: Management’’ for their healthcare professionals and patients which were released by the National Institute for Health and Care Excellence in May 2017 (NICE, 2017). Australia published their most recent guidelines, ‘’The General Practice Management of Type 2 Diabetes’’ in 2016. Unlike Canada, these guidelines are written mainly for practitioners. With the aid of the guidelines, practitioners encourage their patients to reach specific goals for optimum self-management of T2DM (Practitioners, 2018).

2.2.1 How to Self-Care for T2DM according to Diabetes Canada Guidelines

Self-care practices are crucial for keeping T2DM under control. Self-care practices include self-monitoring of blood-glucose, adherence to meal plans and exercise routines, and compliance with medication. About 95% of these self-care practices are performed by the patient or by family members. Failure to comply with self-management routines leads to the progression of the disease and severe complications (Bonger, et al., 2018).

To properly begin the management of T2DM, patients should educate themselves with the guidelines provided by the Canadian Diabetes Association. When patients are initially diagnosed with T2DM, healthcare professionals should provide them with education about pharmacological glycemic control, physical activity, and nutritional therapy. The guidelines recommend that anti-hyperglycemic agents should be initiated concomitantly with healthy behaviour interventions, and consideration could be given to initiating combination therapy with 2 agents. Insulin should be initiated immediately in individuals with metabolic decompensation and/or symptomatic hyperglycemia and in the absence of metabolic decompensation, metformin should be the initial agent of choice in people with newly diagnosed T2DM, unless contraindicated. (Diabetes Canada, 2018)

For exercise, Diabetes Canada recommends that patients should try to get at least 150 minutes per week of aerobic exercise (e.g., walking, bicycling or jogging). They should also try to do at least two sessions per week of strength training and avoid prolonged sitting and get up every 20 to 30 minutes. (Diabetes Canada, 2018)

For diet, Diabetes Canada recommends that patients should follow Eating Well with Canada's Food Guide to reach target glycemic levels. Additionally, in people with overweight or obesity with diabetes, a nutritionally balanced, calorie-reduced diet should be followed to achieve and maintain a lower, healthier body weight (Diabetes Canada, 2018). There is not a one-size-fits-all eating plan for T2D, which can make meal planning difficult for patients. For many individuals with T2DM, following a meal plan for glycemic control is the most challenging part of treatment (Association, American Diabetes, 2018).

2.2.2 What Does Following a Meal Plan Entail in the Guidelines

Nutritional management is a primary area that Type 2 diabetics should focus on for self-management and reducing the risk of complications. Because almost 90% of people living with T2DM are overweight or obese, a modest weight loss of 5 to 10% of initial body weight can substantially improve glycemic control (Diabetes Canada, 2018).

The guidelines by Diabetes Canada suggest that patients should eat three meals per day at regular times and space meals no more than six hours apart. If patients eat at regular times, their bodies have better control over managing their blood glucose levels. Patients diagnosed with T2DM should also limit sugars and sweets, because higher levels of sugar mean higher blood glucose levels. The guidelines also encourage people with diabetes to limit high fat foods (i.e., chips and pastries), eat foods high in fiber and limit alcohol consumption as it can lead to weight gain (Diabetes Canada, 2018).

When planning meals, patients should follow Eating Well with Canada's Food guide. Basic Meal Planning from Canada's Food Guide includes lean meat, vegetables, grains & starches and milk and Alternatives as per the recommendations of Diabetes Canada (Diabetes Canada, 2018). Patients are also encouraged to meet individually with a registered dietician to

develop a more personalized plan to help reach their target blood sugar levels. Total caloric intake should reflect the weight management goals for people with diabetes to prevent further weight gain and achieve a lower body weight long term (Diabetes Canada).

2.3 Non-Adherence for Self-Managing T2DM

Adherence and compliance to self-management of T2DM was defined by the WHO as the extent to which a person's behaviour with respect to taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a healthcare provider (World Health Organization, 2003). Patients with T2DM are initially encouraged to maintain a healthy diet, exercise routine and medication therapies. Despite the benefits of following these regimens, less than 50% of patients are achieving the recommended glycemic levels for controlling T2DM from complying with the recommended therapies (Garcia-Perez, et al., 2013).

There is some evidence to support that patients with T2DM find it extremely difficult to self-manage their disease to control their glycemic levels. In 2018, Patient Preference and Adherence published a study from a special care hospital in Ethiopia with 422 patients living with T2DM, from the ages of 30-76, that assessed the adherence to self-care practices for T2DM management. In this study, 75.9% of participants did not adhere to diet management practice, 53.7% of participants did not adhere to exercise practices, and 83.5% of participants did not adhere to the self-monitoring of their blood glucose levels. The study concluded that adherence to T2DM self-management is substantially low and patients have great difficulty self-managing their disease. (Bonger, et al., 2018)

The adoption of new food habits is not an easily achieved goal and is the main challenge in non-adherence to self-management regimes (Alghafri, et al., 2017) (Laranjo, et al., 2015) (Halali, et al., 2016) (Fort, et al., 2013) (Booth, et al., 2013). Diabetic patients encounter several educational, environmental, psychological and lifestyle difficulties in modifying their diets to accommodate disease management. Barriers to dietary adherence include complications with daily life (eating out, social events) and temptations, need for food planning, need for constant

self-care, denial of the severity of the disease, poor understanding of diet-disease associations, misinformation, lack of appropriate social support and time constraints (Yannakoulia, 2006).

2.3.1. Barriers to Self-Managing T2DM

There are various reasons, both individual and environment-related, that contribute to the suboptimal adherence to self-management regiments. Table 2-2, below, highlights self-reported barriers to the self-management of T2DM. Limitations of such studies include reliance on self-report data given that data may be exaggerated or may be subject to social desirability bias. Additionally, data may not be accurate because of a person's introspective ability, meaning participants may not be able to accurately assess themselves.

The barriers that were frequently reported among most studies were lack of support system, lack of knowledge around self-managing diabetes, and lack of motivation, self-discipline and knowledge around following a diet for diabetes management. Studies also reported that participants had difficulties coming to terms and disclosing their disease, had little access to resources for T2DM management (healthy foods, healthcare, dieticians), experienced difficulties with exercising and experienced emotional suffering from living with T2DM.

Table 2-2 Reasons for Non-Adherence to the Self-Management of T2DM

Study Objective	Barriers Identified for the Self-Management of T2DM
To identify family behaviours that adults with T2DM perceive as having an impact on their diabetes self-management. (Vongmay, et al., 2017)	1. Obstructive behaviours (regular reminders and/or nagging) 2. Lack of support or engagement
To identify barriers to performing leisure time physical activity and explore differences based on gender, age, marital status, employment, education, income and perceived stages of change in physical activity of people with T2DM. (Alghafri, et al., 2017)	1. Lack of willpower 2. Lack of resources 3. Lack social support 4. Lack of time
To identify barriers to performing leisure time physical activity and explore differences based on gender,	1. Situational barriers/difficulty resisting temptation

Study Objective	Barriers Identified for the Self-Management of T2DM
age, marital status, employment, education, income and perceived stages of change in physical activity in adults with T2DM in Oman. (Halali, et al., 2016)	2. Stress-related eating problems/high expenses 3. Difficulty with meal and snack plans 4. Confusion about dietary recommendations 5. Work-related problems 6. Small portion sizes 7. Lack of palatability/family support
To actively engage community members in research to identify strategies to improve T2DM self-management in an urban community in Baltimore, MD. (Purnell, et al., 2016)	1. Neighbourhood resources 2. Daily environment 3. Healthcare quality
To identify factors associated with T2DM self-management. (Luo, et al., 2015)	1. Locus of control 2. Depressive symptoms 3. Complications 4. Living alone
To assess the facilitators, barriers and expectations in the self-management of T2DM, as perceived by patients. (Laranjo, et al., 2015)	1. Diet (Lack of motivation, self-control, will-power, cost, lack of knowledge and skills, portion control, and lack of social support around dieting.) 2. Physical exercise (Lack of motivation and will power, not having habit formed, fatigue, muscle and joint pain, limiting co-morbidities, lack of knowledge/information, and lack of social support). 3. Lack of Glycaemic control (stress, confusion, discomfort)
To explore perceived barriers and facilitators to T2DM self-management. (Shen, et al., 2013)	1. Overdependence on but dislike of Western medicine 2. Family role expectations 3. Cultural cuisine 4. Lack of trustworthy information sources 5. Deficits in communication between clients and health professionals 6. Restriction of reimbursement regulations
To identify factors associated with T2DM self-management. (Fort, et al., 2013)	1. Not accepting the disease 2. Lack of information about symptoms 3. Vertical communication between providers and patients

Study Objective	Barriers Identified for the Self-Management of T2DM
	4. Difficulty negotiating work & health care commitments 5. Perception of healthy food as expensive or not filling 6. Difficulty adhering to treatment and weight loss plans 7. Additional health complications 8. Health care becoming monotonous
To explore the views of individuals recently diagnosed with T2DM in relation to self-management of dietary intake and physical activity, and to compare these with the views of health professionals. (Booth, et al., 2013)	1. Changing established habits 2. Negative perception of the new regimen (dislike food recommendations/diet planning for T2DM meal planning) 3. Lack of social support around dieting 4. Lack of knowledge and understanding around T2DM self-management 5. Lack of motivation 6. Not recognizing T2DM as a serious condition 7. Practicalities (cost of healthy diet, access to healthy diet, exercise facility/environment)
To identify perceived barriers among Hispanic immigrants with T2DM and their family members. (Hu, et al., 2013)	1. Emotional/physical suffering from diabetes 2. Difficulty managing medication 3. Difficulty controlling diet 4. Difficulty with exercise 5. Lack of resources and support social support
To better understand differences in diabetes self-management, specifically needs, barriers and challenges among men and women living with T2DM. (Matthew, et al., 2012)	1. Disclosure and identity as a person living with diabetes 2. Self-monitoring of blood glucose 3. Diet struggles across varying contexts 4. Utilization of diabetes resources 5. Social support
To identify facilitators and barriers to self-management of T2DM among urban African American adults. (Chlebowy, et al., 2010)	1. Time consumption 2. Lack of self-control 3. Pain 4. Memory failure
To identify the barriers to and facilitators of self-management adherence in Korean older adults with T2DM. (Song, et al., 2010)	1. Aging-related physical and cognitive limitations 2. Lack of self-discipline 3. Restrictions related to specific culture factors

Study Objective	Barriers Identified for the Self-Management of T2DM
	4. Poor understanding of self-management

2.3.2 T2DM Self-Management Interventions

Clearly, there are many barriers and challenges associated with the self-management of T2DM. It is a complex series of self-management behaviors; efforts to positively influence T2DM self-management must acknowledge this complexity. When designing complex behavioural interventions, recent developments in the field of behavioral change encourage a theoretical, systematic approach that has the potential to inform the choice of intervention components through the identification of barriers (Richardson, et al., 2019). One issue with having little or no theoretical basis for intervention planning is that strategies adopted for implementation, and tools selected as mechanisms to induce behavior change, are neither tightly linked to strategy nor to any underlying theory; as a result, there is little reason to believe these strategies would succeed in changing behavior (Sales, et al., 2006).

In 2013, a systematic review examined current T2DM interventions and their effectiveness. The review identified 16 randomized controlled trials with 3578 participants that used various types of interventions including clinic-based, internet based, and mobile-phone based. None of the included studies showed evidence of a theory-informed intervention. The study concluded that existing interventions to help adults self-manage T2DM appeared to have a small positive effect on blood sugar control and that there was no evidence of the interventions helping with health-related quality of life. (Pal, et al., 2013)

In 2017, a study that incorporated a cognitive behavioural approach to change the behaviour of patients living with T2DM proved to be effective. The intervention was a 9-month program which included a motivational program, a nutrition program, and an exercise program. A significant improvement ($p<0.05$) was observed in all self-management behaviors for T2DM (Galle, et al., 2017). Furthermore, a systematic review of 20 studies with 5802 participants looked at interventions utilizing one or more theories showed evidence at being much more effective than those which were not theory-informed (Zhao, et al., 2016). The pooled main outcomes by a random-effects model showed significant improvements in HbA1c, self-efficacy,

and T2DM knowledge (Zhao, et al., 2016). The review concluded by recommending implementation research (involving the role of the patient in research/design of intervention) in future studies to produce more effective theory-based interventions (Zhao, et al., 2016).

Evidently, there is an existing gap between research and practice that can be bridged by working with the population of interest to address the implementation issues. There is ample research completed that highlights the many challenges/barriers for self-managing T2DM (as outlined in Table 2.2) and many existing interventions (as noted above). However, people living with T2DM still find it challenging to change their behaviour to better manage their condition. With the use of implementation research and theoretical frameworks, there is an opportunity to systematically create an intervention that is both theory- informed and evidence-based to successfully help people living with T2DM change their behaviour.

Implementation Research is the ‘’scientific inquiry into questions concerning implementation – the act of carrying an intention into effect, which in health research, can be policies, programmes, or individual practices called interventions’’ (Peters, et al., 2013). The intent of implementation research is to work with populations that will be affected by an intervention. The TDF has been used extensively in implementation research and provides a theoretical lens to view the cognitive, affective, social and environmental influences on behaviour (Atkins, et al., 2017).

2.4.1 The TDF

The TDF was constructed in collaboration with implementation researchers and behavioural scientists to synthesize behaviour change factors that may enable or impede the implementation of evidence-based practice and guidelines (Michie, et al., 2017). The TDF was developed through a rigorous consensus process, including factor analysis and validation to identify psychological and organizational theory related to behaviour change (Phillips, et al., 2015). The framework is a collaboration of theoretical constructs and various theories that are relevant to implementation questions and condensed into an accessible framework, which allow researchers to find determinants that enable or impede behaviour or behaviour change (Atkins, et al., 2017).

Originally, the framework was a synthesis of 33 theories of behaviour and behaviour change and contained 128 key theoretical constructs clustered into 12 domains to assess implementation and other behavioural issues and inform intervention design with healthcare professionals in a clinical setting (Atkins, et al., 2017). Following further refinement, the framework is now clustered into 14 domains with 84 constructs, which is now available to various disciplines to assess implementation issues with patient populations, in addition to healthcare professionals (Atkins, et al., 2017). The final 14 domains are: Knowledge, Skills, Professional Role and Identity, Beliefs about Capabilities, Optimism, Beliefs about Consequences, Reinforcements, Intentions, Goals, Memory, Attention and Decision Process, Environmental Context and Resources, Social Influences, Emotions, and Behavioural Regulation. The TDF domains and their descriptors, as well as their respective constructs are outlined in the following Table. Definitions for the domains and constructs were selected from the study 'Validation of the theoretical domains framework for use in behaviour change and implementation research', which were selected/constructed from dictionaries, (e.g. American Psychological Association Dictionary of Psychology) (Cane, et al., 2012) . Table 2.3 below presents the definition of each domain and their respective constructs and also includes a definition of the domain in the context of following a meal plan for the self-management of T2DM.

Table 2-3 The Fourteen Domains of the TDF with Defintions and Constructs

Domain (definition)	**Constructs**	**Definition in the context of this study**
1. **Knowledge** (An awareness of the existence of something)	• Knowledge (including knowledge of condition/scientific rationale) • Procedural knowledge • Knowledge of task environment	Individual's awareness and familiarity of following a meal plan to help self-manage T2DM
2. **Skills** (An ability or proficiency acquired through practice)	• Skills • Skills development • Competence • Ability • Interpersonal skills	Individual's skills, practice, and ability to follow a meal plan to help self-manage T2DM

	• Practice • Skill assessment	
3. **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 • Organizational commitment	This domain was omitted from study as the questions from the template questionnaire were found to be inapplicable to a patient population
4. **Beliefs about capabilities** (Acceptance of the truth, reality or validity about an ability, talent or facility that a person can put to constructive use)	• Self-confidence • Perceived competence • Self-efficacy • Perceived behavioural control • Beliefs • Self-esteem • Empowerment • Professional confidence	Individual's confidence in following a meal plan to help self-manage T2DM
5. **Optimism** (The confidence that things will happen for the best or that desired goals will be attained)	• Optimism • Pessimism • Unrealistic optimism • Identity	Individual's confidence that they will follow a meal plan to help self-manage T2DM
6. **Beliefs about Consequences** (Acceptance of the truth, reality, or validity about outcomes of a behaviour in a given situation)	• Beliefs • Outcome expectancies • Characteristics of outcome expectancies • Anticipated regret • Consequents	Individual's belief about benefits/disadvantages of following a meal plan to help self-manage T2DM
7. **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	The extent of recognition and reward the individual will receive for following a meal plan to help self-manage T2DM

8. Intentions (A conscious decision to perform a behaviour or a resolve to act in a certain way)	• Stability of intentions • Stages of change model • Trans theoretical model and stages of change	Individual's intentions of following a meal plan to help self-manage T2DM
9. Goals (Mental representations of outcomes or end states that an individual wants to achieve)	• Goals (distal/proximal) • Goal priority • Goal/target setting • Goals (autonomous/controlled) • Action planning • Implementation intention	The relative importance for an individual to follow a meal plan to help self-manage T2DM
10. Memory, attention and decision processes (The 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/tiredness	Individual's aptitude to follow a meal plan to help self-manage T2DM as part of their regular practice
11. Environmental context and resources (Any circumstance 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 • Organizational culture/climate Salient events/critical incidents • Person × environment interaction • Barriers and facilitators	Individual's environment/situation that encourages/discourages following a meal plan to help self-manage T2DM
12. Social influences (Those interpersonal processes that can cause individuals to change their thoughts, feelings, or behaviours)	• Social pressure • Social norms • Group conformity • Social comparisons • Group norms • Social support • Power • Intergroup conflict • Alienation • Group identity	Individual's surrounding relationships that influences them to follow a meal plan to help self-manage T2DM

	• Modelling	
13. 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	Individual's emotions to following a meal plan to help self-manage T2DM
14. Behavioural regulation (Anything aimed at managing or changing objectively observed or measured actions)	• Self-monitoring • Breaking habit • Action planning	Individual's management/planning of following a meal plan to help self-manage T2DM

2.4.2 Interventions Supported by Theory

As stated previously, the TDF provides a systematic approach for the exploration of implementation issues, the necessary steps for designing an implementation intervention to enhance that issue, and a simpler understanding of behavior change processes while carrying out evidence-based care (Francis, et al., 2012). In the context of this project, the TDF is a practical approach to implementation research and can capture the perceived barriers that are inhibiting diabetics from living healthy lifestyles, as well as identify the domains that are acting as facilitators to encourage behaviour change. The idea behind using the TDF is that its systematic approach to identifying significant diabetes self-management barriers allows targeted treatment interventions via the Behaviour Change Wheel (BCW). Together, the TDF and the BCW make it possible to inform the choice of intervention components (Richardson, et al., 2019).

The BCW consists of ''COM-B'' model (Capability, Opportunity and Motivation to Behaviour) at the hub of the wheel. This model recognizes that behaviour is part of an interacting system involving all these components (Michie, et al., 2014). The BCW was developed as a ''behaviour system'' designed to link the identified determinants of behaviour (using the TDF) to the mapping of appropriate Behaviour Change Techniques (BCT) to inform interventions

(Cowdell, et al., 2019). BCTs are a reliable method for creating interventions that lead to behaviour change and provide a pathway to determine the intervention content needed to achieve behaviour change for a target behaviour (Michie, et al., 2017). Research shows that when interventions are designed using this approach, the intervention is found to be more effective (Michie, et al., 2017). In the context of this project, for example, if knowledge was found to be a significant barrier to T2DM self-management, the BCW displays which interventions would be most effective in targeting changes in knowledge. Other domains (e.g., emotions, habits, environment) have specific interventions linked to them in the BCW. Theoretically, this targeted linking of behavioral barrier to specific intervention should increase intervention effectiveness.

2.4.3 The use of TDF in Practice

The TDF has been cited in over 800 publications and has been extensively used across a vast range of clinical settings (based on library searches, this number has nearly doubled in 2020) (Atkins, et al., 2017). In most cases, the TDF has been applied to healthcare professional populations, and not patients. Table 2-4, on the following page, demonstrates various contexts where the TDF has been successfully applied to professionals, and in recent cases patients, to identify determinants of behaviour that will be targeted to change behaviour.

Table 2-4 Examples of when the TDF has been used in Implementation Research

Title of Study	Population	Justification for Study	Conclusion
Use of the TDF Framework to evaluate factors driving successful implementation of the Accelerated Chest Pain Risk Evaluation (ACRE) project. (Skoien, et al., 2016)	Clinician Stakeholders who attended an ACRE project forum	The translation of healthcare research into practice is typically challenging and limited in effectiveness. The ACRE project has successfully translated research into practice, by implementing an intervention to improve the assessment of low to intermediate risk patients presenting to emergency departments (EDs) with chest pain.	‘’The ACRE project was successful, and therefore, a perfect case study for understanding factors which drive implementation success. The overwhelmingly positive response suggests that it was a successful programme and likely that each of these domains was important for the implementation. However, a lack of variance in the responses hampered us from concluding which factors were most influential in driving the success of the implementation. The TDF offers a useful framework to conceptualise and evaluate factors impacting on implementation success. However, its broad scope makes it necessary to tailor the framework to allow evaluation of specific projects.’’
The demonstration of a theory-based approach to the design of localized patient safety interventions. (Taylor, et al., 2013)	Practitioners	This work aimed to demonstrate the applicability, feasibility, and acceptability of a theoretical domains framework implementation (TDFI) approach for co-designing patient safety interventions.	‘’The TDF is a feasible and acceptable framework to guide the implementation of patient safety interventions. The stepped TDF approach engages healthcare professionals and facilitates contextualization in identifying the target behavior, eliciting local barriers, and selecting strategies to address those barriers. This approach may be of use to implementation teams and policy makers, although our promising findings confirm the need for a more rigorous evaluation; a balanced block evaluation is currently underway.’’
to Develop an App to Increase Uptake and Attendance at NHS Stop Smoking	Patients	Smokers who attend National Health Service SSS are four times more likely to stop smoking; however, uptake has been in	‘’In Phase 1 we collected data to explore the barriers and facilitators to people using SSS. In Phase 2, data from extant literature and Phase 1 were subject to behavioural analysis, as outlined by the BCW

Services (SSS) StopApp: Using the (Fulton, et al., 2016)		decline. We report the development of an intervention designed to increase uptake of SSS, from a more motivated self-selected sample of smokers.	framework. Relevant BCT were identified in order to address these, informing the content of the StopApp intervention. In Phase 3 we assessed the acceptability of the StopApp. Smokers and ex-smokers identified a number of barriers to attending SSS, including a lack of knowledge about what happens at SSS (Capability); the belief that SSS is not easy to access (Opportunity); that there would be 'scare tactics' or 'nagging'; and not knowing anyone who had been and successfully quit (Motivation).''
Barriers and Enablers to Implementation of Dietary Guidelines in Early Childhood Education Centers in Australia: Application of the TDF. (Grady, et al., 2017)	Professional Cooks	To identify perceived barriers and enablers to implementation of dietary guidelines reported by early childhood education center cooks, and barriers and enablers associated with greater implementation based on assessment of center menu compliance.	''Cooks perceived social/professional role and identity, and beliefs about consequences to be enablers to dietary guideline implementation; however, only the skills domain was associated with greater implementation. There are opportunities to target the incongruence in perceptions vs reality of the barriers and enablers to implementation. Future research could examine the utility of the TDF to identify barriers and enablers to implementation to inform intervention development and for evaluating interventions to examine intervention mechanisms. ''
Barriers and facilitators towards implementing the Sepsis Six care bundle (BLISS-1): a mixed methods investigation using the TDF. (Roberts, et al., 2017)	Healthcare Professionals	The 'Sepsis 6', a care bundle of basic, but vital, measures (e.g. intravenous fluid, antibiotics) has been implemented to improve sepsis treatment. However, uptake has been variable. Tools from behavioral sciences, such as the TDF may be used to understand and address such implementation issues. This study used a behavioral science approach to identify barriers and facilitators towards	''A range of barriers and facilitators towards Sepsis Six performance across different staff groups were systematically identified using a theoretically informed approach. This can inform development of targeted performance improvement interventions. ''

		Sepsis Six implementation at a case study hospital.	
Barriers and facilitators to the implementation of a school-based physical activity policy in Canada: application of the TDF. (Weatherson, et al., 2017)	Teachers	In British Columbia Canada, a Daily Physical Activity (DPA) policy was mandated that requires elementary school teachers to provide students with opportunities to achieve 30 min of physical activity during the school day. However, the implementation of school-based physical activity policies is influenced by many factors. A theoretical examination of the factors that impede and enhance teachers' implementation of physical activity policies is necessary to develop strategies to improve policy practice and achieve desired outcomes. This study used the TDF to understand teachers' barriers and facilitators to the implementation of the DPA policy in one school district.	''Teachers identified barriers and facilitators relating to all TDF domains, with ECR, Beliefs about consequences, Social influences, Knowledge and Intentions being the most often discussed influencers of DPA policy implementation. Use of the TDF to understand the implementation factors can assist with the systematic development of future interventions to improve implementation.''
Improving Behavioral Support for Smoking Cessation in Pregnancy: What Are the Barriers to Stopping and Which Behavior Change Techniques Can Influence	Professional Cessation Experts	Behavioral support interventions are used to help pregnant smokers stop; however, of those tested, few are proven effective. Systematic research developing effective pregnancy specific behavior change techniques (BCTs) is ongoing. This paper reports contributory work identifying potentially effective BCTs relative to known important	''From 14 trials, 23 potentially-effective BCTs were identified (e.g., information about consequences). Most B&Fs fell into "Social Influences", "Knowledge", "Emotions" and "Intentions" TDF domains; few potentially-effective BCTs mapped onto every TDF domain. B&Fs identified by experts as important to cessation, are not sufficiently targeted by BCT's currently within interventions for smoking cessation in pregnancy.''

These? Application of TDF. (Campbell, et al., 2018)		barriers and facilitators (B&Fs) to smoking cessation in pregnancy; to detect priority areas for BCTs development.	
Application of the TDF to identify factors that influence hand hygiene compliance in long-term care. (Smith, et al., 2018).	Healthcare Professionals	Healthcare worker (HCW) hand hygiene compliance is key to patient safety; however, compliance is suboptimal. Nevertheless, hand hygiene compliance is not well studied in the long-term care setting.	‘’There are several barriers to hand hygiene compliance that persist in long-term care. A behaviour change theory-informed framework such as the TDF can be helpful to identify those barriers. This study identified several key behavioural constructs aligned with the TDF that can be targeted when developing novel hand hygiene interventions.’’

2.5 The Use of Technology as a Platform for T2DM Interventions

We live in a world of exponentially increasing technology advancements and as these technological innovations continue to grow, there is a valuable opportunity to develop the ideal platform to encourage people living with T2DM to adopt and maintain healthy behaviours. Recent findings have reported that the adoption of technology may improve older adults' quality of life, facilitate independent living for longer, and bridge the gap across generations by teaching older people to use technological devices (Vaportzis, et al., 2017). One particular way to achieve greater quality of life through technology is through a mobile application, more commonly referred to as an ''App'', which can be accessed on any smartphone. A study from 2019 revealed that approximately 26.1 million Canadians (69.4% of Canada's population) have a mobile phone with internet capabilities (i.e., a smartphone) and that number is expected to grow in the next few years (Clement, 2019).

There are many forms of clinical intervention (i.e., internet-based, mobile-based, and clinic-based); however, mobile application interventions are said to be an ideal platform for efficient interventions due accessibility (easy way to reach target group) and are cost effective compared to other types of interventions (Lee, et al., 2018). In previous years, mobile applications could be used to access information and feedback, self-reporting, monitoring, data collection, and schedule reminders. However, with technological advancements such as real-time feedback, people can receive individualized information about their health, may feel increased motivation due to the ability of instant communication and community, and lastly can ultimately change behaviour (Lee, et al., 2018). Therefore, as the global prevalence of T2DM continues to grow and technology continues to develop, a mobile application may provide the ideal platform to provide a theory-informed intervention for the self-management of T2DM.

2.6 Summary of Gaps in the Clinical Literature

In summary, a review of the clinical literature revealed that T2DM is a major health crisis, with a rising prevalence, and that a major gap exists in relation to the self-management of T2DM. T2DM is a challenging disease that often requires individual behavior change. There are several self-management interventions that exist; however, very few seem particularly effective

except in the short-term. Implementation research in relation to T2DM appears to be relatively unexplored area of study and most interventions are not informed by theory. Given the global public health burden of T2DM, its composition of several complex behaviors (diet, physical activity, medication adherence, and emotional barriers, disease denial) and the necessity of intervening with some chance of success – the TDF is a logical choice in which to frame the question of what are the barriers that could be targeted in future intervention research.

Chapter 3 : Methods

This a cross-sectional study. A questionnaire was mailed out to patients living with T2DM enrolled in the RMP at Eastern Health. The questionnaire examined the barriers and enablers of following a meal plan to help people living with T2DM better manage their disease. Using the questionnaire, the goal of the study was to identify the most significant barriers and facilitators that predict intention to follow a meal plan as set out by Eating Smart with Canada's Food Guide. The questionnaire development process included the use of the TDF), multiple patient engagement sessions, and followed a validated TDF generic questionnaire. This cross-sectional study is the first to use a TDF-based questionnaire to assess behaviour related implementation issues in this population. This chapter provides an overview of the study's research questions and objectives, study population, population recruitment, questionnaire development, data analysis, and ethical considerations.

3.1 Research Question

In adult patients, living with T2DM and enrolled in the RMP in NL, which behavioural domains of the TDF are predictors for their intention to follow a meal plan for successful T2DM management?

3.2 Objectives

The primary objective of the study is to identify which behavioral domains of the TDF (e.g., knowledge, social influence, skills) will predict the intention to follow a meal plan for the self-management of T2DM for subsequent intervention development.

The secondary objective is to explore if patients in the RMP would use technology to help manage their T2DM and whether they perceive technology as an effective tool for self-management.

3.3 Recruitment of Participants

Study participants included all patients registered for the RMP at the time of recruitment. All participants were reached through the postal system and received an envelope that contained a cover letter to explain the purpose of the study and what participation would entail, as well as the questionnaire itself. The envelope contained a letter from the RMP manager that explained :(a) that the RMP agreed to send out the questionnaires on behalf of the research team, (b) the purpose of the study, (c) participation entailed filling out an 8-page questionnaire, and (d) participation was completely voluntary.

3.3.1 Population and Sample

At the time of questionnaire distribution, there were 300 participants registered in the program, all of whom were sent a questionnaire package. The population enrolled in the RMP include adults 18 years of age or older, living with T2DM in various regions across NL, including both urban and rural areas. As part of the
RMP, patients were advised on how to follow the guidelines set out by Diabetes Canada. They also received two handouts from Diabetes Canada on Nutrition called ‘’Just the Basics’’ and ‘’Beyond the Basics’’. Additionally, the program discussed the appropriate carbohydrate and protein intake for meals and snacks and explained to patients how to read and use food labels.

3.4 Questionnaire Development

The TDF was used to develop the questionnaire and in the interpretation of survey results. The TDF was chosen as a method for this study because it incorporates 33 theories of behavior and behavior change and because of its use in implementation research (Atkins, et al., 2017). The use of the TDF allows a systematic approach to evidence-based intervention design and will allow for future development of an intervention to help patients better manage their diabetes (Atkins, et al., 2017) (Seward, et al., 2017) (Beenstock, et al., 2012). Various patient engagement activities were completed to inform the content of the questionnaire. The final

behavior, following a meal plan, for the self-management of T2DM was carefully chosen based on the common themes of the patient engagement sessions and literature.

3.4.1 Questionnaire Item Generation

Theoretically-framed questions were derived from following the guidelines and template provided in a study by (Huijg, et al., 2014). The template questionnaire used was constructed to assess the 14 domains of behavioral determinants from the revised TDF (14 domains versus the original 12) that can be tailored to suit different targets, actions, contexts and times of interest (Cane, et al., 2012). The items for this study were adapted to suit the target behavior of ‘’following a meal plan for the self-management of T2DM’’. The items were reviewed with a research team that included a health psychologist, Dr. Holly Etchegary, an expert on weight management, Dr. Laurie Twells, and a health services and implementation researcher, Dr. Amanda Hall. The questionnaire was also piloted prior to sending out the final version to the project participants. Two people affected by T2DM reviewed the questionnaire for any potential issues; the only major feedback was the length of the questionnaire as well as the repetitiveness in some questions, both issues that could not be changed due to the nature of the TDF.

The template questionnaire, like most previous TDF studies, was designed for healthcare professionals’ implementation behaviors; therefore, questions in the current study were reworded for administration in a patient population and domains that were not applicable to a patient population were removed. As a result, the final questionnaire included questions that measured the effect of 13 behavior domains versus 14 domains. ‘Social and Professional Role and Identity’ was excluded from the study, as this domain on the template survey focused on the social aspect of a healthcare professional’s role in the workplace and was not relevant to a study assessing patient’s self-management of T2DM. The generic questionnaire that was used to design this study tool, with questions relating to a healthcare professional population can be found in Appendix A-Template Questionnaire with Items and Related Constructs and Domains.

3.4.2 Diabetes Self-Management Behaviors

For the TDF to be an effective implementation tool, researchers must choose only one specific target behavior and action when creating the data collection tool (Atkins, et al., 2017).

This was particularly difficult for this study, since the self-management of diabetes includes several behaviors.

The American Diabetes Association of diabetes educators has defined the outcome of diabetes self-management care as behaviour change (Mulcahy, et al., 2003). There are seven core behaviours that measure the effectiveness of self-care management in the context of diabetes. They are as follows:

1. Being active: physical activity
2. Eating: following a meal plan
3. Medication Taking
4. Monitoring of blood glucose
5. Problem solving especially for blood glucose
6. Reducing risks of diabetes complications
7. Living with diabetes (psychosocial adaptation)

It is not possible to measure all seven behaviours with one TDF questionnaire. Rather, the TDF approach suggests choosing a behaviour that is modifiable, that is central to bringing about the desired change in a clinical setting, that will not subsequently cause negative effects on other related behaviours, and that can be measured (Atkins, et al., 2017). There is evidence that following the recommended food guidelines for managing diabetes can result in positive self-management of diabetes and clinically successful reductions in Hemoglobin a1C levels as well as a healthy weight loss (1-2 pounds (lbs) per week) (Mulcahy, et al., 2003).

3.4.3 Patient Engagement

A number of patient engagement activities were completed that informed the development of the questionnaire and helped with narrowing down which behavior to focus on for the self-management of T2DM. The first patient engagement session was held on May 28th 2017 at the Walk for Diabetes Event followed by the second, held on May 30th at Memorial University of Newfoundland's medical school and lastly the third session was held on November 28th at a Sobeys's diabetes cooking class along with a registered dietician. During the three sessions, the researchers engaged with patients living with T2DM and healthcare professionals who work directly with patients living with T2DM. Patients and healthcare professionals

highlighted key challenges of self-managing T2DM. Research team members took detailed field notes, including some verbatim quotes. All notes were documented and are included in Appendix C. One of the main themes that emerged during these engagement sessions was the challenges around eating. All engagement sessions helped inform the development of the content for each of the 73 TDF questions on the questionnaire.

3.3.4 Target Questionnaire Behaviour

With the importance of diet for T2DM management and the themes that emerged during the three patient engagement sessions, researchers felt that following a meal plan was an adequate target behaviour to measure and investigate the determinants of behaviour that are preventing or enhancing behaviour change for the self-management of T2DM. By choosing just one of the seven core behaviours of T2DM self-management, the results will be more precise and give a greater specificity to the barriers and enablers identified (Atkins, et al., 2017). The final questionnaire can be found in Appendix B Appendix B-Complete Questionnaire Package.

3.5 Data Instrument

The questionnaire was divided in two sections: “Part A – Experience with following a meal plan to help manage your diabetes” and "Part B – Some information about you”.

3.5.1 Part A

The TDF portion of the questionnaire included 73 items to assess the barriers and enablers of following a meal plan to self-manage T2DM. Questionnaire items were generated based on their respective domains. The questionnaire used at least two questions relating to each domain to ensure that each domain was accurately assessed. The following 13 domains were included on the questionnaire, 1) knowledge 2) skills, 3) beliefs about capabilities, 4) optimism, 5) beliefs about consequences, 6) reinforcement, 7) intentions, 8) goals, 9) memory, attention and decision processes, 10) environmental context and resources, 11) social influences, 12) emotion and 13) behavioral regulation. Each of the 73 items utilized a 5-point Likert scale, where higher scores indicated higher agreement. Each question was derived using a similar target (i.e., self-

management of T2DM) and action (i.e., following a meal plan). The questionnaire was developed to take less than 30 minutes to complete.

3.5.2 Part B

A subsequent section called "Part B-some information about you" was added. This section included items designed to collect demographic data (e.g., sex, age, height, weight and health authority) and self-reported health data, such as whether the participant had high blood pressure, sleep apnea, high cholesterol, osteoarthritis, coronary artery disease or whether patients were on medications to manage their T2DM (e.g., insulin usage) and lastly how long the participant has been diagnosed with T2DM.

A final single item was added as an open-ended question to ask for participants' thoughts on whether they would use an e-intervention to help manage their T2DM and whether they would find an intervention of this type effective for the self-management of T2DM.

3.6 Procedure

The research team prepared the questionnaire package for dissemination. The full package included:

A 1 x 11''x14'' envelope containing:

i. An 8''x10'' 5-page questionnaire
ii. An 8''x10'' 1-page letter from RMP
iii. An 8''x10'' 4-page cover letter for project
iv. 1 folded 11x14 envelope (postage-paid)
v. Pre-paid postage card for Visa Draw

After questionnaire packages were completed and sealed, the research team delivered them to the RMP at the Waterford Hospital located in St John's, NL. Program staff labeled all envelopes with the appropriate addresses and the questionnaire was disseminated by Eastern Health's mailroom on behalf of the study team. Participants received a questionnaire package from the RMP containing the letter of information which gives a description of the questionnaire, asked participants to complete the enclosed questionnaire, and expressed that participation is completely voluntary. The letter from the RMP explained to the patients that Eastern Health has agreed to send out questionnaire packages on behalf of Memorial University Researchers for this

project. The postage paid envelope was included so patients could return the questionnaire free of charge, and the postage card was included so patients had a chance to win a $50 dollar Visa gift card, and finally the questionnaire itself. Patients used the provided pre-paid envelope to return the questionnaire back to the research team with no personal identifiers on the questionnaire. The full questionnaire package can be found in Appendix B-Complete Questionnaire Package Mailed to Study Participants.

3.6.1 Assessment time points

Questionnaire packages were mailed out on January 7th, 2019. The data collection period ended April 8th, 2019.

3.8 Sample Size

The goal of the project was to determine the predictors of intention to follow a meal plan. Green (Green, 1991) provides a comprehensive overview of the procedures used to determine regression sample sizes. He suggests N > 50 + 8m (where m is the number of independent variables) for testing the multiple correlation and N > 104 + m for testing individual predictors (assuming a medium-sized relationship). If testing both, use the larger sample size. There were 12 independent variables (e.g., the content domains of the theoretical framework) for predicting intention to follow a meal plan whereas the domain intention was used as the dependent variable in this study. Thus, to test the overall regression equation, there needed to be 50 + 8 (12) = 146 questionnaire respondents.

3.9 Data Management

All returned questionnaires were received by post and stored in the office of the project lead, Taylor Wilson. The data was entered directly into IBM Statistical Package for Social Science (SPSS) Statistics v23 and stored electronically in a password protected data file on a password-protected computer in the locked office of the project lead. All hard copies of the questionnaires were stored in a locked filing cabinet in the locked office of the project lead.

3.9.1 Data Coding

When entering the data into SPSS, coding rules were applied as follows: All missing data were coded as ‘’-99’’ for TDF items one through 73. When participants circled more than one

response, the most conservative score was chosen (i.e., the lower value on the scale). When participants circled “Strongly Disagree” or “Strongly Agree” instead of choosing a value of one or five respectively, we coded “Strongly Disagree” as a one and “Strongly Agree” as a five. Lastly, if a participant replied “N/A” we input that response as a missing score (-99). For the last question, item number nine in Part B of the questionnaire, if participants left the open-ended question blank we coded it as “M/I” for missing information. If participants responded, “I don’t know” or if the question was not properly answered or left for interpretation, we coded it as “M/I”. Otherwise, responses were entered verbatim as free text.

3.9.2 Data Cleaning

Multiple steps were taken to ensure that data were accurately entered into SPSS. To begin the data cleaning, we ran frequency checks on each item on the questionnaire to check if any scores were outside of the scoring range one to five. No data was found outside of range. In addition to frequency checks, data cleaning included a 10% random data entry sample check. This resulted in a 0.68% data entry error.

3.9.3 Score Scaling

As per a similar study, questionnaire items where a score of five did not indicate a positive response, we reverse scored them to reduce response bias (Mulligan, et al., 2018). The rules for reverse scoring were as follows: let scores of one equal five, scores of two equal four, scores of three remain at three, scores of four equal two, and scores of five equal one. Reverse scaling was performed to 14 items in total. Questions 20, 21, and 22 under the domain Optimism, 26 under Beliefs about Consequences, 36, 37, 38 and 39 under Goals, 41, 42, 45, and 46 under Memory, Attention, and Decision Making, and 61 and 63 under Emotions.

3.10 Data Analysis Procedure

Data were analysed using IBM SPSS Statistics v23.

3.10.1 Descriptive Statistics

Descriptive statistics were used to examine demographic variables and whether participants would find technology to be an effective tool for self-managing T2DM. For some of

the continuous demographic variables, the following equations were used to convert height, weight, and Body Mass Index (BMI) respectfully, height(m)=height (cm) x 0.01 and height (m)=height (inches) x 0.0254. Participant weights were converted from lbs to kilograms (kg) using weight(kg)=weight (lbs) x 0.4536. Participants BMI was calculated using BMI=weight(kg) ÷ height(m)^2. All categorical variables were presented as n (%).

Prior to reverse scoring, descriptive frequencies were also reported for each question item on the questionnaire, i.e. how many people scored 1, 2, 3, 4, or a 5 as well as mean scores for each item. Once reverse scoring was completed, we then reported the average domain score to report respondents experience with following a meal plan.

3.10.2 Reliability Analysis

Internal consistency reliability is a way to gauge how well a test or questionnaire is actually measuring what you want it to measure (Glen, 2016). A reliability analysis was performed to check the internal consistency of predictor scales by computing Cronbach's alpha to measure how closely related each question under their respective domain are as a group, as previously done in similar studies (Beenstock, et al., 2012). An Alpha between 0.70 and 0.95 was considered acceptable as per a similar TDF study (Seward, et al., 2017). If the Cronbach alpha value was under a 0.7, a matrix correlation between items was completed and if an item deviant was found, it was removed from the domain and Cronbach's Alpha was recalculated (Tavakol, et al., 2011).

3.10.3 Regression Analysis

Upon completion of the reliability analysis, composite variables representing the 13 domains of behaviour for following a meal plan to help manage T2DM were created in SPSS. Composite variables were used for the remainder of the analysis. A multiple linear regression analysis was undertaken to explore which variables were independently associated with the self-reported behaviour 'I intend to follow a meal plan to help me manage my Type 2 diabetes', by taking the mean of the domain intention and using that as the outcome variable. The variables used for the regression analysis are shown below in Table 3-1.

Table 3-1 Definitions of Variables used in the Multiple Linear Regression Model

Dependent Variable	Independent Variables
(1) intention	1) knowledge, 2) skills, 3) beliefs about capabilities, 4) optimism, 5) beliefs about consequences, 6) reinforcement, 7) goals, 8) memory, attention and decision processes, 9) environmental context and resources, 10) social influences, 11) emotion and 12) behavioral regulation.

To enter all the 12 independent variables outlined above in the multiple linear regression analysis, based on a medium effect size, with 80% power and alpha 0.05, required a sample size of 146. To examine which were the strongest explanatory variables of intention to follow a meal plan for the self-management of T2DM, independent variables that were significant ($p<.05$) were identified from the multiple linear regression model. A significance level of ($p<.05$) was chosen as per a previous study completed using the TDF (Mulligan, et al., 2018). For all analyses, effects were reported with corresponding standard deviations (SD) and the R^2 statistics were reported. Significant predictors of intention to following a meal plan for the self-management of T2DM were identified with p values < 0.05.

3.10.3 Thematic Analysis of the Effectiveness of Mobile Applications as a Self-Management Tool for T2DM Management

All responses from the open-ended question "Do you think a mobile application (APP), a program that goes on your phone or tablet that provides help with managing T2DM, would be an effective tool to help you manage your diabetes? Would you use the APP? Why or why wouldn't it help? Briefly Explain." were carefully read to assess whether the data collected in this study could subsequently inform a mobile application intervention for people living with T2DM. A qualitative descriptive approach was undertaken to analyse open-ended comments (Chafe, 2017). This form of naturalistic inquiry makes no theoretical assumptions about the data. Its goal was to

present the data in the language of participants, without aiming to interpret the data in more theoretical ways. The result is a comprehensive summary of the question asked to participants. Each question response was read and re-read several times in order to identify and index into the following three categories (1) Yes - the respondent expressed that a mobile Application would be an effective self-management tool for T2DM, (2) No – the respondent expressed that a mobile Application would not be an effective self-management tool for T2DM, or (3) Inconclusive – the respondent has made it unclear whether they would find a mobile Application for T2DM self-management effective or ineffective. 'Furthermore, re-emerging themes were identified in the same manner and reported within their respective category.

The analyst was careful to suspend personal opinions and biases in an effort to be as objective as possible in categorizing the themes. Further, care was taken to be aware of negative cases (quotes/narratives that seemed to be at odds with emerging themes and ideas). The analyst purposefully sought out data that undermined developing themes instead of seeking data to support themes that already existed. Additionally, as themes and ideas were emerging, these were shared with the larger research team to verify ideas from their content expertise.''

3.11 Ethical Considerations

Ethical considerations were addressed in the planning and implementation of this research study. The Health Research Ethics Board (HREB), Memorial University of Newfoundland approved this research project before data collection began. Ethics approval was given by the HREB and granted for one-year effective September 18th, 2018.

A letter of information was mailed out with the questionnaire that contained all elements of consent set out in Article 3.2 of the 2nd edition of the Tri-Council Policy Statement (TCPS2). This letter clearly explained to potential participants: (a) that participation in the study was voluntary, (b) that a completed or partially completed questionnaire constituted for implied consent which guarantees that respondents are willing choosing to participate in the study, (c) that all questionnaires responses would remain anonymous, (d) that participants should not include any potentially identifying information on the questionnaire, and (e) that questions were welcomed by phone or e-mail to the research team member or her supervisor.

Additionally, the RMP manager was responsible for mailing questionnaires to potential participants to ensure anonymity and ensure all identifying information was concealed from the research team. All returned questionnaires were mailed back to the research team and locked in a filing cabinet in the Memorial University's Medical School Building. Questionnaires were only accessible to co-investigators and one research team member ensured confidentiality of patient information.

Chapter 4 : Results

The following chapter presents the studying findings in three sections. The first section describes the demographic profile of the sample population including weight measures, T2DM profile, and socio-demographic characteristics. The second section presents findings from participants' experience with following a meal plan to help manage their T2DM including descriptive information and the statistical analysis. The third section presents the results for the secondary research objective including the samples response to whether technology is an effective self-management tool for T2DM and their attitudes regarding technology as a self-management tool.

4.1 Demographic Profile

4.1.1 Response Rate

The questionnaire was mailed to 300 patients who were enrolled in the RMP at Eastern Health on January 7th, 2019. The window for the data collection period ended on April 8th, 2019. 54 questionnaires were returned in the three-month data collection window yielding a 18% response rate.

4.1.2 Socio-Demographic and Health Status Characteristics

Table 4.1 presents the socio-demographic and health status characteristics that include: gender, age, BMI, residence of health authority, comorbidities, medication status, and the average duration of time participants have been diagnosed with T2DM. The study sample of participants living with T2DM who were enrolled in the RMP with Eastern Health and returned the questionnaire to the research team included 54 people of 300 candidates, a response rate of

18%. The sample included 33 women (61.1%), 18 men (33.3%) and 3 missing responses (5.6%). The mean age ± SD of the sample was 63.7 ± 10.5 years with the average person living with T2DM for 16.4 ± 11.3 years. Most of the sample (98.1%) were taking medication to control their T2DM. The mean weight, height and BMI of the sample was 203.8 ± 47.7 pounds, 64.7 ± 3.3 inches and 34.5 ± 9.2 kg/m^2. The sample resided in various health authorities around NL with the most respondents from the Eastern health authority (72.2%), followed by the Labrador-Grenfell health authority (14.8%), Western health authority (9.6%). There were no responses from patients living in the Central Health Authority.

The sample population reported significant comorbidity. Respondents were presented with a list of comorbidities associated with T2DM and asked if they had "ever been diagnosed by a doctor with any of the following conditions?" In response to this question the mean number of self-reported comorbid conditions was 2.0±1.2 comorbidities. The five most common comorbidities were high blood pressure (59.3%), high cholesterol (53.7%), coronary artery disease (27.8%), osteoarthritis (27.8%), and sleep apnea (14.8%). Respondents also indicated if they had "other" comorbidities (20.4%) that were not listed on the questionnaire.

Table 4-1 Characteristics of Sample from Remote Monitoring Project (N=54)

Characteristic	**Mean ± SD**	
Age, years	63.7 ± 10.5	
BMI, kg/m^2	34.5 ± 9.2	
Number of chronic conditions	2.0 ± 1.2	
T2DM duration, years	16.4 ± 11.3	
	n	**%**
Female	33	61.1
Male	18	33.3
Health Authority		
Eastern	39	72.2
Western	5	9.3
Central	8	14.8
Taking Medication	53	98.1

All data are self-reported

4.2 Experience with Following a Meal Plan

This section presents the results for the 73-item TDF portion of the questionnaire including domain descriptive statistics, the reliability analysis, correlation analysis, and finally the regression analysis.

4.2.1 Descriptive Statistics for Behavioral Domains

The questionnaire had 73 final items that assessed 13 behavioral domains, 12 predictors and one outcome variable. The higher the mean score, the higher the belief in the perceived task. A score of five indicated high or strong beliefs, a score of four indicates fair belief, a score of three indicated a neutral belief, a score of two indicated low belief and a score of one indicated no belief. Each domain had a composite value created for each participant, then an overall average±SD from all completed questionnaires was reported for each domain. The domain Knowledge had a mean average ± SD of 4.1±0.86 indicating that participants exhibited a *fair*

amount of knowledge around meal planning and the number of participants that fully completed each item under the knowledge domain was 53 participants (n). Skills (3.7 ± 0.97, n=52) indicated respondents believed they exhibited *some of the skills* required to follow a meal plan for the self-management of T2DM. Beliefs about Capabilities (3.7 ± 0.87, n=52) indicating the sample believed they exhibited *some confidence* to follow a meal plan. Optimism (3.6 ± 0.80, n=54), indicated respondents felt *some optimism* about following a meal plan for T2DM management. Beliefs about Consequences (4.5 ± 0.73, n=53) indicated participants had a *strong belief* that following a meal plan was beneficial for the self-management of T2DM. Reinforcement (4.1±0.76, n=52) indicates respondents receive a *fair amount* of reinforcement for following a meal plan to help manage their T2DM. The domain Intentions (3.9±1.1, n=54) signifies that respondents displayed some intention to follow a meal plan over the following 10 days after the questionnaire was completed. Goals (3.3 ± 1.0, n=50) indicated respondents were slightly above neutral about setting goals to help manage their T2DM. Memory, Attention, and Decision Making (3.3 ± 0.80, n=49) signifies that respondents were slightly above neutral regarding memory, attention, and ability to prioritize following a meal plan. Environmental Context and Resources (3.6 ± 0.84, n=44) indicates that some respondents had the resources necessary to be able to follow a meal plan. Social Influences (3.8 ± 1.0, n=47) indicates respondents have somewhat of a support system to help them follow a meal plan for T2DM management. Emotions (3.8 ± 0.93, n=53) signifies that respondents feel slightly positive about their ability to follow a meal plan. Behavioral Regulation (3.5 ± 1.1, n=47) indicates respondents have made plans about following a meal plan and monitoring their progress with following a meal plan for T2DM management. Table 4.2 Behavioral Domain Characteristics, on the following page, summarizes the data above and provides additional information including the number of questionnaire items under each respective domain that made up the composite variable, N and the number of participants who completed all questions within each domain, n.

Table 4-2 Behavioral Domain Characteristics

Domain	N	n	mean ± SD
Knowledge	6	53	4.1 ± 0.86
Skills	4	52	3.7 ± 0.97
Beliefs about Capabilities	6	52	3.7 ± 0.87
Optimism	5	54	3.6 ± 0.80
Beliefs about Consequences	3	53	4.5 ± 0.73
Reinforcement	2	52	4.1 ± 0.76
Intentions	4	54	3.9 ± 1.1
Goals	7	50	3.3 ± 1.0
Memory, Attention, and Decision Making	8	49	3.3 ± 0.80
Environmental Context and Resources	7	44	3.6 ± 0.84
Social Influences	5	47	3.8 ± 1.0
Emotions	4	53	3.8 ± 0.93
Behavioral Regulation	10	47	3.5 ± 1.1

Note: Questions requiring reverse scoring were reversed prior to computing averages

4.2.2 Reliability Analysis

To test the internal consistency of the questionnaire, a Cronbach's alpha (α) was calculated for each behavioral domain that included more than two question items. A score of 0.7 or higher indicates a high internal consistency.

The analysis of Cronbach's alphas established that all questions reliably measured the same construct for the following domains, Knowledge (α=0.872), Skills (α=0.839), Beliefs about Capabilities (α=0.880), Intentions (α=0.937), Goals (α=0.927), Memory, Attention, and

Decision Making (α=0.799), Environmental Context and Resources (α=0.797), Social Influences (α=0.884), Emotions (α=0.701), Behavioral Regulation (α=0.949). The domain Optimism measured the reliability among six questionnaire items. The original α reported for Optimism was 0.685 therefore, item-total statistics were completed to determine Cronbach's alpha if an item was deleted. Item 17 on the questionnaire; '' With regard to following a meal plan that will help manage my T2DM in uncertain times (e.g., when things are going so good in my life or during periods of upheaval likes moving house, changing jobs or travelling for work, etc.), I usually expect the best.'' was deleted as it was not reliably measuring the same domain as the other items and the α increased to 0.700. The same was repeated for the domain Beliefs about Consequences which measured an α at 0.600 comparing four items. Question 26 ''If I follow a meal plan to help me manage my T2DM, it will have disadvantages for my health'' was removed and the α increased to 0.819, an acceptable α. Table 4.3, on the following page, further summarizes the reliability statistics for each domain.

Table 4-3 Reliability Statistics for each Domain

Domain	Cronbach's Alpha	Number of items
Knowledge	0.872	6
Skills	0.839	4
Beliefs about Capabilities	0.880	6
Optimism	0.700	5
Beliefs about Consequences	0.819	3
Reinforcement	0.298	2
Intentions	0.937	4
Goals	0.927	7
Memory, Attention, and Decision Making	0.799	8
Environmental Context and Resources	0.797	7
Social Influences	0.884	5
Emotions	0.701	4
Behavioral Regulation	0.949	10

a. Listwise deletion based on all variables in the procedure.

4.2.3 Correlations

This section reports the results for the correlational analysis between the dependent variables (12 domains) and the independent variable (intentions) as well as the correlations between demographic variables (BMI, comorbidities, T2DM duration, medication, sex, age, and health authority) and the independent variable (intentions). Any variable which was significant at the 0.05 level (p=0.05) was included in the multiple linear regression model for further analysis. All 12 dependent domains (Table 3) were significantly correlated ($p < 0.05$) with intention to follow a meal plan and were included in the multiple linear regression analysis as per Table 4.4 on the following page. As per Table 4.5 on page 47, none of the demographic variables were

significantly correlated with the domain intention ($p>0.05$) and were therefore not included in the multiple linear regression model.

Table 4-4 Domain Correlation Statistics

Domain	Pearson Correlation	Sig. (2-tailed)	N
Intentions	1	-	54
Knowledge	.374**	.006	53
Skills	.597**	.000	52
Beliefs about Capabilities	.689**	.000	52
Optimism	.535**	.000	54
Beliefs about Consequences	.552**	.000	53
Reinforcement	.587**	.000	52
Goals	.754**	.000	50
Memory, Attention, and Decision Making	.570**	.000	49
Environmental Context and Resources	.684**	.000	44
Social Influences	.757**	.000	47
Emotions	.468**	.000	53
Behavioral Regulation	.630**	.000	47

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

Table 4-5 Demographic Correlations with Intention to Follow a Meal Plan

Demographic	Pearson Correlation	Sig. (2-tailed)	N
Intentions	1	-	54
BMI	-.228	.100	53
Comorbidities	-.262	.055	54
Duration	-.085	.544	53
Health Authority	-.062	.662	52
Age	-.154	.268	54
Sex	-.099	.488	51
Medication	-.142	.305	54

4.2.4 Regression Analysis

The multiple linear regression model included 12 independent variables, Behavioral Regulation, Beliefs about Consequences, Optimism, Knowledge, Reinforcement, Memory, Attention, and Decision Making, Emotions, Social Influences, Skills, Environmental Context and Resources, Goals, Beliefs about Capabilities. The regression model accounted for 87.9% of the correlation between the 12 predictors and the outcome variable. The multiple linear regression model accounted for 72.2% of variation in the final model, which was significant (Table 4-6). **The multiple linear regression model indicated only two significant predictors of intention to follow a meal plan.** Emotions (-.648, p=0.003) and Social Influences (.475, p=0.0026) were the two key domains of the TDF that predicted an intention to follow a meal plan to help self-manage T2DM. In other words, emotional health and the influence of others in ones social environment are significant predictors of the intention to follow a meal plan for self-management of T2DM.

Table 4-6 ANOVA[a]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	26.330	12	2.194	6.493	.000[b]
	Residual	7.772	23	0.338		
	Total	34.102	35			

a. Dependent Variable: Intentions

b. Predictors: (Constant), Behavioural Regulation, Beliefs about Consequences, Optimism, Knowledge, Reinforcement, Memory, Attention, and Decision Making, Emotions, Social Influences, Skills, Environmental Context and Resources, Goals, Beliefs about Capabilities

Table 4-7 Results from ANOVA[a] and Regression Model

	Unstandardized Coefficients		Standardized Coefficients		
Domain	**B**	**Std. Error**	**Beta**	**t**	**P value**
Knowledge	-.098	.218	-.084	-.452	.655
Skills	.034	.254	.031	.133	.895
Beliefs about Capabilities	.189	.314	.155	.603	.552
Optimism	.065	.178	.050	.365	.719
Beliefs about Consequences	.281	.230	.191	1.222	.234
Reinforcement	-.016	.227	-.012	-.071	.944
Goals	-.082	.257	-.079	-.320	.752
Memory, Attention, and Decision Making	.031	.239	.024	.128	.899
Environmental Context and Resources	.328	.280	.288	1.169	.254
Social Influences	.475	.199	.510	2.384	**.026**
Emotions	-.648	.193	-.597	-3.358	**.003**
Behavioural Regulation	.345	.321	.358	1.075	.294

a. Dependent Variable: Intentions

b. Predictors: (Constant), Behavioural Regulation, Beliefs about Consequences, Optimism, Knowledge, Reinforcement, Memory, Attention, and Decision Making, Emotions, Social Influences, Skills, Environmental Context and Resources, Goals, Beliefs about Capabilities

4.3 Technology as a Self-Management Tool

The research team wanted to determine the direction of this project and assess whether the data collected in this study could subsequently inform a mobile application intervention for people living with T2DM. Respondents were asked "Do you think a mobile application (APP), a program that goes on your phone or tablet that provides help with managing type 2 diabetes, would be an effective tool to help you manage your diabetes? Would you use the APP? Why or why wouldn't it help? Briefly Explain." The first part examined of this question was whether technology, more specifically a mobile application (APP), would be an effective self-management tool. Because the question was open-ended, some respondents did not directly state whether they believed a mobile application to be an effective self-management tool, in these cases, the research team deemed them inconclusive. Most of the sample disclosed that they thought technology would be an effective self-management tool for T2DM (76.0%) whereas 9.3% of respondents disclosed that they do not think a mobile application would be an effective tool, and 14.8% were inconclusive.

The rest of the question "Would you use the APP? Why or why wouldn't it help? Briefly Explain." The following excerpts were taken directly from the responses provided on the questionnaire. Only responses that answered the question were reported on Table 4.8. The common themes that emerged from the respondents' attitudes concerning the mobile application being an effective self-management tool were as follows: accountability; respondents felt that technology would hold them accountable for self-managing their condition, information; respondents felt that having immediate access to information regarding T2DM on a mobile application including meal planning, blood sugar levels, and medication would be effective at helping them self-manage their T2DM, reminders; respondents felt that having a tool that could provide reminders for meals, checking sugars, and taking medication would be beneficial for self-management, convenience; respondents reported that if they had had an intervention that could go anywhere with them for self-management they could success manage wherever they may be, and lastly, resource; respondents felt that having a mobile application on their smartphone was one additional aid for T2DM management.

Reasons that a mobile application would not be an effective or were inconclusive about using technology as a self-management tool for T2DM had two common themes, access; respondents lacked access to the technology needed to use a mobile intervention such as a smartphone or tablet and knowledge; respondents reported that they did not know how to use mobile apps and had no interest in learning.

Table 4-8 Participant Excerpts Regarding Mobile Application for T2DM Intervention

Effective	Identified Theme-Excerpt from response
Yes	***Accountability***-*"It would be very effective. I would definitely use the app as it would help me to be accountable daily and watch my progress of managing my blood sugars and weight."* ***Information***- *"It would help in that I presume the meals would be planned for me. This would save me from having to make the choices myself. Note: The trouble with meal planning for diabetes, in my case at least, is that most days I can't eat a full three meals and even when I do I'm not hungry enough to consume the whole meal. Most days one meal or 2 at the most is all I need and then not all of the items in those meals are eaten. This is age related I'm sure!!"* ***Resource***- *"Yes I would like to use it. Because I would like to manage my diabetes more."* ***Accountability***- *"It would be I would use it keeps me accountable."* ***Resource***- *"My husband has many health issues, 10 years older and my 1st priority is his health + comfort + there is no support group for Diabetes."* ***Accountability-"****Yes! Yes! Yes! I know what has to be done for the most part. I just need some accountability. It would be great to have a place for food intake, medicine intake, and sugar monitors. What are your sugars before and after a meal? It would be good if other sugar monitors can sync with it. I use freestyle libre that I use with my phone, which would be cool to sync to a food diary app."* ***Reminder***- *"I think it would remind me more so as to what and when to eat"* ***Convenience***- *"I would use it at certain times. I think it would really help when I am not at home."* ***Reminder***- *"Yes It would help due to the top of mind awareness."* ***Resource***- *"I am positive it would help. As the Remote Monitoring Program helped. When finished I lost interest. I find it so hard. I would use it for sure."* ***Information***- *An APP would be beneficial for many Type 2 diabetics as information is important however, diabetics have a choice to make a change. As long as a choice to better manage diabetes is chosen an APP would be great!"* ***Resource***-*"Absolutely would use this type of APP. Currently use the Weight Watchers APP on my phone daily. Been using it for 10 months & it is fantastic. The best part is connecting with other people who are doing the same*

	program. So a diabetic-friendly community with an APP would be a source of great encouragement & hopefully inspiration." ***Information****-"I would use the APP. It would probably be more beneficial to diabetics who have just been diagnosed then it would be for someone who has been trying to manage B/S readings for years and knowledgeable in the carb content in most foods."* ***Resource****- "I think it would help and I would use it. I think it will keep my sugars under control."* ***Convenience*** *- I am always very conscious of my diabetes and try to keep my medications and meals at proper intervals. Anything that can be readily accessible to help has to be a positive in helping to manage our disease."* ***Resource-****"Yes for me because I am visually impaired."*
No	***Access****- "Not interested in App. I have an Ipod but for my own family use. I do not have computer. Viewing by paper is more appropriate for my well-being. I will always have that information at my side immediately. Thank you"* ***Knowledge-****"Not very familiar with apps. Would not help me and I would not use it."*
Inconclusive	***Access****-" I don't have a phone and I don't think a tablet would work. I could use some counseling with planning meals. I was never offered any advice by medical people about the appropriate diet."* ***Knowledge****- "I'm not sure. I don't use the phone much so I guess it would depend on what is involved with the app that would make me use it. I'm not up to date on this new technology yet. I Don't like a lot of foods I should eat so it makes following a 22healthy meal plan very hard. That's my biggest challenge food & too busy to eat right"*

Chapter 5 : Discussion

T2DM is a progressive, life-long chronic disease that affects many globally. Preventing or delaying the complications associated with T2DM is possible when self-management regimes are followed. The current study examined the theoretical determinants of intention for successfully following a meal plan for the self-management of T2DM for patients who were enrolled in the RMP at Eastern Health. A secondary aim was to explore patient attitudes regarding an e-intervention, specifically a mobile APP, for the self-management of T2DM and their interest in using such an app to help manage their condition.

The discussion of findings is organized based on the research question and objectives outlined in Chapter 3. The first section describes the determinants of behaviours identified that have the largest influence on following a meal plan for T2DM self-management and how they

compare with the barriers/facilitators previously identified in T2DM self-management studies. The second section discusses patient attitudes towards e-technology as a tool for self-management and compares the results to similar populations and their perceived attitudes of technology-driven interventions. The third section describes the strengths and limitations of this study, while the final section discusses the clinical implications study findings.

5.1 Experience with Following a Meal Plan for T2DM Self-Management

This novel study applied a comprehensive implementation framework to conduct a theoretical assessment of the behaviour associated with meal planning for the self-management of T2DM as phase one of a two phase project. Our study drew upon the TDF, which has been widely used to inform behavior change interventions for healthcare providers, but less so in patient settings. Only two domains were found to significantly predict intention to follow a meal plan for the self-management of T2DM: emotions and social influences. However, most respondents scored fairly high on the other domains. They felt they had the awareness and knowledge around planning meals to help self-manage their condition. They indicated they had adequate skills to proficiently follow a meal plan and a high acceptance of the benefits of following a meal plan to help manage their condition. Most people self-reported that they were optimistic about meal planning and that they had a good environment with the necessary resources to self-manage. In addition, participants agreed about setting goals for meal planning and had the ability to retain the necessary information related to meal planning and focus their attention on meal planning.

While our sample scored fairly high on all domains in the TDF, most of the existing literature highlights that adherence to a specific diet for T2DM management is an extremely challenging aspect of self-care regimes (Hu, et al., 2013) (Booth, et al., 2013). Although there were only two significant predictors for following a meal plan to help self-manage T2DM in our study (Social Influences and Emotions), many studies have identified additional barriers for nonadherence to healthy diets. Booth et al. found that patients were struggling with following a meal plan because of behavioural regulation, simply meaning patients found it difficult to break old habits and to action plan for preparing meals (Booth, et al., 2013). Other studies reported a lack of knowledge around foods and meal planning and environmental context and resources as

significant barriers to self-management (Laranjo, et al., 2015) (Purnell, et al., 2016). Our sample was comprised of patients who had already taken part in a diabetes management program, and this experience could account for high knowledge and resources scores.

Application of the TDF resulted in identification of two significant determinants of behaviour out of a total of 12 behavioural determinants being tested, since one behavioural determinant was omitted (professional role and identity) from the study and one was used as the outcome variable (i.e., intention). Emotions (-.648, p=0.003) and Social Influences (.475, p=0.0026) were the two key domains of the TDF that predicted an intention to follow a meal plan to help self-manage T2DM. Emotions and Social Influences accounted for a large portion of the variance (72.2%), suggesting they are indeed important variables to target in interventions to change the behavior related to following a meal plan to self-manage T2DM.

5.1.1 Social Influences

Social Influence can be described in the context of the TDF as those interpersonal processes that can cause individuals to change their thoughts, feelings, or behaviors (Cane, et al., 2012). We were not surprised to find that Social Influences is a significant predictor for intention to follow a meal plan for T2DM, given the many published studies that have reported Social Influences as a significant component, both a barrier and a facilitator, in the self-management of T2DM.

Our findings may suggest that the more social support a person has, the more likely that person has an intention to follow a meal plan for the self-management of T2DM. Shen et al. reported comparable results. In that study, support from families, especially from spouses, was frequently mentioned as a facilitator of T2DM self-management (Shen, et al., 2013). Identified family support included financial support for medicine costs, help with housework, constant reminders and sincere consolation (Shen, et al., 2013). In our study, participants felt they could rely on family members when things got tough and that their families were helpful in the self-management of T2DM. Participants in our study further reported that they had colleagues they could confide in to help them self-manage their condition. Like our results, Shen et al.'s study reported that patients stressed that peer support was irreplaceable and highly valued the support of others (Shen, et al., 2013). Qualitative research on the self-management of T2DM also

supports the results of our study. For example, Purnell et al. reported that when patients were open about their T2DM with family and friends, patients received more support for the self-management of their disease (Purnell, et al., 2016). Positive social influences appear to be extremely beneficial in the self-management of T2DM.

In contrast to the above, social influences can also serve to hinder the self-management of T2DM Comparable studies for T2DM management reported social influences as a significant barrier to T2DM. In Hu et al's study, many participants experienced a lack of family support, particularly with dietary changes. In that study, Hu et al. quoted a participant saying, "The other day my teenage daughter started teasing me at the store; she grabbed a chocolate bar and started waving it in my face saying "Look! Look!" to make me feel bad'' and "My sons, they don't like vegetables or fruits. All they want is pizza and hot dogs". Reflections such as these highlight the difficulty of following a healthy meal plan for T2DM self-management without the support of family.

5.1.2 Emotions

Emotions can be described in the context of the TDF as a complex reaction pattern, involving experiential, behavioral, and physiological elements, by which the individual attempts to deal with a personally significant matter or event (Cane, et al., 2012). Many studies report emotions such as anxiety, fear, stress, depression, and negative affect as a significant barrier to the self-management of T2DM (Halali, et al., 2016) (Luo, et al., 2015) (Booth, et al., 2013).

In a study that looked at the association between depression and the self-management of T2DM, depression was strongly associated with adverse health outcomes in persons with T2DM including poor glycemic control, increased risk of complications, decreased adherence to medications, decreased adherence to dietary recommendations, and increased health care costs (Egede, 2005). Because of the large number of studies published that support this association, we were expecting our study to support this data. However, our findings suggested that when patients were happy and exhibited good emotional wellbeing, they were less likely to follow a meal plan for the self-management of T2DM.

We suspect that when people are feeling happy, it is easy to ignore the difficult parts in your life, such as following a meal plan for T2DM management or to avoid those tasks that might dampen a good mood. Emotional eaters are often presumed to eat in response to negative emotions, yet positive emotions might also be associated with over-eating. For example, a 2013 study showed a significant increase in food intake for positive emotional eaters, but reported no effect for participants in a negative mood (Bongers, et al., 2013). Another study published in 2013 studied positive emotions as a trigger for food intake; the results indicated that positive emotions evoked increased caloric intake compared to control conditions (Evers, et al., 2013).

5.2 Attitudes of e-technology

Although determining the attitudes of patients towards the effectiveness of e-technology as a T2DM self-management tool wasn't the main objective of this study, the research team was interested in informing phase 2 of this project. Technology, including smartphones and tablets, are becoming increasingly more popular. For example, the number of adults aged 65-74 years using tablets to go online more than tripled in recent years, increasing from 5% in 2012 to 17% in 2013 (Vaportzis, et al., 2017). Our findings suggest that most participants in the study appear eager and willing to adopt technology, more specifically a mobile APP, for the self-management of their T2DM. These results compare to a similar study of older adults (aged 65-76 years), which focused on determining their perceptions of technology. Like our study, these results showed that most participants were eager to adopt technology; however, they did voice apprehension about lack of knowledge and clarity in instructions and support (Vaportzis, et al., 2017). In our study, participants who deemed technology to be an ineffective intervention for them, reported lack of knowledge or lack of smart device as the main reason for their apprehension.

5.3 Strengths and Limitations

Identifying the factors that influence a given behaviour is essential for any successful intervention that aims to change existing behaviour. Michie's et al.'s TDF of behaviour change has been used extensively to assess implementation issues across a wide range of disciplines,

involving professionals and now patients, via interviews and surveys (Michie, et al., 2017). In this study, the TDF's comprehensive framework identified only two behavioural determinants (social influences and emotions) that influence the behaviour around following a meal plan for T2DM management. The strength of this systematic approach is that intervention content can be developed around these variables. The TDF content domains are linked to evidence-based behavior change interventions. Thus, social influences and emotions can now be targeted to other tools developed by behavioural scientists (i.e., BCW, BCT's). The COM-B, the hub of the BCW, distills the TDF into three key domains that interact to predict behaviour, including people's capability, motivation and opportunities for the behaviour (Richardson, et al., 2019). Having the COM-B system at the hub of the BCW is unique in that it helps to identify which components need to change for the target behaviour (i.e., following a meal plan for T2DM management) to occur, and provides guidance on the strategies that can be used to modify that behaviour.

To our knowledge, this is one of few studies completed in a patient population to assess perceived implementation difficulties related to following a meal plan to self-manage T2DM using a theory-informed framework. The postal survey was relatively inexpensive and reached a greater geographical area than in-person methods, including hard-to-reach groups such as rural areas, which helped lessen selection bias for this study. The questions for this study were developed based on literature relative to T2DM management, but also informed by patient engagement sessions. These revealed a key behavior related to self-management (i.e. meal planning) and provided a patient-informed area of study focus. Further, the reliability analysis revealed that the questionnaire displayed high internal consistency.

There are always limitations associated with cross-sectional studies and questionnaires. Cross-sectional studies only provide a "snapshot" in time - meaning that if the questionnaire was mailed during a different time-frame, the results could be different. Unfortunately, given the nature of this study, this was difficult to avoid. However, when possible, we incorporated phrases into the questionnaire such as ''in the past two weeks'', "in your everyday life'' or ''in your normal day-to-day life'' to try to reduce the "snapshot" effect. Relying on self-reported data from questionnaires is another limitation whereas data may be exaggerated or data may be subject to social desirability bias. However, we are heartened that discussion during our patient

engagement sessions was in line with survey findings about meal planning. This suggests that self-reporting bias may be minimal.

Another limitation for this study was that the sample size was too small to yield reliable analyses. Unfortunately, the small sample size limits the stability and power of the analyses. Further, with numerous predictors, Type I error is inflated. Because the study is underpowered, this has implications for the reliability of the domain scales, and hence the regression analysis. However, because this was a pilot, project we wanted to know if it was even feasible to create domain scales in a patient population and combine these as suggested by TDF analysis frameworks. Therefore, we decided to perform the analyses as recommended for TDF studies. However, future research with bigger sample sizes that are adequately powered would allow for a more reliable analysis.

At, 18%, the response rate could be considered low. However, the sample was fairly small, but appears similar to the average person living with T2DM. The mean age ± SD of the sample was 63.7 ± 10.5 years with the average person living with T2DM for 16.4 ± 11.3 years. A study published by Iglay et al., reported that the average age of a person living with T2DM in the US was 65 years old (Iglay, et al., 2016). Like most people living with T2DM, the participants in this study did not live with T2DM in isolation. The mean number of self-reported comorbid conditions in this study was 2.0±1.2 comorbidities, with high blood pressure being the most predominant (59.3%). Iglay et al. reported that 88.5% of people in the US lived with at least two comorbidities (Iglay, et al., 2016) with hypertension being the most prominent (82.1%).

For this study, we tried to adapt this questionnaire from a framework that was originally designed for a professional population which is a radically different population than a patient population. The questionnaire was lengthy (73 items) and extremely repetitive given the nature of the TDF.

Having a low response rate does create a response bias for this study, which increases the probability that the characteristics of those who respond may be different than those who don't, especially since the survey is measuring a person's intention. However, a mitigation of this bias

is that the sample demographic profile was comparable to other studies previously done with T2DM populations. Additionally, it was not possible to conduct a full psychometric analysis of our tool in this small and specific patient population. While we removed two items during our reliability analysis, we do not know if that would generalize to the use of the tool in other populations of patients with T2DM. Future researchers should conduct psychometric analyses on the tool in their samples, for example, perform a confirmatory factor analysis if sample sizes permit and assess the TDF domain scales' reliability in each study.

An important limitation of this study to note is that all the participants in this study could be considered highly motivated to control their T2DM. The sample population willingly chose to enroll in a T2DM self-management program, the RMP. Based on the literature and previous patient engagement, the research team expected knowledge to be a significant predictor of following a meal plan to self-manage d T2DM; however, results indicated otherwise. We believe this may be due to the educational sessions that were delivered to this population prior to the delivery of the RMP. Thus, study findings may not be generalizable to those patients living with T2DM who have never had educational sessions or similar knowledge provided to them. Further research should consider selecting from a more general pool of people living with T2DM to better represent the target population.

Another limitation is the lack of measurement of actual behaviour. This has implications for the inclusion of the TDF domain behavioural regulation; however, we did not have the ability within the study design to measure actual dietary behaviour. In an effort to comprehensively predict behaviour we chose intention as a factor that could be used to explain the variance in actual behaviour. Therefore, future research would benefit from the measurement of actual behaviour.

5.4 Clinical Implications and Future Research

T2DM may be one of the largest health crisis that exists today. Many people live with uncontrolled T2DM and it is important to understand what hinders their behaviours and what can facilitate behaviors to self-manage this condition. Using the TDF has furthered our understanding of some of the influences that have the greatest effect on following a meal plan for the self-management of T2DM. Having identified Social Influences and Emotions as critical

behavioural determinants for self-managing T2DM, we are cautiously optimistic that strategies designed to target these domains can be applied in a clinical setting and be used as a starting point for helping patients change behaviour related to T2DM management. If patients do not have social support, then perhaps clinicians could provide resources for social support groups as a starting point for a T2DM self-management plan. Additionally, if patients seem to be doing well emotionally, this could paradoxically be a red flag in that patients may not have their T2DM as a primary concern. In this situation, clinicians can remind patients living with T2DM of the importance of being cautious with T2DM management, even if things are good.

Most importantly, the results obtained from this study can inform phase 2. Phase 2 of this project is to develop content for an intervention for T2DM management. Having identified Social Influences and Emotions as significant predictors in the self-management of T2DM, we are cautiously optimistic that we can now map out these behavioural determinants onto the BCW. For example, Social Influences falls under the social opportunity category in the COM-B model of behaviour (the BCW hub), which further identifies enablement, environmental restructuring and restriction as behaviour change interventions. Table 5.1 below describes the intervention functions for Social Influences and provides an example of how the intervention can be used for smoking cessation (Michie, et al., 2011).

Table 5-1 Interventions Functions for Social Influences

Intervention	**Definition**	**Example**
Enablement	Increasing means/reducing barriers to increase capability or opportunity	Behavioural support for smoking cessation, medication for cognitive deficits, surgery to reduce obesity, prostheses to promote physical activity
Environmental Restructuring	Changing the physical or social context	Providing on-screen prompts for general practitioners to ask about smoking behaviour
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)	Prohibiting sales of solvents to people under 18 to reduce use for intoxication

The behavioural determinant, Emotion, falls under the category of automatic motivation. Automatic motivation can be achieved through associative learning that elicits positive (or negative) feelings and impulses and counter-impulses relating to the behavioural target, imitative learning, habit formation or direct influences on automatic motivation processes. Suggestions for these intervention functions would be persuasion, incentivising, coercion, environmental restructuring, modeling, and enablement. For example, a clinician could use the intervention, persuasion, to help change the behaviour related to the self-management of T2DM. The definition of persuasion in the context of an intervention is using communication to induce positive or negative feelings or stimulate action. Perhaps a clinician could use imagery to persuade a patient to follow a certain meal plan to help manage their T2DM and illicit positive emotions in said patient. (Michie, et al., 2011)

Lastly, technology now supports or streamlines many day-to-day activities for most people. As the global prevalence of diabetes continues to grow and technology continues to develop, there is an obvious potential for technology to help support individuals self-manage chronic diseases. Our findings from the open-ended question, "Do you think a mobile application (APP), a program that goes on your phone or tablet that provides help with managing T2DM, would be an effective tool to help you manage your diabetes? Would you use the APP? Why or why wouldn't it help? Briefly Explain" supports the development of an e-technology as a self-management tool for T2DM. In terms of behavior change, there has been a limited impact for T2DM interventions thus far, however mobile applications present a valuable opportunity to be a promising tool for successfully delivering a theory-informed behavior change intervention.

Chapter 6 : Conclusion

The TDF is an evidence-based systematic method used to change behaviour related to health. In the past, the TDF was used to assess the behavioural determinants of a target behaviour in professional populations. In this novel study, however, the TDF was used to predict the most significant behaviour determinants of following a meal plan for the self-management of T2DM in patients. This research project was a product of several patient engagement sessions which helped inform the content of the questionnaire that was mailed out to patients who enrolled in the RMP for T2DM. Patients living with T2DM self-reported their experience with following a meal

plan for the management of T2DM as phase one of a two phase project. Our study findings suggested that Emotions and Social Influences were two significant predictors of the TDF for following a meal plan for the self-management of T2DM. Most patients also reported that they would be willing to use technology as a means to control their disease.

The data from this small pilot are promising and seem to suggest further research in this area is warranted. Upon completion of further research and the second phase of this project, patients using a technology-based intervention that is both evidence-based and theory informed, may be supported to experience changes in their self-management behaviours resulting in better controlled T2DM.

Chapter 7 : Bibliography

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Chapter 8 :Appendices

Appendix A-Template Questionnaire with Items and Related Constructs and Domains

Domain		Construct	Item	Source
D1	Knowledge	Knowledge (3)	I am aware of the content and objectives of [innovation/guideline]	Adapted from Amemori et al. [34] and Beenstock et al. [35]
			I know the content and objectives of [innovation, guideline]	
			I am familiar with the content and objectives of [innovation/guideline]	
		Procedural knowledge (3)	I am aware of how to [A] in [C, T] with [Ta]	
			I know how to [A] in [C, T] with [Ta]	
			I am familiar with how to [A] in [C, T] with [Ta]	
			(Strongly disagree – strongly agree)	
D2	Skills	Skills (4)	I have been trained how to [A] in [C, T] with [Ta]	New items
			I have the proficiency to [A] in [C, T] with [Ta]	
			I have the skills to [A] in [C, T] with [Ta]	
			I have practiced [A] in [C, T] with [Ta]	
			(Strongly disagree – strongly agree)	
D3	Social/ professional role and identity	Professional role (4)	[A] in [C, T] with [Ta] is part of my work as a [profession]	New items
			As a [profession], it is my job to [A] in [C, T] with [Ta]	
			It is my responsibility as a [profession] to [A] in [C, T] with [Ta]	
			Doing [A] in [C, T] with [Ta] is consistent with my [profession]	
			(Strongly disagree – strongly agree)	
D4	Beliefs about capabilities	Self-efficacy (2)	I am confident that I can [A] in [C, T] with [Ta] even when [Ta] is not motivated	Adapted from Bandura [42]
			I am confident that I can [A] in [C, T] with [Ta] even when there is little time	
		Perceived behavioral control (4)	I am confident that if I wanted I could [A] in [C, T] with [Ta]	Adapted from Ajzen [41]
			(Strongly disagree – strongly agree)	
			How much control do you have over [A] in [C, T] with [Ta]? (No control at all – a lot of control)	
			For me, [A] in [C, T] with [Ta] is… (Very difficult – very easy)	
			For me, [A] in [C, T] with [Ta] is… (Impossible – possible)	
D5	Optimism	Optimism (3)	With regard to [A] in [C, T] with [Ta] in uncertain Times, I usually expect the best	Adapted from Scheier et al. [52]
			With regard to [A] in [C, T] with [Ta] I'm always optimistic about the future	
			With regard to [A] in [C, T] with [Ta] overall, I expect more good things to happen than bad	
		Pessimism (3)	With regard to [A] in [C, T] with [Ta] if something can go wrong, it will	
			With regard to [A] in [C, T] with [Ta] I hardly ever expect things to go my way	
			With regard to [A] in [C, T] with [Ta] I rarely count on good things happening to me	

			(Strongly disagree – strongly agree)	
D6	Beliefs about consequences	Attitudes (2)	For me, [A] in [C, T] with [Ta] is… (Useless – useful) For me, [A] in [C, T] with [Ta] is… (Bad – good)	Adapted from Ajzen [41]
		Outcome expectancies (2)	If I [A] in [C, T] with [Ta] it will benefit public health If I [A] in [C, T] with [Ta] it will have disadvantages for my relationship with [Ta] (Strongly disagree – strongly agree)	Adapted from Bandura [42]
D7	Reinforcement	Reinforcement (3)	Whenever I [A] in [C, T] with [Ta], I get financial reimbursement Whenever I [A] in [C, T] with [Ta], I get recognition from professionals who are important to me If I [A] in [C, T] with [Ta], I feel like I am making a difference (Never – always)	New items
D8	Intentions	Intention (4)	For how many of the next 10 [Ta] do you intend to [A] in [C]? (1 – 10) I will definitely [A] in [C] with [Ta]in the next [T] I intend to [A] in [C] with [Ta] in the next [T] (Strongly disagree – strongly agree) How strong is your intention to [A] with [Ta] in [C] in the next [T]? (Not strong at all – very strong)	Adapted from Ajzen [41]
D9	Goals	Action planning (4)	I have a clear plan of how I will [A] in [C, T] with [Ta] I have a clear plan under what circumstances I will [A] in [C, T] with [Ta] I have a clear plan when I will [A] in [C, T] with [Ta] I have a clear plan how often I will [A] in [C, T] with [Ta] (Strongly disagree – strongly agree)	Adapted from Sniehotta et al. [46]
		Priority (4)	Generally, in [C, T] with [Ta], how often is covering something else on your agenda a higher priority than [A] Generally, in [C, T] with [Ta], how often does covering something else on your agenda take precedence over [A] Generally, in [C, T] with [Ta], how often is covering something else on your agenda more urgent than [A] Generally, in [C, T] with [Ta], how often is covering something else on your agenda more pressing than [A] (Never – always)	New items
D10	Memory, attention and decision processes	Memory (4)	[A] in [C, T] with [Ta] is easy to remember (Strongly disagree – strongly agree) How often do you forget [A] in [C, T] with [Ta]? How often do you have to check the [innovation/guideline] before [A] in [C, T] with [Ta]? (Never – almost always) To what extent do you know [innovation/guideline] by heart to [A] in [C, T] with [Ta]? (Not at all – very much so)	New items
		Attention (4)	When I need to concentrate to [A] in [C, T] with [Ta], I have no trouble focusing my attention When I am working hard on [A] in [C, T] with [Ta], I still get distracted by events around me When trying to focus my attention on [A] in [C, T] with [Ta], I have difficulty blocking out distracting thoughts	Adapted from Derryberry and Reed [51]

			When concentrating on [A] in [C, T] with [Ta], I can focus my attention so that I become unaware of what's going on around me (Strongly disagree – strongly agree)	
D11	Environmental context and resources	Resources/ material (8)	[Innovation/guideline] has a good fit with routine practice [Innovation/guideline] provides the possibility to adapt it to the [Ta]'s needs (e.g., culture) In the organization I work [A] in [C, T] with [Ta] is routine In the organization I work there is enough time to [A] in [C, T] with [Ta] Within the socio-political context there is sufficient financial support (e.g., from local authorities, insurance companies, the government) for [innovation/guideline] Within the socio-political context there are good networks between parties involved in [innovation/guideline] Prior to delivery of [innovation/guideline] professionals are provided with a training to [A] in [C, T] with [Ta] During the delivery of [innovation/guideline] professionals are provided with sufficient financial reimbursement to [A] in [C, T] with [Ta] (Strongly disagree – strongly agree)	New items
D12	Social influences	Social support (4)	I can rely on the team of professionals with whom I deliver [innovation] when things get tough on [A] in [C, T] with [Ta] My colleagues are willing to listen to my problems related to [A] in [C, T] with [Ta] The team of professionals with whom I deliver [innovation] is helpful in getting [A] in [C, T] with [Ta] done I can rely on my colleagues when things get tough on [A] in [C, T] with [Ta]	Adapted from Frese [50]
		Subjective norm (2)	Most people who are important to me think that I should [A] in [C, T] with [Ta] Most people whose opinion I value would approve me of [A] in [C, T] with [Ta]	Adapted from Ajzen [41]
		Descriptive norm (2)	The team of professionals with whom I deliver [innovation/guideline] [A] in [C, T] with [Ta] Respected colleagues [A] in [C, T] with [Ta] (Strongly disagree – strongly agree)	Adapted from Cialdini et al. [53]
D13	Emotion	Affect (2)	Thinking about yourself and how you normally feel as a professional that delivers [innovation/guideline], to what extent do you generally feel inspired with regard to [A] in [C, T] with [Ta] Thinking about yourself and how you normally feel as a professional that delivers [innovation/guideline], to what extent do you generally feel nervous with regard to [A] in [C, T] with [Ta]	Adapted from Thompson [49]
		Stress (2)	Have you recently, during the past two weeks been able to enjoy your normal day-to-day activities? Have you recently, during the past two weeks been feeling unhappy and depressed?	Goldberg and Blackwell [48]

			(Never always)	
D14	Behavioral regulation	Automaticity (2)	[A] in [C, T] with [Ta] is something I do automatically [A] in [C, T] with [Ta] is something I do without thinking	Adapted from Gardner et al. [47]
		Self-monitoring (4)	I keep track of my overall progress towards [A] in [C, T] with [Ta] I tend to notice my successes while working towards [A] in [C, T] with [Ta] I am aware of my day-to-day behavior as I work towards [A] in [C, T] with [Ta] I check regularly whether I am getting closer to attaining [A] in [C, T] with [Ta]	Adapted from Maes et al. [45]
		Action planning (4)	I have a clear plan of how I will [A] in [C, T] with [Ta] I have a clear plan under what circumstances I will [A] in [C, T] with [Ta] I have a clear plan when I will [A] in [C, T] with [Ta] I have a clear plan how often I will [A] in [C, T] with [Ta] (Strongly disagree – strongly agree)	Adapted from Sniehotta et al. [46]

Note. [A], action; [C], context; [T], time; [Ta], target

Appendix B-Complete Questionnaire Package Mailed to Study Participants

August 1, 2018

Dear XXXX:

A team of researchers at Memorial University has asked the Remote Monitoring Project to help invite participants to a research study that will explore what might help and what might make it hard to follow a meal plan to help manage diabetes. The team hopes to gather information that will eventually help develop an intervention to help patients better manage their diabetes. The study involves filling out one survey that is included with this letter.

If you are interested in taking part, simply complete the survey and send it back to the researchers in the included envelope. If you are not interested in taking part, please feel free to ignore the survey. You can contact the lead study researcher directly. Her name is Taylor Wilson, and she can be reached at 709-864-6620 or by email at tdw523@mun.ca. Taylor is a research student within the Faculty of Medicine, Memorial University. She is happy to answer any questions you may have about the study.

We thank you for taking the time to think about the research study. Again, please feel free to contact Taylor if you have any questions. If you would like to talk to someone who is not involved with the study, but who can advise you of your rights as a participant, you can call or email the Ethics Office at 709-777-6974 or info@hrea.ca.

Best regards,

The Remote Monitoring Project Team
Eastern Health

Title: Exploring the Barriers and Facilitators of Following a Meal Plan for Type 2 Diabetes: A Survey Using the Theoretical Domains Framework

Researcher: Taylor Wilson
1-709-864-6620
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Co-Supervisors: Dr. Laurie Twells Dr. Holly Etchegary
1-709-861-6655 1-709-864-6605
ltwells@mun.ca *holly.etchegary@med.mun.ca*

Hello, we are pleased to invite you to participate in a research project in your community entitled "Exploring the Barriers and Facilitators of Following a Meal Plan for Type 2 Diabetes: A Survey Using the Theoretical Domains Framework."

This form is part of the process of informed consent. It should give you a basic idea of what this project is about and what your participation will involve. It also describes your right to withdraw from the project. In order to decide whether you wish to participate in this research project, you should understand enough about the potential risks and benefits to be able to make an informed decision. This is the informed consent process.

Take time to read this carefully and to understand the information given to you. Please contact the researcher, Taylor Wilson before you consent to participate if you have any questions about the study or for want more information not included here.

Introduction/ Background to the study

My name is Taylor Wilson and I'm a graduate student at Memorial University of Newfoundland. A team of researchers at Memorial University, including myself, have partnered with the Remote Monitoring Project at Eastern Health to invite participants to a research study that will explore what might help and what might make it hard to follow a meal plan to help manage diabetes.

Research shows that patients living with Type 2 diabetes find it hard to make health and lifestyle choices that might reduce the negative impacts associated with uncontrolled diabetes on their long-term health. The study involves filling out one survey that is included with this letter.

Purpose of study

The purpose of the study is to determine what the challenges are for people living with diabetes. We hope the information we gather will eventually help develop an intervention to help patients overcome the challenges of living with diabetes.

What you will do in this study

This study includes filling out one survey. Your participation in this survey is completely voluntary. If you decide to complete the survey, all responses will be kept confidential and anonymous. It is your choice to decide if you want to take part in the survey. Your decision to fill out this survey will have no impact on your health care. You may stop the survey at any time. If you agree to participate in this survey, please answer each question the best you can. The survey is 7 pages in total. When finished the survey, you can return the survey to the research team using the postage-paid envelope provided. Please do not write your name on the survey itself.
If you choose to complete the survey, we would like to thank you by entering your name in a draw for a chance to win a $50 Visa gift card. To enter the draw, please fill out the enclosed, postage-paid return card with your name, address, email, and phone number. This information will not be linked to your survey. After the draw, your personal information will be safely destroyed.

Length of time

The survey included with this letter will take approximately 30 minutes or less and can be completed in the comfort of your home.

Withdrawal from the study

It is entirely up to you to decide whether or not to take part in this research. If you choose not to take part in this research or if you decide to withdraw after the research it has started, it will not affect you. All completed and returned surveys will not have any personal identifying information; therefore, once the survey has been returned, we cannot exclude your results from the survey.

Possible benefits

There are no direct benefits to you by filling out the survey. The possible benefits of this study will be to help in the future development of an intervention that is theory-informed for patients with type 2 diabetes. The intervention will be developed by focusing on the things that patients tell us in this survey are the hardest challenges in managing diabetes.

Possible risks

We don't anticipate any risks for the participants for filling out the survey. The questions on the survey are not sensitive for the average person, but admitting you have difficulties with following a meal plan could cause some participants to reflect on their prior actions. There are no physical discomforts associated with completing the survey as well as no emotional/mental discomforts for the average person.

Privacy and Confidentiality
Confidentiality is ensuring that identities of participants are accessible only to those authorized to have access.

All surveys are to be returned with no personal identifiers (name, address, contact information). All data from the surveys will be anonymous and not linked to the participant in any way.

Anonymity
Anonymity refers to not disclosing participants' identifying characteristics, such as name or description of physical appearance.

All survey data will be anonymous and will not be linked to a participant's personal information.

Storage of Data

Anonymous survey data will be stored electronically in a password protected data file on a password-protected computer in the locked office of the PI; hard copies of surveys will be stored in a locked filing cabinet in the locked office of the Principal Investigator, Taylor Wilson. Taylor Wilson will have access to the anonymous data. The All data will be stored for 5 years. After the 5 years, paper surveys will be shredded and disposed of in the faculty of Medicine building at Memorial University in the Business Centre Room 4M400 in the locked recycling container. Electronic files will be permanently deleted.
Reporting of Results

The data collected from the surveys will be used in a thesis project. The results will be in no way connected to any patient who participated in the survey. Data will be reported in a summarized form only (e.g., percentage of survey respondents responding to an item). Results will be reported in academic journals and through presentations at Memorial University and Eastern Health. Additionally, a plain language summary of the results will be provided to the Remote Monitoring Project to be sent back for participants to see.

Sharing of Results with Participants
A plain language summary of the results will be provided to the Remote Monitoring Project to be sent back for participants who are interested. The results will include our findings of the most challenging behaviors of living with diabetes. We will post a copy of the results summary on our website at Memorial University and the nurses who work with the Remote Monitoring Program will have the link for any patient who is interested. Interested patients can also contact the researchers directly for a copy of the summary.
Conflict of Interest
There are no conflicts of interest.

Questions or problems
If you have any questions about taking part in this study, you can contact the researcher who is in charge of this study, Taylor Wilson can be reached at 1-709-864-6620. You can also contact her co-supervisors, Laurie or Holly, at any time with questions or concerns. Laurie can be reached at 864-6655, Holly can be reached at 864-6605.
You can also speak with someone who is not involved in the study but can advise you on your rights as a participant in this study.
This person can be reached at:
Ethics Office, Health Research Ethics Authority
709-777-6974 or by email at info@hrea.ca

CLINICAL EPIDEMIOLOGY, FACULTY OF MEDICINE
MEMORIAL UNIVERSITY OF NEWFOUNDLAND
TDF SURVEY FOR T2DM
ROOM 4M123, FACULTY OF MEDICINE BUILDING
300 PRINCE PHILIP DR
ST. JOHN'S NL A1B 3V6

For your chance to win a $50 Visa gift card, please complete

the below and return separately from your completed survey:

Name:_____

Address:_____

_____

_____

Email:_____

Phone:_____

Part A – Experience with Following a Meal Plan to Help Manage your Diabetes

Please give us your opinion on the following statements by circling one response for each item.

We are using a specific question format to understand the challenges of following a diabetes meal plan. This format involves a specific number of questions to make sure we are not missing any important information. This means that there may seem like there is a lot of repetition, but each question is important. We really appreciate you taking the time to complete the survey.

Knowledge							
1. I am aware of the content and objectives of Eating Well with Canada's Food Guide.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
2. I know the content and objectives of Eating Well with Canada's Food Guide.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
3. I am familiar with the content and objectives of Eating Well with Canada's Food Guide.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
4. I am aware of how to follow a meal plan that will help me manage my diabetes.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
5. I know how to follow a meal plan to help me manage my diabetes.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
6. I am familiar with how to follow a meal plan that helps me manage my diabetes.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
Skills							
7. I have been trained on how to follow a meal plan to help me manage my diabetes.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
8. I have the ability to follow a meal plan to help me manage my diabetes.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
9. I have the skills to follow a meal plan to help me manage my diabetes.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
10. I have practiced following a meal plan to help me manage my diabetes.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**

Beliefs about Capability							
11. I am confident that I can follow a meal plan to help me manage my diabetes even when I'm not motivated.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
12. I am confident that I can follow a meal plan to help me manage my diabetes even when there is little time.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
13. I am confident that if I wanted, I could follow a meal plan to help me manage my diabetes.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
14. How much control do you have over following a meal plan that will help you manage your diabetes? (e.g., Are you the cook at home? Do you have access to healthy foods? Etc.)	**No Control**	1	2	3	4	5	**A lot of Control**
15. For me, following a meal plan to help me manage my diabetes is…	**Impossible**	1	2	3	4	5	**Possible**
16. For me, following a meal plan to help me manage my diabetes is…	**Very Difficult**	1	2	3	4	5	**Very Easy**
Optimism							
17. With regard to following a meal plan that will help manage my diabetes in uncertain times (e.g., when things aren't going so good in my life or during periods of upheaval like moving house, changing jobs or travelling for work, etc.), I usually expect the best.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
18. With regard to following a meal plan that will help me manage my diabetes, I'm always optimistic about the future.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
19. With regard to following a meal plan that will help me manage my diabetes overall, I expect more good things to happen than bad.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
20. With regard to following a meal plan that will help me manage my diabetes, if something can go wrong, it will.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
21. With regard to following a meal plan that will help me manage my diabetes, I hardly ever expect things to go my way.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**

22. With regard to following a meal plan that will help me manage my diabetes, I rarely count on good things happening to me.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
Beliefs about Consequences							
23. For me, following a meal plan to help me manage my diabetes is…	**Useless**	1	2	3	4	5	**Useful**
24. For me, following a meal plan to help me manage my diabetes is…	**Bad**	1	2	3	4	5	**Good**
25. If I follow a meal plan to help me manage my diabetes, it will benefit my health.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
26. If I follow a meal plan to help me manage my diabetes, it will have disadvantages for my health.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
Reinforcement							
27. Whenever I follow a meal plan to help me manage my diabetes, I get recognition from people who are important to me.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
28. If I follow a meal plan to help me manage my diabetes, I feel like I am making a difference for my health.	**Never**	1	2	3	4	5	**Always**
Intentions							
29. For how many of the next 10 days do you intend to follow a meal plan to help you manage your diabetes?	**Never**	1	2	3	4	5	**Always**
30. I will definitely follow a meal plan to help me manage my diabetes for the next week.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
31. I intend to follow a meal plan to help me manage my diabetes for the next week.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
32. How strong is your intention to follow a meal plan to help you manage your diabetes in the next week?	**Not Strong**	1	2	3	4	5	**Very Strong**
Goals							

33. I have a clear plan of **how** I will follow a meal plan to help me manage my diabetes.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
34. I have a clear plan **when** I will follow a meal plan to help me manage my diabetes. (e.g., at work, at home, on vacation, etc.)	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
35. I have a clear plan **how often** I will follow a meal plan to help me manage my diabetes. (e.g., how many days a week)	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
36. How often does something come up in your day-to-day routine that is a higher priority than following a meal plan to help you manage your diabetes and instead you eat something more convenient? (e.g., work function, meeting, social event, vacation)	**Never**	1	2	3	4	5	**Always**
37. How often does something come up in your day-to-day routine take precedence over following a meal plan to help you manage your diabetes and instead you eat something more convenient? (e.g., work function, meeting, social event, vacation)	**Never**	1	2	3	4	5	**Always**
38. How often is covering something else on your agenda more urgent than following a meal plan that will help you manage your diabetes? (e.g., work function, meeting, social event, vacation)	**Never**	1	2	3	4	5	**Always**
39. How often is covering something else on your agenda more pressing than following your meal plan to help you manage your diabetes? (e.g., work function, meeting, social event, vacation)	**Never**	1	2	3	4	5	**Always**
Memory, Attention, and Decision Making							
40. Following a meal plan that helps me manage my diabetes is easy to remember.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
41. How often do you forget to follow a meal plan that will help you manage your diabetes?	**Never**	1	2	3	4	5	**Almost Always**

42. How often do you have to check the Eating Smart with Canada's Food Guide before following your meal plan to help manage your diabetes?	**Never**	1	2	3	4	5	**Almost Always**
43. To what extent do you know Eating Well with Canada's Food Guide by heart to follow a meal plan to help manage your diabetes?	**Not at all**	1	2	3	4	5	**Very much so**
44. When I need to concentrate on following my meal plan to help manage my diabetes, I have no trouble focusing my attention.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
45. When I am working hard on following my meal plan to help manage my diabetes, I still get distracted by events around me.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
46. When trying to focus my attention on following a meal plan that helps me manage my diabetes, I have difficulty blocking out distracting thoughts.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
47. When concentrating on following a meal plan that helps me manage my diabetes, I can focus my attention so that I become unaware of what's going on around me.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
Environmental Context and Resources							
48. Following a meal plan that helps manage my diabetes is a good fit with my daily life.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
49. Following a meal to help manage my diabetes can be adapted to my individual needs. (e.g., food availability)	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
50. In my place of work, following a meal plan to help manage my diabetes is routine.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
51. In the organization I work, there is enough time to follow a meal plan that helps me manage my diabetes.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
52. I have sufficient financial resources to follow a meal plan to help me manage my diabetes.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**

53. Within the community where I live, I have access to the recommended foods to follow a meal plan to help me manage my diabetes.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
54. I have access to healthcare professionals to help me follow a meal plan to help manage my diabetes. (e.g., dieticians, general practitioner)	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
Social Influences							
55. My colleagues are willing to listen to my problems related to following a meal plan that helps me manage my diabetes.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
56. The people around me (in my home) are helpful when I'm trying to follow a meal plan that is good for my diabetes management.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
57. I can rely on the people around me when things get tough for following a meal plan that helps me manage my diabetes.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
58. Most people who are important to me think that I should follow a meal plan that helps me manage my diabetes.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
59. Most people whose opinion I value would approve me of following a meal plan that helps me manage my diabetes.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
Emotions							
60. As a person with Type 2 Diabetes to what extent do you generally feel inspired with regard to following a meal plan that will help you manage your diabetes ?	**Never**	1	2	3	4	5	**Always**
61. As a person with Type 2 Diabetes to what extent do you generally feel nervous with regard to following a meal plan to help you manage your diabetes?	**Never**	1	2	3	4	5	**Always**
62. Have you recently (during the past two weeks) been able to enjoy your normal day-to-day activities?	**Never**	1	2	3	4	5	**Always**
63. Have you recently, during the past two weeks been feeling unhappy and depressed?	**Never**	1	2	3	4	5	**Always**
Behavioural Regulation							

64. Following a meal that helps me manage my diabetes is something I do automatically.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
65. Following a meal that helps me manage my diabetes is something I do without thinking.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
66. I keep track of my overall progress towards following a meal plan that help me control my diabetes.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
67. I tend to notice my successes while working towards following a meal plan that helps me manage my diabetes.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
68. I am aware of my day-to-day behavior as I work towards following a meal plan that helps me manage my diabetes.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
69. I check regularly whether I am getting closer to reaching success in following a meal plan that helps me manage my diabetes.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
70. I have a clear plan of how I will follow a meal plan that will help me manage my diabetes.	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
71. I have a clear plan of how I will follow a meal plan that will help me manage my diabetes when my normal day-to-day routine changes (e.g., when I have guests over or when I'm out for dinner, etc.).	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
72. I have a clear plan of when I will follow a meal plan that will help me manage my diabetes (e.g., at work, at home, out for dinner).	**Strongly disagree**	1	2	3	4	5	**Strongly agree**
73. I have a clear plan of how often I will follow a meal plan that is good for managing my diabetes. (e.g., I know how many days a week I will stick to my meal plan).	**Strongly disagree**	1	2	3	4	5	**Strongly agree**

Part B – Some information about you. Please answer the following questions:

1. Sex
Male ☐
Female ☐
Other ☐

2. Age (in years)

3. Height (cm or inches)

4. Weight (lbs or kg)

5. What health authority do you reside in?
Eastern ☐ Western ☐ Central ☐ Labrador-Grenfell ☐

6. Have you been diagnosed by a professional with any of the following conditions (check all that apply):
High Blood Pressure ☐ Sleep Apnea ☐ High Cholesterol ☐
Coronary Artery Disease ☐ Osteoarthritis ☐ Other ☐

7. Are you on medication for your diabetes? Please provide medication (e.g., Insulin)
Yes ☐ No ☐

8. How long have you been diagnosed with diabetes (in years)?

9. Do you think a mobile application (APP), a program that goes on your phone or tablet that provides help with managing type 2 diabetes, would be an effective tool to help you manage your diabetes? Would you use the APP? Why or why wouldn't it help? Briefly Explain.

Appendix C-Supplemental Data 1 - Patient Engagement Sessions Field Notes

The following data were collected as part of the pre-survey patient engagement. Data were taken from field notes and direct quotes by patients at three patient engagement sessions. The first session was at the Diabetes walk in 2017. Members of the research team engaged with healthcare professionals from Eastern Health who were part of the RMP for Type 2 diabetes. The nurses at the Remote Monitoring Project then identified two sisters living with diabetes and the research team was given permission to contact them and arrange a time to meet. The research team also reached out to cooking classes for people living with diabetes and the team received an invite to attend a session and were allotted time to ask patients about their experience with Type 2 diabetes. All three of these sessions informed the content for the questionnaire.

Table 8-1 Walk for Diabetes Excerpts Taken from Onsite

Walk for Diabetes May 28th 2017
We spoke with exhibitors and organizers approximately 2 hours prior to the start of the walk. Most participants did not turn out until 15-20 minutes before the walk started. It was difficult to talk at this point, as registrants had to visit every booth and the registration desk. Most were children with Type 1 diabetes and their parents (who were not the audience we wanted to engage with). Though we did speak briefly with one sister of a person with Type 2 diabetes. The event did not result in talking with patients, but was very useful from a provider perspective. We took detailed notes from providers as follows. **Rep from Diabetes Canada and the local chapter:** "Our number one question is 'what should I eat?' Knowledge is an issue. A lot of doctors are diagnosing patients and not referring them on, so no education. A lot of doctors don't do that. So people really don't know." "Exercise is the next big thing. People know they should do it, but don't have the time, or the cost factor, that kind of thing." "Goal setting is the number one problem. They don't know how to do it. Goal setting needs to be a huge part of whatever you do." [meaning – whatever intervention we create] In her opinion, some intervention delivered on cell phones should work: "well, we all have these things with us everywhere we go." **Three personal trainers** "E-technology could be very useful. Part of it could be a tracking APP. My Dad has Type II Diabetes. He had his treatment plan, but doesn't want to write stuff down. He's like, insulin?

Was that this morning or yesterday?" So something that tracked that kind of thing would be useful."
"When you have a lot of different elements in your treatment plan, and other health issues, that would be helpful. To keep track of meds and insulin, that stuff."
"You don't want people to be googling and scaring themselves. They need information that is simple. You need to keep it simple for people."

Two physiotherapists

"People don't get the seriousness of diabetes and the implications it will have later in life. They just think about their sugars. I had one gentleman with peripheral neuropathy and he never thought it would happen to him. If you don't take care of it now, it will get worse."
"A lot of people don't even know if they have Type I or Type II. Well, it's usually the Type II's that don't know. Oblivion is a great place to live."
In terms of developing an intervention – "Those constant reminders of 1) knowing the consequences, and 2) self-managing their diabetes are critical." And, "A personalized plan that people can fill in themselves."
"People don't understand the highs and lows of blood sugars, what that means."
"Reminders would be good for sure. People in general don't take care of their health. You might only get people interested that are actually ready to change. And that might be a good place to start."
"Education is lacking. People feel as long as I take my insulin, I'm fine. Education really is an issue."
"People really don't get the seriousness down the road. People don't want to deal with it."
"You need repetition, repetition, repetition."
"The people who get admitted with the things like peripheral neuropathy, they are unfortunately more likely to be of lower socioeconomic status, and not using e-technology. They are the most challenging population."
"And what are parents telling their kids? They are the kids and market that would be the users of e-technology."

Sister of a person with diabetes

"What's challenging is losing the weight and keeping it off. Like anyone else. Knowing you have diabetes and have to lose it, that's the challenge. My sister is educated. That's no problem. For everyone else, it's just a plate of fish and chips every now and then. But for a diabetic, it's more important."

Table 8-2 Meeting at Medical School Field Notes

May 30th 6:30pm-8:30pm **Meeting with Type 2 Diabetic Patients at Memorial Medical School**
Two sisters, both diabetic; husband of one also attended. Diabetic for about 10 years. Ages: Late 40's – early 50's. Both sisters in the Remote Monitoring Program, and that's where conversation started…both largely endorsed the program, but began by noting things they thought could be better…

"We can put in our readings, but can't go back and change anything if you make a mistake."
"You can't record the amount of insulin you use. I need to keep a record of what I take, but you can't do it here. I have to write it down somewhere else."
"Our regimens are totally different. It needs to be individualized. These things [meaning e-technologies] need to be individualized to the person."
"There is also no way to make a note back to the nurse on the ipad. You have to call and wait for them to call back."
On the chronic disease self-management program which both sisters are also doing (or will be):
"It would be nice if we could focus only on diabetes. They could give us updates on new things."
Moving on to the topic of how to help people with diabetes…challenges/facilitators
"If you are on the coast of Labrador, it is not that easy to see a health professional. But they [meaning diabetics] all need access to many healthcare professionals."- Husband
"He is a great supporter. This is a facilitator. I find him really helpful." Wife
"An app you can get for your phone that tracks everything you eat. If you are tracking your food by writing it all down, you won't get it all. The app would be really helpful." - Husband
"I have a flip phone, I don't have a smart phone. So that wouldn't work for me. If I could get a tablet, that would work, and the older generation, they aren't up on technology. But the tablet is really easy to use. It's user friendly. The remote monitoring tablet is menu driven. You can select what you need to do."
"One of the barriers is communication. No one wants to be told what they can and can't eat. We need to be non-judgmental."
"Newfoundlanders don't want to take responsibility for their health. That's a barrier you have to bridge. People believe there is no consequence to their eating cause their grandfather and father lived to be 91. So they see this and it's hard to get over that."- Husband
"You hear stories of others and that's what you remember. You don't hear about the 100 people who follow the diet and live well. You remember the outliers."
"A lot of information is fine when you are first diagnosed as a diabetic. The dietician told me after 3-4 visits, you have all the information, now go do it. I needed more information. I need help."- Sister
"I find the exercise makes a difference for me. See, individual differences again? So for me, exercise is good. For him, eating seems to make the difference."- Wife
"I work where I live. I don't get a lot of time. If it's a big complicated app you have to do, that's not going to work either." -Sister.
"A reminder might be helpful [on specific things the app might do]. Every 15 minutes, get up and move. People don't know this."- Husband
"Something has to change. It needs to be a lifetime change. That needs to come from within. But something has to trigger that. How do you trigger that? That's the question."- Wife
"Because you're being monitored, there's something in your head. As long as you're being monitored, you have a different mindset. It's the accountability factor."- Husband
"The accountability factor works for me. I know someone is watching me. It keeps me on track, it really does." -Wife
"Diabetes is a constant thing. It's every day, all day. It's those numbers. It's how you feel, it's what you eat, and what you do and exercise."

"Lots of things are deceiving. Eat lots of veggies. But not the frozen ones. I never thought there would be more carbs in frozen veggies. I didn't know. And my supermarket is over an hour away. So you can't always eat fresh." Sister "Little tips on the app could be helpful. Like an Asian pear has 20 grams of carbs, most fruit has 15. So even if you think you are doing well [as in food choices], you have limits on you there too." Sister "I would like to know what kinds of exercise I can do. I have other conditions, so I need to be careful. I would like tips on what I can do." Wife "Family doctors are not helpful on giving information about exercise." All three agreed there was very little support from family doctors or information on exercise and certainly nothing individualized. "They don't send you anywhere. There's no one to talk to about exercise. You don't know where to go for advice on exercise." -wife "You could see a physiotherapist, but not everyone can afford one, not everyone can access one. If you are in rural newfoundland or the coast of Labrador.." -Husband "If you had a question about diabetes, without having to go to a doctor, someone, somewhere should be able to answer that. You put in the question and the information comes up."- Sister "Diabetes is a full time job." -Sister "Yes it's a constant, constant thing." -Wife "Eating out is a real issue. If I went to A&W, I wouldn't know what I could eat. But I know what I can have at McDonald's. They have the information sheet. So if this was on the app. Not all restaurants obviously, but the popular ones."- Sister "Family doctors seem to know nothing about the Remote Monitoring Program. It would be good if they could go and check your numbers." "I'm just starting to use my fitness app. Certain things I like, but certain things I don't. I can't enter some stuff because you need to know the calories, and it won't let you go to the next page." "We're all going forward with technology, and the younger ones are for sure. The older ones could use the ipad fairly easily." "I don't know how much insulin to take. If there was some way to have that information. My diabetic nurse doesn't want to teach me the sliding scale. She doesn't want to involve me with that."- Sister This led to discussion of clinical issues like adjusting the amount of insulin, where to inject needles, etc. We advised the app could not really help with these sorts of clinical issues, but would likely focus on lifestyle changes. All three agreed this would still be helpful and suggested a frequently asked question section would also be useful.

Table 8-3 Diabetes Cooking Class Field Notes

November 28th, 2017 **Diabetes Cooking Class with Registered Dietician, Torbay Road, St John's**
Participants: 5 Females 1 Male -Two of the six people here are spouses attending on behalf of their affected spouses. -Average age ~50 years old

- Patients interested in learning about nutrition of foods at certain restaurants around St John's and surrounding areas.

Research team gives description of project and the idea of developing a mobile application (APP) as a form of intervention and asks what the main barriers appear to be when self-managing diabetes

- "We think we're doing a great job because we eat apples or foods that seem to be healthy but we don't know what to pair our foods with"
- Patient doesn't have computer at home nor do they have a smartphone
- "I could get used to having a mobile app"
- "knowing what to look for on food labels is difficult"
- "Going to social events is really difficult, especially when guests bring food over, we don't know what is in the food or the sugars in it"
- "I've never liked to exercise that is my worst thing"

Note: Most challenging part of managing diabetes in this class appear to be knowledge and are all related to food content and not knowing

Patients are open to the idea of app and give app suggestions

- Creating combinations and suggestions for food pairings
- Something for reading labels when at the food market
- Scan food items at grocery stores like weight watchers does
- Something to keep an eye on feet, eye sight, and something that gives us reminders
- Pedometer for goal setting
- Different settings so you can enter age group and physical ailments so that results and suggestions are specific to each person
- Real life stories so we can relate to others who have gone through the same thing and what their solutions were