A thesis submitted for the Degree of Doctor of Philosophy

**Project Title:**

# The Use of Mobile Text Messaging as a Behavioural Intervention to Increase Physical Activity in Adults with T2DM in Saudi Arabia

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**Acknowledgment**

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**Abstract:** This feasibility study has informed the suitability of the protocol design for a future full-size RCT. Our findings have demonstrated that the research processes for our feasibility design have been feasible and acceptable. Our collected data demonstrated a small but statistically significant increase in exercise self-efficacy, physical activity levels and barriers to physical activity, although these findings need to be confirmed by randomised experimental trials in the future.

**Aims:** The primary aim was to assess the feasibility and acceptability of mobile phone text messaging intervention for people with T2DM. The secondary aim is to explore whether certain outcomes are sensitive to change by comparing outcomes of measurement before and after the intervention.

**Methods:** A mixed method using a parallel design was chosen as an appropriate method in this study to address the aim and objectives of this thesis. The evaluation was carried out during the study to explore the rate of recruitment, adherence to the intervention, retention, data completion and any adverse events. The intervention was delivered over six-week period as a medium-term, combining a single-group feasibility clinical trial with pre-post measures.

**Conclusion:** The quantitative and qualitative findings of this feasibility study suggest the feasibility and usefulness of using text messages for patients with T2DM to improve their physical activity levels. This feasibility study used a novel approach and informed the development of a protocol for a large RCT. In future studies, if text messaging is proven effective, this would have a potential impact to reach widely population at a low cost.

# Chapter 1: The Use of Mobile Text Messaging as a Behavioural Intervention to Increase PA in Adults with T2DM in Saudi Arabia


## Abstract

This chapter introduces and evaluates the current knowledge relating to Type 2 Diabetes Mellitus (T2DM); its prevalence, incidence, complications, and treatment management options. The importance of the promotion of physical activity (PA) for the establishment of T2DM management is also justified in this chapter, together with detailed justification of mobile phone messaging use as an intervention and a communication tool to promote PA. Each aspect of these is introduced in the following sections.


## 1.1. Introduction

Diabetes mellitus (DM) is already a major chronic disease in the twenty-first century and is a growing public health concern in both developed and developing countries (Al Dawish et al., 2016). The World Health Organisation has defined DM as:

> *A metabolic disorder of multiple aetiology characterized by chronic hyperglycaemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action, or both. The effects of diabetes mellitus include long-term damage, dysfunction, and failure of various organs.* (World Health Organisation, 1999)

DM can occur when the pancreas gland does not produce enough of the hormone known as insulin, insulin is produced essentially to transport glucose through the bloodstream to cells in the body, where it is eventually converted into useful energy. Insufficient insulin, or bodily cells resistance to insulin, can lead to a rise in the blood glucose level; this is referred to medically as hyperglycaemia (IDF, 2017).

DM is a long-term disease that can include long and short-term dysfunction or damage to major organs. The most common short-term effects are hypoglycaemia, hyperglycaemia, and diabetic emergencies, which is very high blood glucose. DM can increase the risk of other serious conditions, including macrovascular problems, kidney diseases and diabetic retinopathy (Dixit et al., 2014). DM can be classified into three main categories, type 1 diabetes mellitus (T1DM), type 2 diabetes mellitus (T2DM) and gestational diabetes. This study will focus on T2DM due to the presence of a strong link between T2DM and lifestyle factors, such as low physical activity levels, obesity, poor nutrition and sedentary behaviour (Chatterjee et al., 2017).

### 1.2 Type 2 Diabetes Mellitus

Type 2 Diabetes Mellitus (T2DM) is the most common form of diabetes and is also the form that marks the onset of the disease for many sufferers. This type of diabetes occurs as the result of the insufficient production of insulin and the body's resistance to insulin. T2DM is commonly diagnosed in middle-aged and older adults (Chatterjee et al., 2017). The major concern with T2DM is that the initial symptoms may not be instantly noticeable; therefore, patients may have already developed serious side-effects and diabetes-related complications before they are diagnosed (Nolan et al., 2011).

#### 1.2.1 Prevalence and Incidence of T2DM

In developed and developing countries has risen substantially, making diabetes a key health priority globally. The number of people with diabetes has risen from 108 million in 1980 to 422 million in 2014 (WHO, 2018). T2DM accounts for 85-90% of all diagnosed cases of diabetes (WHO, 2018). This estimate is expected to rise to 642 million by 2040, and the largest increases will come from the regions experiencing economic transitions amongst low-income and middle-income levels (Yan et al., 2017).

The reasons for the escalating epidemic of diabetes mellitus are multiple, including population ageing, economic development, urbanisation, unhealthy eating habits and sedentary lifestyles (Yan et al., 2017).

### 1.2.2 Characteristic and Aetiology of T2DM

T2DM is a chronic metabolic condition and typically results from excess intake of calories in comparison to energy expenditure. It is characterised by a progressive poor insulin sensitivity, or poor or no insulin secretion which increases the body's demand for insulin in order to retain glucose homeostasis. Insulin is a hormone made in the pancreas which controls the entry of glucose into the cells throughout the blood steam (IDF, 2017). If the pancreas fails to secrete enough insulin to compensate for increasing insulin demand, the blood glucose level will be raised gradually. This is known as hyperglycaemia, or raised blood sugar; it is a common effect of uncontrolled diabetes and this can lead to short or long-term damage, dysfunction, or failure of different organs, especially the heart, eyes and nerves resulting in increasing levels of morbidity and mortality (American Diabetes, 2014). The aetiology of T2DM has been widely researched but not fully understood, with the possibility of both environmental and genetic components contributing to the disease. There are several risk factors including: obesity, diet, and physical inactivity, increasing age, family history of diabetes, sub-optimal intrauterine environment, and ethnicity (IDF, 2018). A specific aetiology known as the autoimmune destruction of β-cells where it does not occur, and patients do not have any of identified factors (Keytsman et al., 2015). Most of patients with T2DM are overweight or obese and this can worsen some degree of insulin resistance. Those who are not overweight by traditional weight criteria may have an increased percentage of body fat distributed in the abdominal region (Chatterjee et al., 2017).

### 1.2.3 Diagnosis of T2DM

In the past, T2DM was most prevalent in older adults. But due to widespread of poor lifestyle and habits, it is becoming increasingly common in younger people. The diagnosis of T2DM can occur more commonly at the age of 25 and 40 years. However, recently, more children are being diagnosed with the condition, some as young as seven (Milo and Connelly, 2019).

- **Clinical Diagnosis**

There are four methods identified by the American Diabetes Association, and World Health Organisation, whereby T2DM can be clinically diagnosed: 1) A fasting plasma glucose test, following no food intake for ≥8hours, of 7mmol/l or higher; 2) A random plasma glucose of ≥11.1mmol/l, 3) A 2-hour plasma glucose value of 11.1mmol/l following a 75g oral glucose tolerance test; and finally, 4) A HbA1c of ≥ 48mmom/mol (6.5%), a level of between 42- 47mmom/mol ( 5.7- 6.4%)(ADA, 2018). Studies have reported that HbA1c is the most widely used measure of glycaemic haemoglobin control and it indicates the average glucose in the blood steam over a period of 8-12 weeks (Milo and Connelly, 2019). However, The WHO recommend the use of HbA1c as a clinical diagnosis and screening of T2DM (WHO, 2018).

### 1.2.4 T2DM Related Complications

T2DM is a pathology that stands out for the potential of developing short and long-term complications, especially in the absence of good glycaemic control. At a macrovascular level, patients with T2DM may develop serious heart diseases such as ischemic heart disease, cerebrovascular disease, and peripheral vascular disease; these often can lead to morbidity and mortality.

At a microvascular level, T2DM can lead to vision impairment (retinopathy), neuronal damage (neuropathies), and kidney disease (nephropathy) (Umpierrez and Pasquel, 2017). Studies have approved that the severity of T2DM can affect many organ systems in the body and the consequences can severely compromise patients' quality of life. The impact of these complications can reduce the life expectancy of T2DM individuals; for example, a 60-year old male or female may lose up to 10 years of life if no adequate treatment is followed (Papatheodorou et al., 2018). In summary, careful attention should be considered in the treatment of patients with T2DM; glycaemic control management is an effective way of avoiding uncontrolled hyperglycaemia, hypoglycaemia, and other organ-related complications.

### 1.2.5 Treatment and Management of T2DM

The ultimate goal of diabetes self-management is to control glucose levels and eliminate or slow the development of T2DM related complications. Several therapeutic and non-therapeutic classes of T2DM management have been developed to achieve an optimal reduction in glucose goals (Dixit et al., 2014). In this thesis, we have solely focused on PA, this will enable us to ensure that the effect of our intervention on PA related outcomes is attributed to physical activity-related message content, and no other contents such as diet, lifestyle, and general diabetic education. However, we provided a brief background and introduction to each aspect of T2DM management.

- **Lifestyle Change**

There is growing evidence that leading a healthy lifestyle can improve glucose control and reduce the risk of diabetes related complications (ADA, 2018). Normal plasma glucose levels in a healthy individual totally depend on the dietary intake of nutrients,

physical activity and hormones that control the glucose homeostasis, especially insulin sensitivity. The American Diabetes Association (ADA) recommends that patients with T2DM should strive to achieve a glycaemic target or good glycaemic control of HbA1c ≤7.0% (ADA,2017). People with T2DM are exposed to several challenges, they have to make adjustments in their everyday living habits. Therefore, a self-management approach should be considered in T2DM patients' care; this is a critical component that requires patients to obtain the proper skills and knowledge to largely manage their condition on their own. A self-management concept can be defined as a person's ability to manage the symptoms and consequences of living with a chronic disease, including therapeutic and non-therapeutic treatments (Barlow et al 2015). Self-management for T2DM is a lifelong task, it ranges from intensive (frequent blood glucose monitoring and medication adherence) to relatively fewer complex treatments (primarily physical activity and diet).

- **Blood Glucose Monitoring**

Blood glucose monitoring is considered as a key component of other treatment regimens in patients with T2DM. Studies have shown that blood glucose monitoring has a direct effect on a long-term glycaemic haemoglobin control and supports the preventive strategies of short and long-term T2DM related complications (Sapkota et al., 2017). A meta-analysis conducted by Oliver Schnell et al. (2013) compared two treatment strategies using the blood glucose monitoring strategy in addition to following a usual care plan. This study was based on 2552 patients from six trials; results showed significant reduction of HbA1c levels in patients with T2DM (Schnell et al., 2013). The difference in mean reduction at the 3 and 6-months follow-up phases was 0.25% and at 12 months this was found to be 0.35%. The difference in HbA1c levels was consistent across baseline HbA1c levels in relation to age, sex and duration of diabetes (Schnell et al., 2013).

From these clinical studies, patients with T2DM have had less hypoglycaemia and, importantly, they had HbA1c reduction without the intensification of their existing treatments. This demonstrates the importance of blood glucose monitoring in T2DM and should be incorporated into a patient's treatment plan.

- **Dietary Pattern**

Unhealthy dietary habits are one of the leading causes of T2DM. Failure to follow a healthy diet plan can lead to permanently high blood sugar levels and eventually develop T2DM-associated complications (Beigrezaei et al., 2019). Dietary intake has been strongly linked with obesity; this is not only related to the volume of food but also in terms of the composition and quality of diet (McGuire et al., 2016). The most robust research available related to healthy eating patterns for T2DM are low-fat, or low carbohydrate eating plans. Several mechanisms can explain the effect of food intake on T2DM. Meat is one example of a fatty food that contains saturated fatty acids and nitrosamines. These compounds can be toxic to beta cells; therefore, it can stimulate insulin secretion and lead to persistent hyperglycaemia which characterizes T2DM (Beigrezaei et al., 2019). In one of the longest randomized clinical trials (RCTs), the PREDIMED trial, compared a low-fat eating pattern to a Mediterranean style eating pattern. After 4 years, the findings showed that there was statistically a significant improvement in glycaemic control and the need for glucose-lowering medications was lower than the Mediterranean-style eating pattern group (Evert et al., 2019). Low carbohydrate eating patterns have also been shown to reduce HbA1c and lower the need for antihyperglycemic medications. A meta-analysis conducted to compare low-carbohydrate to high-carbohydrate eating patterns, the larger the carbohydrate restriction, the greater the reduction in HbA1c was observed (Evert et al., 2019).

Another meta-analysis of RCTs compared a low carbohydrate eating pattern to a low-fat eating pattern (both were defined as and <40% of calories from carbohydrate and <30% of calories from fat). In this meta-analysis, the low-carbohydrate eating pattern improved HbA1c, lowered triglycerides, raised HDL-C, lowered blood pressure, and resulted in greater reductions in glucose-lowering medications (Evert et al., 2019).

- **Medication**

As T2DM progresses over time, the blood sugar levels naturally tend to rise and at some point, people with T2DM might need insulin replacement to feel better; this can take the form of either tablets or insulin injections. Metformin (MET) and Sulfonylurea are the most common first-line medications. Considering this strategy of T2DM management represents a key determinant in successfully ensuring the achievement and maintenance of glycaemic haemoglobin control in the short and long-term period (Gordon et al., 2018). These medications can sometimes elicit a good initial glucose-lowering response; however, in some cases intolerable side effects can be experienced (including hypoglycaemia) and a combination of other regimens should be considered. Other regimens may include other oral antihyperglycemic agents (OHA) such as sodium-glucose co-transporter-2 inhibitors (SGLT-2i), thiazolidinedione (TZD) and dipeptidyl peptidase-4 inhibitors (DPP-4i) or injectable regimens including glucagon-like peptide-1 (GLP-1) and insulin-based therapies (NICE, 2019). Failure to ensure medication adherence in T2DM can negatively influence time to treatment intensification, rate of hospitalisations and T2DM related complications (Jannoo and Mamode Khan, 2019).

- **Physical Activity**

For many years, physical activity (PA) has been part of the first line T2DM care management (McGuire et al., 2016). PA can help people with T2DM to achieve a variety of goals, including increased vigour, improved glycaemic haemoglobin control, decreased insulin resistance, increased cardiorespiratory fitness, improved lipid profile, blood pressure (BP) reduction and maintenance of weight loss (Sigal et al., 2018). Several reviews and meta-analyses have summarised the health benefits of PA in T2DM. In a pooled analysis of 23 randomised controlled trials (RTCs) with 12–52 weeks of aerobic and resistance exercise, significant reductions were observed in HbA1c compared to non-exercising control participants (mean difference -0.73%, -0.57% and -0.51%) (Sargeant et al., 2018). It has been recognised that PA can help achieve the target blood glucose control and delay the onset of T2DM related complications (NICE, 2015). A recent meta-analysis of a walking group examined the impact of structured PA on HbA1c levels. The intervention ranged from between 30-120 minutes of a daily walking steps 3 times per week over a 24-week period. Their results showed significant reduction in HbA1c levels, which was more than a 0.56% in comparison with the control group receiving routine PA instructions (Sigal et al., 2018).The ultimate goal of using diabetes management strategies is to keep the HbA1c to a healthier percentage because the poorer blood sugar is a factor that negatively influences those who have a higher risk of T2DM-related complications (Sigal et al., 2018).

### 1.2.6. Why Physical Activity?

- **Definition and Related Concepts**

Physical activity (PA) is defined as "any bodily movement produced by skeletal muscles that results in energy expenditure" (Paoli and Bianco, 2015). This broad definition includes any kind of activity since most movements can produce energy expenditure. PA is unstructured and should not be confused with other terms such as exercise, physical fitness, and active living. Exercise is a sub-category of PA and is defined as a "planned, structured, repetitive and purposive activity with the objective to improve or maintain physical fitness" (Paoli and Bianco, 2015). PA is defined as "a set of attributes that individuals have so that they have the ability to perform physical activity and carry out daily tasks without feeling fatigue" (Paoli and Bianco, 2015). Lastly, active living is a way of life which recommends being active with at least 30 minutes of physical activity daily. PA is best described on the required metabolic equivalent tasks (METs). METs are used to express the intensity of physical activity. MET is the ratio of a person's working metabolic rate or energy cost when they are resting. One MET is equivalent to a caloric consumption of 1kcal/kg/hour (Mendes et al., 2018).

- **PA Guidelines**

There are scientific based guidelines developed to inform on the form, volume, intensity, and frequency of PA required to promote and maintain an individual's health. These guidelines are relevant to all healthy groups aged 18–64 years (Audsley, 2019). There are three level of measures: low intensity, moderate intensity, and vigorous intensity (SBRN, 2018). The current guidelines recommend that healthy people should undertake a minimum of 150 minutes of moderate-intensity physical activity, or 75 minutes of vigorous-intensity throughout the week (Gibson-Moore, 2019).

It is highly recommended to accumulate bouts of 10 minutes or more of moderate and vigorous intensity, and this can include daily living activities such as: walking, gardening, and climbing stairs (Gibson-Moore, 2019). These activities should include strengthening major muscles (chest, legs, hips, back, shoulders, abdomen, and arms) on at least 2 days a week. Strengthening activities can include activities such as: chair aerobics, lifting weights, dancing and carrying heavy bags of shopping (Dowd et al., 2018). PA is recognised as fundamental to the management of diabetes. The American Diabetes Association (2018) has updated their guidelines regarding PA in people with T2DM. People with T2DM should accumulate 150 minutes of moderate activity or 75 minutes of vigorous activity throughout the week, this is relevantly similar in healthy groups (ADA, 2018). People with diabetes should keep active at least 3 days of the week to notice improvement on the long run in glycaemic management (Sigal et al., 2018).

- **Level of Guideline Achievement**

Insufficient levels of physical activity have clearly been shown to be the fourth leading risk factor of global deaths and major diseases (Guthold et al., 2018). In the world, around 23% of groups aged 18 and above have been identified as not active enough (men 20% and women 27%) (WHO, 2018). This percentage has been higher in high-income countries, around 26% of men and 35% of women were considered insufficiently physically active. In low-income countries, around 12% of men and 24% of women did not meet the recommended PA guidelines (WHO, 2018). There are several factors that can discourage people from becoming more active, such as: environmental factors (e.g. urban sprawl, street connectivity, walkability), social networks, neighbourhood safety, public transportation, customs, beliefs and socioeconomic limitations (WHO, 2018).

In England, by 2018, two-thirds of adults (66% male) were considered physically active and 22% of female were to be inactive, this is as per the government guidelines (NHS, 2019). The Saudi population showed high percentage of the male and female population were inactive, with recent research showing that nearly 78% of adult women and 52.1% of men were inactive (Al-Hazzaa and Almarzooqi, 2018).

- **Measuring PA**

There are various physical activity measurement approaches in the literature, it helps to quantify the amount and type of movement, to predict the intensity of physical activity as well as the duration and frequency. These methods have been extensively implemented, studies to date have focused on specific methods (i.e. self-report questionnaires, self-report activity diaries/logs, direct observation, accelerometers, pedometers and heart rate monitors or a comparison of two or more methods) (Dowd et al., 2018). The selected measurement is justified in detailed (see chapter 4).

- **PA in T2DM Management**

PA has been recommended as an important non-pharmacological therapeutic strategy for the management of T2DM (WHO, 2019). Several systematic reviews examined the impact of PA on T2DM related health outcomes, and the results were significant (Avery et al., 2012; Thomas, Elliot & Naughton, 2006; Umpierre et al., 2011). A review by Thomas et al. (2006) showed that exercise-based interventions significantly reduced HbA1c levels by 0.6% in those T2DM compared to the control group. A systematic review and meta-analysis by Avery et al. (2012) showed statistically and clinically significant improvements in HbA1c compared with usual care, except for ≥1 month to <6 months. Furthermore, statistically significant improvements were noticed more across the 12 months follow up.

Structured PA of 150 minutes per week were associated with a 0.89% reduction in HbA1c and less than 150 minutes per week showed only 0.36% reduction in HbA1c (Umpierre et al., 2011). Several systematic reviews concluded that there is consistent evidence to suggest a positive association between PA and T2DM related health outcomes (Edwards and Hosseinzadeh, 2018, Sargeant et al., 2018). The American Diabetes Association (2018) has recently highlighted that PA is one of the key lifestyle components necessary for good glycaemic level control in those with T2DM (ADA, 2018). Although PA is a focus T2DM management, people's physical activity levels remain low, making it important to understand why this is and what can be done to improve amongst people with T2DM.

### 1.2.7 Sections Summary

This section has demonstrated the initial background of this thesis by introducing T2DM, its short-long complications and key aspects of T2DM management. PA has been identified as an essential component behind the management of many chronic diseases. Regular exercise has been shown to have a positive effect on T2DM related clinical outcomes such as HbA1c, weight, lipid abnormalities, blood pressure and insulin sensitivity (Sigal et al., 2018). In chapter (2), we will systematically assess this topic and report its findings as part of the MRC guideline.

**Key Points:**

- Globally, about 1 in 11 adults aged 20-79 have diabetes mellitus, in 2015 around 415 million adults had diabetes mellitus. T2DM accounts for 85-90% of all diagnosed cases of diabetes (Yan et al., 2017).

- Saudi Arabia has reached 7 million cases of diabetes with a prevalence of 17.7% in men and 16.4% in women (WHO, 2015).
- Worldwide, the number of people with diabetes aged 20-79 years is predicted to rise to 642 million by 2040 (IDF, 2017).
- Physical activity (PA) remains a major public health concern worldwide and is an important aspect of diabetes management. Globally, 23% of adults aged 18 and over (men 20% and women 27%) do not meet the global physical activity recommendations (WHO, 2018).
- In Saudi Arabia, 58.5% of people are considered physically inactive (52.1% of men and 67.7% of women) (Alahmed and Lobelo, 2018).

### 1.4 Technology and Diabetes Self-Management

Using technology to facilitate diabetes self-management is not a new concept, but as patients become more technologically engaged, devices become more available, and new technologies emerge, the variety of self-management strategies increases. Technology can be utilised to supplement healthcare provider diabetes care by providing both motivational and educational support. Through technology patients can learn new practices and routines related to their diabetes management and this can include blood glucose monitoring, exercising, healthy eating, taking medication, monitoring for complications, and problem-solving (Greenwood et al., 2017). The most suitable term for technology in health care is called eHealth, it can encompass a broad range of areas within healthcare management, and they can be also called digital health. The World Health Organisation has defined eHealth as: "The cost-effective and secure use of Information Communication Technology (ICT) in support of health-related fields, including health-care services, health surveillance, health literature, and health education, knowledge and

research" (WHO, 2016). The term eHealth has been applied in different contexts of health information technology, health information systems and health informatics or medical informatics, this covers several disciplines such as computer science, information, communication technologies and health (Sharifi et al., 2013). eHealth is an umbrella term that covers various areas in health care, such as electronic health records, telemedicine, communications technology solutions and mobile health applications (Sharifi et al., 2013).

Over the past decade, eHealth initiatives have played a key role in expanding access to diagnostic procedures, increasing coordination between health providers, improving the quality of services, increasing patient care management, overcoming rural patient healthcare access challenges and engaging patients to play an active role in their own healthcare and well-being (van Den Heuvel et al., 2018). eHealth services can be classified into several categories: clinical, organisational, professional, financial, and patient-related benefits. These services can deliver a variety of advantages including: reduction in operational expenses, increasing accuracy of procedures and less medical errors, effectiveness, efficiency of the care processes and workflows, and availability of data (van Den Heuvel et al., 2018). Several studies have reported that the use of eHealth can reduce associated symptoms with secondary diseases. In this study, the occurrence of retinopathy was (6.70% vs. 22.20%; $P<0.001$) and nephropathy (5.90% vs.13.70%; $P<0.026$) (Sood et al., 2018). The glycated haemoglobin (HbA1c) value (14.60% vs. 10.60%; $P<0.016$), blood glucose levels (17.60% vs. 13.10%; $P<0.015$), cholesterol (07.10% vs. 06.10%; $P<0.044$) and body weight of participants decreased (Rasmussen et al., 2016). eHealth systems can also be used during patient education sessions and self-care management to strengthen or improve patients' understanding of their medical condition (van Den Heuvel et al., 2018).

Apart from eHealth development, mHealth has significantly enhanced the scope of medical care and improved patient's related health care quality (Short et al., 2018). mHealth refers to mobile health as well as medical and public health practices using mobile devices, computers, wireless technology, and tablets (WHO,2016). The mHealth field has witnessed a fantastic growth as an industry, mainly because of the massive use of mobile phones in both developed and developing countries (Sahin et al., 2019a). The literature has identified several examples of using mHealth platform in the process of digitalisation of health care services, such tools can be utilised to stimulate a positive health behaviour change, assist people to lead a healthier lifestyle, or to support diagnosis and treatment of diseases (Short et al., 2018).

### 1.5. Mobile Health (mHealth)

Since eHealth is mainly focused on information and communication technologies, mHealth seeks to explore more into mobile phone devices and wireless communications. Mobile phone penetration has witnessed a rapid spread around the world in both, high and low-income countries. Today, 95% of the world have full access to mobile networks, approximately 5 billion mobile phones are being used every day across the globe and this expected to exceed 5.5 billion by 2022 (Globalindex, 2020). The potential contribution of mHealth has been widely recognised in making health care delivery more effective and efficient (Early et al., 2019). The use of mHealth is expected to carry all the promises of eHealth, although eHealth and mHealth are not much different from each other, but mHealth is more concerned with mobile phone devices (Early et al., 2019). The World Health Organisation defined mHealth as "a practice of public and medical health care supported by mobile devices, such as smartphones, patient monitoring devices, personalised digital assistance and other wireless devices" (2011, WHO).

The characteristics of mHealth have transformed the delivery of health care services, especially in low- and middle-income countries. This innovation is increasingly being utilised to address a range of issues to many populations in various health areas (Marcolino et al., 2018). The literature has shown that the use of mHealth has improved access to a wide range of services at all levels of health care system: primary, secondary and tertiary, in covering chronic conditions such as diabetes, mental illness, heart diseases, cancer and trauma (Early et al., 2019). mHealth is an umbrella term that includes multiple platforms such text messaging (short message service, SMS), health applications, multimedia message services and Bluetooth technology (Marcolino et al., 2018). Mobile text messaging is the most popular form of mHealth and it has been used in various health care interventions to enhance personalised patient-provider interactions (Early et al., 2019). Mobile text messaging has been extensively researched and considered part of the larger strategy of mHealth in various population health programs (Schwebel and Larimer, 2018). A meta-analysis conducted by Head et al. (2013) showed that the first study using text messaging for health interventions was published in 2002 (Neville et al., 2002). Since then, dozens of published studies have been undertaken to explore the potential use of text messaging interventions in various health populations. The first systematic review was published in 2009 and the main aim of this review was to widen the evidence of health behaviour change interventions delivered via texting messaging; each study has demonstrated a positive result in different aspects of either improving or protecting individuals' health care (Fjeldsoe et al., 2009b).

### 1.6. Mobile Text Messaging (SMS) Application in Diabetes management

Mobile text messaging has become ubiquitous in the healthcare field, over 85% of healthcare providers possess mobile phones, permitting them to exchange basic communications (Text messages, SMS messages) related to clinical work and patient care management (Schwebel and Larimer, 2018). The growing body of literature on text messaging usage has been mainly focused on two areas: behaviour change interventions and reminders; both areas fall under the umbrella of mHealth. Behaviour change interventions can serve as coaching or prompts to help facilitate new healthy behaviours, such as the self-management of chronic diseases. Whereas reminders primarily focuses on outcomes such as appointment attendance and patient adherence (Schwebel and Larimer, 2018). The management of chronic diseases is a dynamic process that can be sometimes challenging due to various factors, such as the lack of patient access to care, geographical barriers, patient-physician communication gap especially in rural areas, shortage of hospital beds, missed appointments and the lack of self-management awareness (Alanzi, 2018). A considerable amount of literature has shown that text messaging based interventions can be effective in improving health change related behaviours and bridging the gaps for people living with chronic diseases (Hamideh Lari et al., 2018). A review conducted by Abaza and Marschollek (2017) showed that several clinical trials have used text messaging to monitor nutritional, encourage weight loss and physical activity goals (Markowitz et al., 2014, Sirriyeh et al., 2010, Steinberg et al., 2013, Shaw et al., 2013, Hebden et al., 2014, Napolitano et al., 2013). A meta-analysis conducted on two studies using text messages for smoking cessation, over the six months study period quit rates were significantly improved with pooled estimate of relative risk (RR) = 2.16; 95% CI: 1.77, 2.62; $p < 0.0001$ (Schwebel and Larimer, 2018).

A randomised controlled trial (RCT) study assessed the effect of a 2-week text messaging scheme which promoted shoulder exercises in people with frozen shoulders. They found significant improvement in shoulder mobility and higher exercise adherence in the SMS group compared with the control group who received only routine exercise instructions (Eysenbach et al., 2019). The effectiveness of text messaging on specific healthcare outcomes have been systematically assessed in this thesis and findings were synthesised in detail to establish an adequate scientific base to support this proposed research, see chapter (2).

### 1.7. The Rationale use of mobile Text Messaging in Saudi Arabia

It is apparent from the conducted review that mobile text messaging–based interventions have been quite effective in a variety of populations and settings, particularly in developing countries (Dèglise et al., 2012, Van Olmen et al., 2016). The portability of mobile phones makes it a flexible means of communication through which people can be easily be reached and respond at their own convenience (Chu et al., 2018). Text messages are relatively inexpensive, easily customized and can be automatically sent directly to receivers. Mobile phones have rapidly become the most popular technology and part of many individuals' daily life (Haider et al., 2019b). The potential effectiveness of text messaging appears to be determined upon the environment it is employed in. The implementation of text messaging in healthcare does not require people to be technologically fluent or have a strong organisational infrastructure (Eysenbach et al., 2019). The literature has shown that the most imperative barrier faced by other advanced mHealth platforms usage is the contextual nature (Coles et al., 2017).

Most of advanced mHealth solutions have been developed and implemented in developed countries (Western societies); thus, the lived experiences, values, beliefs and cultures are most likely to be different from the developing countries (Coles et al., 2017). This finding, while preliminary, suggests that advanced mHealth platforms would not be able to replicate positive results from one to the other unless they have been scientifically tested and approved to be effective (O' Connor and O' Donoghue, 2015). Saudi Arabia is still a developing country, they lack the foundation for advanced technologies and there is very little knowledge about the use of such communication tools. Therefore, the purpose of this study is to explore the feasibility and acceptability of mobile text messaging in promoting solely physical activity in people with T2DM in Saudi Arabia.

- **Sections Summary**

Mobile text messages is increasingly becoming part of people's everyday lives and are being used more frequently as a means of managing health conditions, particularly T2DM management (NICE, 2019). The presented literature shows the broad use of mobile text messaging-based interventions in promoting a range of health behaviours, including adherence to medication and attendance at clinical appointments, smoking and physical activity with varying success rates. The following chapter will systematically assess the evidence on mobile phone messaging-based interventions to promote physical activity in T2DM, see chapter (2).

**Key Points:**

- Mobile text messaging-based tools have the potential to improve health outcomes, whilst lowering cost and reduce demands on health providers.
- Worldwide, there are approximately 7 billion mobile phone users.

- In Saudi Arabia, by 2016, the number of mobile phone users' subscriptions had reached 47.9 million and this is expected to double twice by 2022.
- Mobile text message-based interventions offer several other advantages compared to face-to-face contact with participants.
- Mobile text messaging-based interventions have been applied to a range of health behaviours.
- Many systematic reviews and meta-analysis concluded that mobile messaging-based interventions helped in reducing HbA1c in people with T2DM.

### 1.8 Saudi Arabia Background

- **Demographic and Religion Profile**

Saudi Arabia (SA) is considered the largest country in Middle East and is situated in the southwest Asia; it take up most of the Arabian Peninsula (Almuayqil, 2017). The total population of SA has reached 33.55 million with a growth rate of 1.87% from a 2013 estimate (General Authority for Statistics, 2019). The population is expected to increase in the future, and it is likely to reach 39.1 million by the end 2030. Saudi has experienced rapid economic development in the last three decades following the discovery of oil. Since 2003 to 2014, the KSA economy has become the 19th largest in the world, the household income increased by 75% and this has made available 1.7 million job opportunities for Saudi citizens. Saudi's economy is considered one of the largest in the developing world, almost everything in Saudi has doubled in size on the back of the protracted oil boom. Saudi underwent a significant modernisation that brought prosperity and society transformation.

Figure 2: Saudi Arabia Map (Einstein, 2007)

According to the Saudi Council of Economic and Development Affairs, Saudi national's household income has been adjusted after its significant economy inflation in 2019; therefore, 450 billion dollars were invested in education, health, and infrastructure, which has improved the living standards and lifestyle quality. The Saudi government have invested in major projects which aim to have the following completed by 2030: the King Abdullah Economic City on the Red Sea, more 6 new universities, new metro transit lines and 81 new hospitals. The number of medical doctors has doubled since 1990, Saudi Arabia's life expectancy has risen by almost seven years to 76 years; this is an age higher in comparison to China, Hungary, and Turkey (Saudi CEDA, 2019). The KSA is the birthplace of the Muslim religion. The religion began in the seventh century when Mohammad (peace been upon him) was born in the city called Mecca, in the Hejaz region of Saudi Arabia. Muslims believe that Mohammad was the prophet and founder of Islam. Today, there are over 1.8 billion Muslims in the world, around 33 million Muslims live in Saudi Arabia. The cultural and religious setting of Saudi Arabia is greatly influenced by Islamic culture. Islamic society tends to be deeply religious, conservative, traditional and strictly adherent to Islamic values.

It is important to stress how Islam plays a major role in peoples' everyday lives, people in Saudi have certain beliefs for example that a female should not do certain activities like mixing with a non-family member in the society for exercises, certain clothes are prohibited and should not be wore in public places. Female in Saudi wear the Islamic clothe which can be very challenging to exercise especially in hot weathers and public places. Subsequently, this has shaped the society's beliefs about perceiving the experiences and the determinants of health and disease (Robert et al., 2017).

- **Health Care System Profile**

The system of healthcare in Saudi is being provided through 3 main sectors: primary healthcare centres, governmental institutions, and the private sector. The governmental bodies include several referral hospitals (e.g. King Faisal Specialist Hospital and Research Centre), army forces medical services, security forces medical services, national guard health affairs, ministry of higher education hospitals (teaching hospitals), school health units of the ministry of education, the red crescent society, royal commission for Jubail and Yanbu health services and Aramco hospitals (Al-Hanawi et al., 2019). Currently, there are 244 hospitals (33,277 beds), 2037 primary health care centres and 125 private hospitals (11,833 beds) with over 2218 dispensaries and clinics. The Ministry of Health (MOH) networks these services and provides 62% of the total care for free. The MOH manages, operates and finances all these sectors with regards to care promotion, disease prevention and treatment strategies (Marwa Tuffaha, 2015). The MOH is responsible for formulating, supervising, and monitoring health policies, health programmes and the government's health objectives. In 2019, The MOH's budget comprised the third largest share of 15.6% in the budget expenditure.

The allocation of this budget has grown around 8% which is about SAR172 billion, as compared to SAR159 billion in 2018. Saudi is facing a high population growth that has resulted in a gap of 14,000 beds in 2016, and this gap is expected to widen to 40,000 beds by 2035 (MOH, 2019). In-spite of these significant improvements achieved in providing healthcare services during the past decades, Saudi Arabia is still facing critical challenges in its healthcare system. These challenges include the rapidly growing population, the growing burden of chronic diseases, the high cost of healthcare services and the poor coordination between other health sectors of care. In 2016, Saudi's government enforced a new vision (for 2030) to urgently take newer initiatives towards healthcare services improvement in Saudi Arabia. This includes fixing the challenges of health care scope, infrastructure, structure, finance, increased demand, increased costs, inequitable access to the services, workforce, quality and safety, the growing burden of chronic diseases, information systems management, referral system and leadership issues.

- **Challenges Facing the Healthcare System in Saudi Arabia: Distance**

Saudi Arabia is considered the largest country in the Middle East, occupying about 80% of the Arabian Peninsula With a land space of approximately 2,150,000 km2 (830,000 sq. mi). Specialist centres tend to be in main urban areas, e.g., Riyadh, Makkah, Dammam, and Jeddah. People with chronic health issues need to travel a long distance for clinical consultations and tests (El Bcheraoui et al., 2015). The low quality of public transport remains a source of dissatisfaction for low and middle-class citizens. The metro network is still under construction and people still use their own vehicles. Most people with T2DM live in rural areas which can prevent them from effectively accessing healthcare and diabetes education programs.

- **Challenges Facing the Healthcare System in Saudi Arabia: Diabetes**

Saudi's healthcare system is experiencing an alarming growth in the prevalence of diabetes mellitus. It has been classified as the second highest rate of diabetes mellitus in Middle East and 7$^{th}$ rank in the developed world (Robert et al., 2017). According to Alanazi (2018), Saudi Arabia reached >1.8 million cases of diabetes with a prevalence of 17.7% are men and 16.4% women. There are over 3 million individuals at higher risk of developing diabetes mellitus, this means that they could become T2DM at any time. It is estimated that this population is to double with a rate of 105.4% increase by 2035, compared with the levels in 2013. The highest levels of prevalence are in the eastern and northern regions, accounting to 27.9% and 26.4% levels, respectively. However, it is estimated more higher within the capital Riyadh city (Alanzi, 2018). In 2015, the government allocated a record budget of 27.6 billion pounds sterling to be used only for health care expenditure, with diabetes accounting for 13.9% of the total healthcare expenditure in Saudi Arabia (Al Dawish et al., 2016). The financial burden of T2DM in Saudi is considerably high, costing 4300 SAR per person. This statistic is leading to the increasing economic costs of diabetes care in Saudi, which is estimated to reach 6.5 billion dollars by 2020 (Alanzi, 2018). In 2015, the number of deaths registered among Saudi adults due to diabetes was 23,420 people. The occurrence of T2DM is expected to double by 2030; this is due to increased obesity and body mass index levels, unhealthy eating patterns, lack of physical activities, increased smoking, rapid industrialisation and increased living standards in the society (Al-Rubeaan et al., 2015, Alanzi, 2018).

There are multidisciplinary expert organisations, such as the American Diabetes Association (ADA) and the World Health Organisation (WHO), whose primary role is updating clinical practice recommendations, current standards, and the guidelines of medical care in treating diabetes. In Saudi Arabia, clinical management guidelines have been set by the ADA and adapted by the Saudi Society of Endocrinology and Metabolism (SSEM).

- **Challenges Facing the Healthcare System in Saudi Arabia: Physical Inactivity**

The lack of adequate physical activity has been heavily correlated with development of many chronic diseases. Physical inactivity is the most important modifiable risk factor for the development of T2DM. Saudi Arabia has gone through noticeable lifestyle changes in the past few decades, which has resulted in an increased prevalence of chronic diseases such as T2DM. The prevalence of physical inactivity is extremely high in Saudi, ranged from 52.1% for males and is 67.79% for females (Alahmed and Lobelo, 2018). There are several common barriers to doing physical activity. In Saudi Arabia, the lack of social support, the lack of facility, the lack of motivation and the lack of self-confidence were found to be top barriers to perform PA among T2DM attending primary care. The Saudi climate goes through extreme weather conditions during both the summer and winter times in most of the region and this could limit outdoor activities and result in serious health conditions, such as dehydration, hypothermia and heat strokes (Alahmed and Lobelo, 2018). Saudi females were reported less active than males because of cultural barriers, lack of social support, the absence of female PA programs and lack of time and resources, all make PA a difficult choice for the Saudis(Al-Hazzaa, 2018). According to our

current knowledge, there is no program or ongoing projects in Saudi Arabia that support physical activity participation in public or private health sectors.

### 1.9 Sections Summary

The previous section identified the obstacles being faced by the healthcare sectors in the Saudi health care system and the rapid spread of T2DM among Saudi population. These findings clearly indicate that there is a large population that is at risk for T2DM related complications due to the contributing factors such physical inactivity. This has put a huge demand on the Saudi healthcare system to face the growing demand for better quality care services; furthermore, it is necessary for the country to also invest more in the field of mHealth to cope with this growing demand. mHealth platforms are being adopted by healthcare sectors in Europe and North America; the case is different in developing countries. In Saudi Arabia, mobile text messaging is still a new approach and results are still inconsistent and further studies are required to assess its feasibility and acceptability.

**Key Points:**

- The population of Saudi has reached 33.55 million with a growth rate of 1.87% from a 2013 estimate. The rate is expected to increase in the future, and it is likely to reach 39.1 million by the end 2030 (General Authority for Statistics, 2019).
- The cultural and religious setting of Saudi Arabia is greatly influenced by the Islamic culture. The society tends to be deeply religious, traditional and this has shaped the society beliefs about experiences and the determinants of health and diseases.

- Saudi Arabia is facing high population growth that created a gap of 14,000 hospital beds in 2016, and this gap is expected to widen to 40,000 beds by 2035 (MOH, 2019).
- The Saudi health care system is facing challenges such as rapid population growth, an increased burden of chronic illness and a high demand of health care services.
- Each T2DM patient in Saudi costs around 4300 SAR; this is estimated to reach 6.5 billion dollars by 2020 (Alanzi, 2018).
- The prevalence of physical inactivity is 52.1% for Saudi males and is 67.79% for Saudi females, it is considered high due to various factors (lack of social support, lack of facility, lack of motivation and lack of self-confidence, extreme weather conditions during both the summer and winter times) (Alahmed and Lobelo, 2018).
- Technology-based health promotion interventions are less common in this context and that the low-tech approach of text messages is appropriate for this audience, Saudi Arabia registered the second rank on the Arab world level and the thirty eighth internationally within the very high-level human development countries.

- **Chapter Conclusion**

Failing to manage T2DM can increase the chance of developing very known T2DM related health complications which may lead to high rate of morbidity and mortality. So, If T2DM is not well managed it could have severed implications on people's lives and as well as the health care system in general. So, the ultimate goal of T2DM management is to basically prevent or delay these known health related complications. So, unlike many health conditions, T2DM can be managed via several therapeutic and non-therapeutic treatment based-interventions and the current thesis has solely focused on one non-therapeutic treatment based-intervention which is (Physical activity). According to the literature, physical activity has shown promising benefits on T2DM related health outcomes. However, in real practice it can be challenging to promote physical activity amongst people with T2DM specially in Saudi context for example: The most common reported factors that limit people to T2DM management were:

- Lack of patient access to health care services
- Geographical barriers
- Patient-physician communication gap especially in rural areas
- Shortage of hospital beds
- Missed appointments
- Lack of self-management awareness or education programs

So here is where mobile text messaging can play its part, as demonstrated in this chapter that text messaging is a promising tool to promote PA amongst people with T2DM in Saudi context. The following chapter will assess that systematically, As outlined in the Medical Research Council (MRC) guidelines where they suggest that identifying the evidence base

prior to clinical studies is important. According to the current knowledge, the feasibility of mobile text messages in PA promotion in the context of Saudi Arabia is till unexplored and this study should contribute to the body of knowledge and act as a guide for main clinical studies.

### 1.10 The Study Objectives

The purpose of this study is to explore the feasibility and acceptability of using mobile phone messaging to promote PA in people with T2DM.

**The main aim of this study** was to explore if text messaging is feasible and acceptable in promoting physical activity in people with T2 diabetes in Saudi Arabia context.

**The secondary aim was** to see if T2DM diabetes related health outcomes are sensitive to change:

- if self-efficacy sensitive to change pre and post the intervention?
- To determine what are the barriers to physical activity?
- To determine physical activity levels
- Are glycaemic haemoglobin (HbA1c) and the body mass index (BMI) sensitive to change pre and post the intervention?

# Chapter 2: The Effectiveness of Mobile Phone Messaging-Based Interventions to Promote Physical Activity in Type 2 Diabetes Mellitus: A Systematic Review and Meta-Analysis

## 2. Introduction

### 2.1 Background

The burden of diabetes is growing, the number of people with type 2 diabetes mellitus (T2DM) across the world has reached 387 million and is expected to increase to 592 million by 2035 (Haider et al., 2019b). This prevalence imposes a high and rising burden of life-long multi-organ complications, leading to an increased disability and risk of premature deaths mainly in low and middle-income countries (NICE, 2019). A considerable amount of literature suggests that better management of T2DM would delay the onset of short-and long-term complications among people diagnosed with T2DM (ADA, 2018, Gordon et al., 2018, Yan et al., 2017). Over the past decades, physical activity (PA) has been part of the first line T2DM care management (Edwards and Hosseinzadeh, 2018). PA includes all movement that increases energy use, however, there are three main kinds of exercise—aerobic, strength training, and flexibility work (Colberg et al., 2016). PA can help people with T2DM to achieve a variety of goals, including increased vigour, improved glycaemic haemoglobin control, decreased insulin resistance, increased cardiorespiratory fitness, improved lipid profile, blood pressure (BP) reduction, and maintenance of weight loss (Sigal et al., 2018). Unfortunately, patients with T2DM are less likely to engage in regular PA, with recent estimates demonstrating a lower participation rate compared to the national average (Sibai et al., 2013). There have been many attempts to explore alternative approaches to improve PA in people with T2DM, mobile phone messaging revolution has brought entirely new opportunities and increased access to self-management education (Haider et al., 2019b).

The literature shows that text messaging-based interventions can be effective in improving health change related behaviours and bridging the gaps between patients and healthcare services for people living with chronic diseases (Hamideh Lari et al., 2018, Kannisto et al., 2014). Text messaging may be one-way (unidirectional) or two-way (bidirectional), they can be standardised or tailored to specific patients and sent at varied frequencies based on the intervention design(Sahin et al., 2019a). Multiple meta-analyses have demonstrated the overall success of mobile phone messaging in promoting various aspects of behaviour change for PA and mental health related disorders (Haider et al., 2019b, Thakkar et al., 2016, Berrouiguet et al., 2016).

### 2.2 Research Problem and Aim

Several studies have assessed the effect of mobile text messaging on physical activity in patients with T2DM. It is crucial to summarise and aggregate findings of such studies to produce a more generalisable and definitive conclusions about the effectiveness of such interventions. Four previous systematic reviews did not bring together the evidence from studies with text messaging interventions that specifically targeted physical activity. Specifically, the first review focused on the impact of education about T2DM delivered via mobile text messaging (Saffari et al., 2014b). The second review assessed the effectiveness of text-messaging interventions on HbA1c in patients with T2DM and that included all self-management strategies (Haider et al., 2019b). The third review identified randomised trials conducted to improve glycaemic control in T2DM which involved the delivery of behaviour change content through a range of digital platforms and approaches (e.g. short-message service: SMS, multimedia message services: MMS, or instant messaging such as WhatsApp (Sahin et al., 2019a).

The fourth review assessed the effectiveness of technology-based interventions to promote physical activity in T2DM; for this review, technology included mobile phones and text messages, websites, CD-ROMs and computer-learning-based based technology (Connelly et al., 2013). This review was conducted approximately seven years ago but studies involving technology-based interventions are rapidly emerging and there may be new published evidence. Therefore, this study aimed to assess the effectiveness of mobile phone messaging on PA in patients with T2DM by summarising and pooling the findings of previous literature.

### 2.3 Methods

A systematic review was conducted and reported in keeping with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (Appendix 1) (Liberati et al., 2009). The protocol for this review is registered at PROSPERO (ID: CRD42020156465).

### 2.4 Search Strategy

#### 2.4.1 Search Sources

The review used the following electronic databases in our search: MEDLINE, Cochrane Library, CINAHL, Web of Science, EMBASE. These databases were searched on April 19, 2020, by the lead author. Auto Alerts were set after searching the databases to conduct an automatic search weekly for 16 weeks (ending on August 9, 2020) and send us the retrieved studies. We also searched the search engine "Google Scholar" to identify grey literature. To identify further studies of relevance to the review, we screened the reference lists of included studies (i.e., backward reference list checking) and identified and screened studies that cited the included studies (i.e., forward reference list checking).

### 2.4.2 Search Terms

The search terms were identified by consulting 2 experts in e-health intervention for patients with diabetes and by checking systematic reviews of relevance to the review. These terms were chosen based on the target population (e.g., type 2 diabetes, diabetes type 2, and type II diabetes), target intervention, (e.g., text messaging, text messages, and short messages), target outcome (e.g., physical activity, physical exercise, HbA1C, weight), and target study design (e.g., trial, experiment, RCT). Appendix 2 shows the detailed search query used for searching MEDLINE.

### 2.4.3 Study Eligibility Criteria

The population of interest was adult patients (≥18 years) with T2DM regardless of their gender and ethnicity. The review excluded patients with T1DM, gestational diabetes, and pre-diabetes. The target intervention in this review is mobile phone text messages (SMS and MMS), but not mobile applications, web-delivered interventions, wearables, or emails. The aim of the text messages had to improve solely physical activity, but not diet, lifestyle, diabetic literacy, or other aspects of self-care. The primary outcomes of interest are subjectively and/or objectively measured physical activity (e.g., step counts), glycaemic control (e.g., hemoglobin A1C (HbA1c), fasting glucose), and anthropometric measures (e.g., change in weight, body mass index (BMI), etc.). Only randomized controlled trials (RCTs) were eligible for inclusion in this review. A review of RCTs is considered higher evidence (Christopoulou et al., 2018). This study considered studies published only in the English language. The English language is generally perceived to be the universal language of science. No restrictions were applied to year of publication, country of publication, comparator, type of publication, or study settings. With regard to

the other forms of evidence, it was not possible to perform qualitative assessment for this systematic review because of the nature of PhD timeline constrains.

### 2.4.4 Study Selection

The review followed two steps in the study selection process. In the first step, MJ (main researcher) searched the titles and abstracts of all retrieved studies. In the second step, AA independently scrutinised the full texts of studies included from the first step. In both steps, any disagreements between the reviewers were resolved through discussion and consensus. Cohen κ in this review indicated a very good level of interrater agreement in the first (0.88) and second step (0.95) of the selection process (Altman, 1990).

### 2.4.5 Data Extraction

Appendix 3 shows the data extraction form that was used in this review to extract the data precisely and systematically from the included studies. The two reviewers (MJ and AA) independently conducted data extraction from the included studies, and they resolved any disagreements through discussion and consensus. Cohen κ showed a very good level of interrater agreement between the reviewers (0.85) (Altman, 1990).

### 2.4.6 Risk of Bias Assessment

To assess the risk of bias in the included studies, the Risk-of-Bias 2 (RoB 2) tool was used, which is recommended by Cochrane Collaboration (Sterne et al., 2019). This tool assesses RCTs in terms of 5 domains: randomization process, deviations from intended interventions, missing outcome data, measurement of the outcome, and selection of the reported result (Sterne et al., 2019). Then, the overall risk of bias is determined for each study based on the risk of bias judgments in the 5 domains (Sterne et al., 2019). Two reviewers (MJ and AA) independently assessed the risk of bias in the included studies, and any disagreements were resolved through discussion and consensus. Interrater agreement

between the reviewers was very good (Cohen κ=0.86) (Altman, 1990). Results of the risk of bias assessment were presented using a graph showing the reviewers' judgments about each "risk of bias" domain in the result section. It also showed reviewers' judgments about each "risk of bias" domain for each included study using a figure in Appendix 4.

### 2.4.7 Data Synthesis

The extracted data was synthesised using narrative and statistical approaches. Specifically, meta-analysis was carried out when at least two studies assessed the same outcome of interest and reported enough data for the analysis (e.g., mean difference, standard deviation (SD), number of participants in each intervention group). When the above-mentioned conditions were not met, we narratively synthesised findings of the included studies. The findings were grouped and synthesised according to the measured outcome (i.e., physical activity, glycaemic control, and weight change).

A meta-analysis was conducted using Review Manager (RevMan 5.4), which is a software developed by Cochrane. The mean difference (MD) was used to assess the effect of each trial and the overall effect when the outcome data were continuous, and outcome measure of each outcome was identical in the meta-analysed studies. However, the standardized mean difference (SMD) was used when, between studies, the outcome was measured using different tools. A random-effects model was used in the analysis due to the clinical heterogeneity between the meta-analysed studies in terms of intervention characteristics (e.g., its directionality, purpose, and frequency) and population characteristics (e.g., sample size and mean age). The clinical heterogeneity of the meta-analysed assessed studies by inspecting characteristics of their interventions, outcomes, participants, and comparator. Further, the evaluated statistical heterogeneity of the meta-analysed studies.

To do so, we calculated a chi-square *P* value and $I^2$ to evaluate the statistical significance of heterogeneity and the degree of heterogeneity, respectively. We judged the meta-analysed studies as heterogeneous when chi-square *P* value is 0.05 or lower (Deeks et al., 2008). The degree of heterogeneity was considered unimportant, moderate, substantial, or considerable when $I^2$ ranged between 0%-40%, 30%-60%, 50%-90%, or 75%-100%, respectively (Deeks et al., 2008). The overall quality of meta-analysed evidence was examined using Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach (Schunemann et al., 2008, Walshaw, 2019). This approach assessed the quality of evidence based on five main criteria: risk of bias, inconsistency (i.e. heterogeneity), indirectness, imprecision, and publication bias (Schunemann et al., 2008). Two reviewers (MJ and AA) independently assessed the overall quality of meta-analysed evidence, and any disagreements were resolved through discussion and consensus. Interrater agreement between the reviewers was very good (Cohen $\kappa$=0.81) (Altman, 1990).

## 2.5 Results

### 2.5.1 Search Results

The conducted review retrieved 541 studies by searching the 6 bibliographic databases (Figure 1). Out of those studies, 83 duplicates were identified and excluded. We screened titles and abstracts of the remaining 458 citations and excluded 423 citations due to reasons shown in Figure 1. By checking the full texts of the remaining 35 studies, 31 studies were not eligible for this review for several reasons (Figure 1). We identified 2 additional studies by backward reference list checking. Overall, 6 studies were included in this review (Agboola et al., 2016, Arovah et al., 2018, Lari et al., 2018a, Lari et al., 2018c,

Polgreen et al., 2018, Ramirez and Wu, 2017). At all steps, consensus was agreed between the two reviewers, and referral to third reviewer was not required.

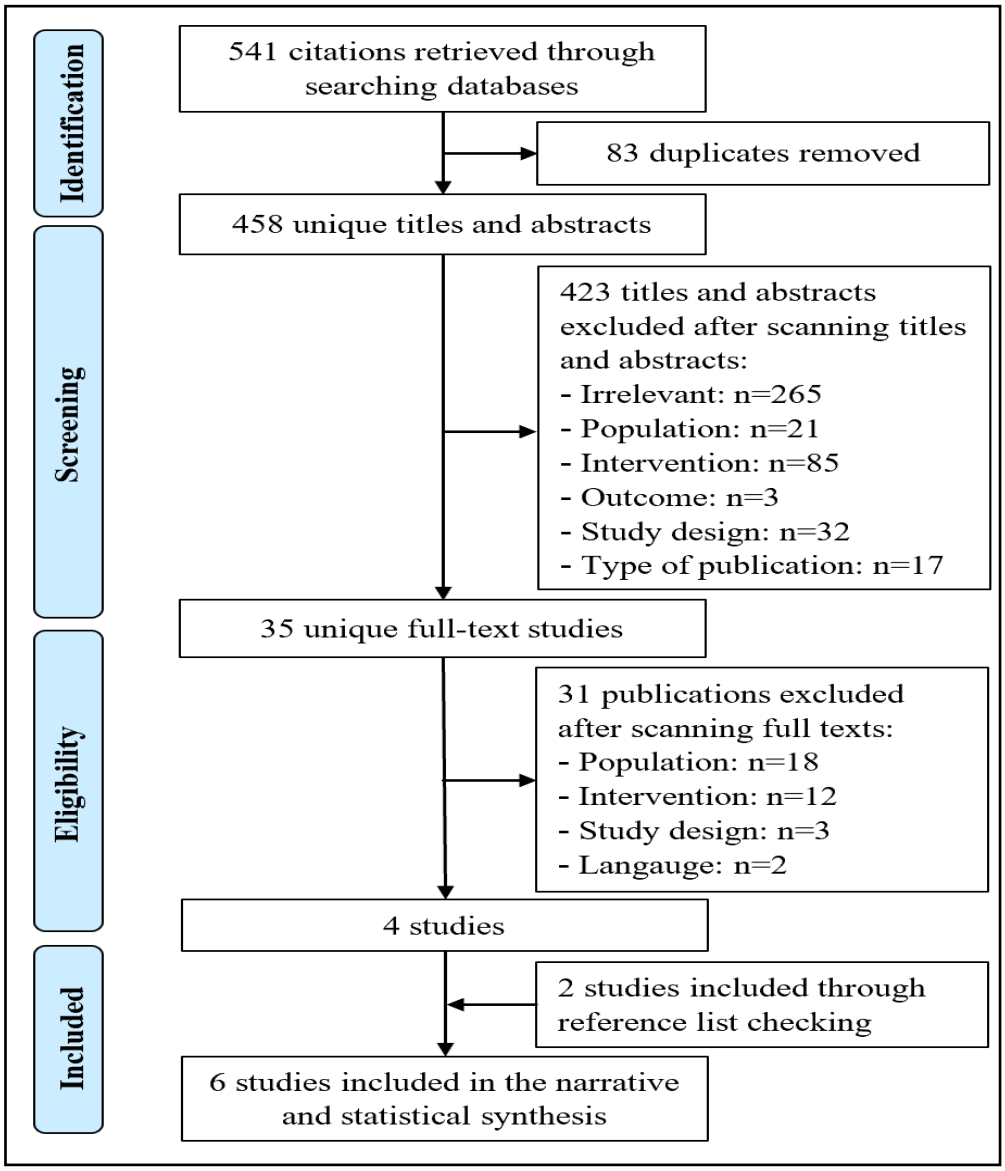



Figure 3: Flow chart of the study selection process

### 2.5.2 Characteristics of Included Studies

As detailed in Table 1, all included studies were randomized controlled trials (RCTs). The included studies were conducted in 3 countries: United States of America (USA) (n=3), Iran (n=2), and Indonesia (n=1); 4 of the studies were published in 2018. The sample size in the included studies ranged between 28 and 138 with an average of 81. The mean age of participants in the included studies varied from 44.6 to 65.5 years, with an average of

51.6 years. Percentage of males in the included studies ranged from 23.3% to 57.9%, with an average of 42.2%. All studies recruited patients with T2DM. The included studies recruited participants from healthcare (n=5) and community (n=1).

Table 1: Characteristics of studies and population.

| Author[ID] | Year | Country | Study design | Sample size | Mean age | Sex (male) | Health condition | Setting |
|---|---|---|---|---|---|---|---|---|
| Agboola[21] | 2016 | USA | RCT | 126 | 51.4 | 48.4% | T2DM | Health centers |
| Arovah[22] | 2018 | Indonesia | RCT | 43 | 65.5 | 37.2% | T2DM | Public hospital |
| Lari[23] | 2018 | Iran | RCT | 73 | 47.6 | 53.4% | T2DM | Diabetes clinics |
| Lari[24] | 2018 | Iran | RCT | 76 | 48.2 | 57.9% | T2DM | Diabetes clinics |
| Polgreen[25] | 2018 | USA | RCT | 138 | 44.6 | 23.3% | T2DM | Community |
| Ramirez[26] | 2017 | USA | RCT | 28 | 52 | 33% | T2DM | Ambulatory care clinic |

The intervention in the included studies were text messages only (n=1), text messages and educational CD about physical activity (n=1), and text messages and pedometers (n=4) (Table 2). Text messages were unidirectional (n=1), bidirectional (n=4), and both (i.e., most messages were unidirectional, and some messages were bidirectional) (n=1). The purposes of the text messages in the included studies were to remind participants to perform physical activity (n=4), encourage them to wear the pedometer, review goals, and/or self-monitor and record their steps (n=4), provide them with feedback about their previous day's activity (n=3), motivate them to walk and exercise more (n=2), and set step goals (n=1). The frequency of text messages sent to participants ranged between 2 per week and 3 per day. The intervention was delivered for 12 weeks in 4 studies and 24 weeks in 2 studies. The intervention in 5 studies was theoretically informed. Specifically, the following theories/ models were used to develop the intervention: Social Cognitive Theory (n=2), Health Promotion Models (n=2), and Transtheoretical Model and Grounded Theory (n=1).

Table 2: Characteristics of interventions.

| Study[ID] | Intervention | Directionality | Purpose | Frequency | Period | Theory used |
|---|---|---|---|---|---|---|
| Agboola[21] | SMS & pedometers | 1 & 2-way | Education, motivation, reminder, feedback | 2/day | 24 weeks | Transtheoretical Model & Grounded Theory |
| Arovah[22] | SMS & pedometers | 2-way | Motivation & reminder | 1-3/day | 12 weeks | Social Cognitive Theory |
| Lari[23] | SMS | 2-way | Education | Phase 1: 2-3/day Phase 2: 2/week | Phase 1: 2 weeks; Phase 2: 10 weeks | Health Promotion Models |
| Lari[24] | SMS + Educational CD | 1-way | Education | 2/week | 12 weeks | Health Promotion Models |
| Polgreen[25] | Int 1: SMS (reminder) + SMS (goal setting) + pedometer. Int 2: SMS (reminder) + pedometer | 2-way | Reminders, feedback, setting goals | Int 1:2/day Int 2: 1/day | 24 weeks | - |
| Ramirez[26] | Int1: SMS + pedometer | 2-way | Education reminders, feedback | ≥4 per week | 12 weeks | Social Cognitive Theory |

The comparison group received pedometers in 4 of the studies or no intervention in 2 studies. The pedometers were used by participants for 12 weeks (n=2) or 24 weeks (n=2). The follow-up period ranged from 4 weeks to 24 weeks. The following outcomes of interest were assessed in the included studies: physical activity (n=6), glycaemic control indicators (n=3), weight (n=1), and BMI (n=1). Step count was the most common outcome measure used in the included studies (n=4), then HbA1c (n=2), weight scale (n=2), metabolic equivalent of task (MET) questionnaire (n=2).

Table 3: Characteristics of comparators and outcomes

| Study[ID] | Comparator | Period (week) | Follow-up (week) | Outcome | Outcome measure |
|---|---|---|---|---|---|
| Agboola[21] | Pedometers | 24 | 24 | Physical activity, glycaemic control, weight | Step count, weight scale, HbA1C |
| Arovah[22] | Pedometers | 12 | 12 & 24 | Physical activity, glycaemic control | Step count, Physical Activity Rating (PAR) questionnaire, HbA1c, fasting glucose, 2-h glucose |
| Lari[23] | No intervention | - | 4 & 12 | Physical activity | Metabolic equivalent of task (MET) questionnaire |
| Lari[24] | No intervention | - | 4 & 12 | Physical activity | Metabolic equivalent of task (MET) questionnaire |
| Polgreen[25] | Pedometers | 24 | 12 & 24 | Physical activity, BMI | Step count, weight scale, stadiometer |
| Ramirez[26] | Pedometers | 12 | 6 & 12 | Physical activity | Step count |

### 2.5.3 Risk of Bias Results

Although all studies used an appropriate random allocation sequence for the randomisation process and had comparable groups, only 2 studies concealed the allocation sequence until participants were enrolled and assigned to interventions. Accordingly, only these 2 studies were rated as low risk of bias in the randomization process (Figure 4). In all studies, participants, their healthcare professional, researchers, and/or individuals delivering the interventions were aware of assigned intervention during the trial. The study also did not report any information about whether a deviation from the intended intervention occurred due to the experimental contexts. Thus, none of the studies were rated as low risk of bias in deviations from the intended interventions (Figure 4). Outcome data were not available for all participants in the included studies, and there was no evidence that the findings were not biased by missing outcome data. However, the reasons for missing outcome data were not related to the true value of the outcome in all studies. Thus, all studies were judged as low risk of bias in the domain of missing outcome data.

In 4 studies, the outcomes of interest were assessed using appropriate measures (e.g., pedometer and HbA1C), which were comparable between intervention groups. For this reason, these studies were rated as low risk of bias in measuring the outcome. Yet, the remaining 2 studies were judged as high risk of bias in this domain because they used subjective outcome measures that depend on participants' recall, and participants and outcome assessors were not blinded in the 2 studies (Figure 4). Only one study was judged as low risk of bias in the selection of the reported studies (Figure 4). This judgment is attributed to the fact that the remaining studies did not publish a pre-specified analysis plan or reported outcome measurements and analyses different from those specified in the analysis plan. Given that 5 studies were judged as high risk of bias in at least one domain, they were rated as high risk in the domain of overall bias. The remaining study was judged to raise some concerns in the domain of overall bias as it had some concerns in one of the domains. Reviewers' judgements about each 'risk of bias' domain for each included study are presented in Appendix 4.

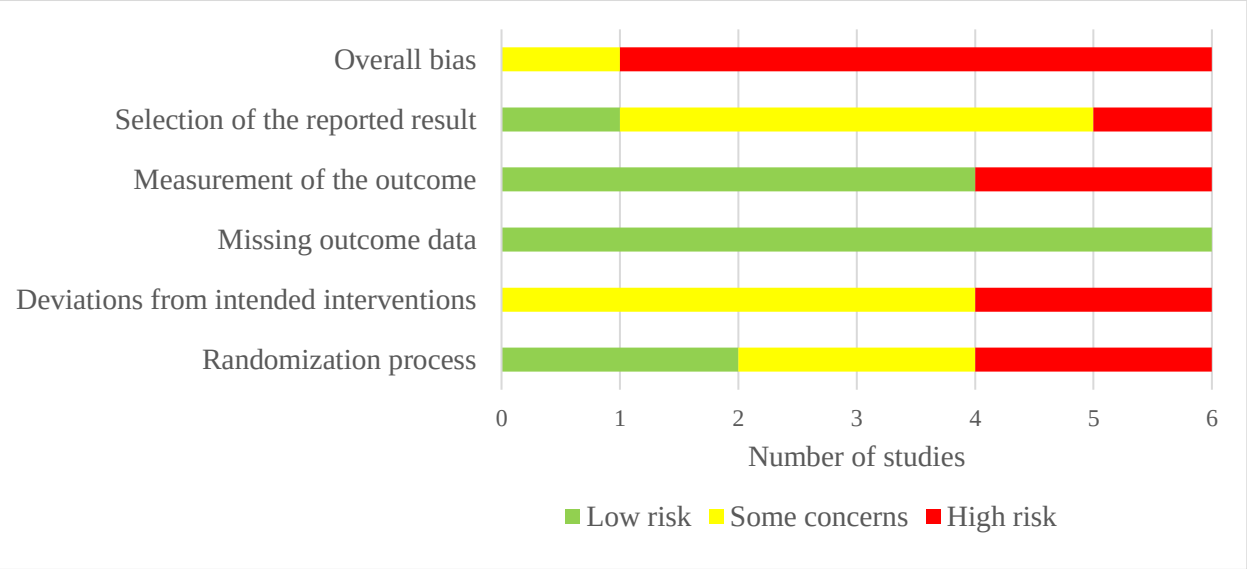



Figure 4: Review authors' judgements about each 'Risk of bias' domain.

## 2.6 Results of Studies

### 2.6.1 Physical Activity

All included studies assessed the effect of using text messages on physical activity among T2DM patients. Three studies showed a statistically significant effect of text messages on physical activity (Lari et al., 2018a, Lari et al., 2018c, Arovah et al., 2018, Ramirez and Wu, 2017). To be more precise, Arovah et al. compared the effect of text messages plus pedometers to only pedometers on physical activity as measured by daily step count, self-reported walking (min/week), and self-reported moderate-to-vigorous-intensity physical activity (MVPA) (min/ week) (Arovah et al., 2018). The study showed a statistically significant effect of 12-week text messages plus pedometers to only pedometers on daily steps ($P$<.001), self-reported walking ($P$=.001), and MVPA ($P$<.001) (Arovah et al., 2018). In two further studies, where data were analysed from different arms of a single RCT in each 'study', Lari et al. compared the effect of text messages only (Lari et al., 2018a) and text messages plus educational CD (Lari et al., 2018c) to no intervention on physical activity as measured by MET questionnaire. Both studies found a statistically significant effect of text messages only ($P$<.001) (Lari et al., 2018a) and text messages plus educational CD ($P$<.001) (Lari et al., 2018c) on physical activity compared with no intervention. The three remaining studies did not find a statistically significant effect of text messages on physical activity (Agboola et al., 2016, Polgreen et al., 2018, Ramirez and Wu, 2017). Specifically, Agboola et al. (Agboola et al., 2016) compared the effect of text messages plus pedometers to pedometers only on physical activity as measured by monthly step count. Although the study found that step counts over 6 months were higher in the intervention group than the control group, this difference was not statistically significant ($P$=.17) (Agboola et al., 2016).

Another study assessed the effect of text messages plus pedometers and only pedometers on physical activity as assessed by daily steps (Ramirez and Wu, 2017). The study did not show any statistically significant difference (*P*=.78) in the physical activity between the two groups (Ramirez and Wu, 2017). In the last study, Polgreen et al. compared the effect of two interventions to only pedometers on physical activity as measured by daily step count (Polgreen et al., 2018). The first intervention was pedometers plus text-message reminders to wear the pedometers (reminders & pedometers) whereas the second intervention was the same as the first intervention plus text messages asking participants to set a step goal (goal setting, reminders & pedometers) (Polgreen et al., 2018). The study found no statistically significant difference in physical activity between the three groups (Polgreen et al., 2018). Five studies were included in the statistical analysis (i.e., meta-analysis) as they reported enough and appropriate data for the analysis (Arovah et al., 2018, Ramirez and Wu, 2017, Lari et al., 2018a, Lari et al., 2018c, Polgreen et al., 2018).

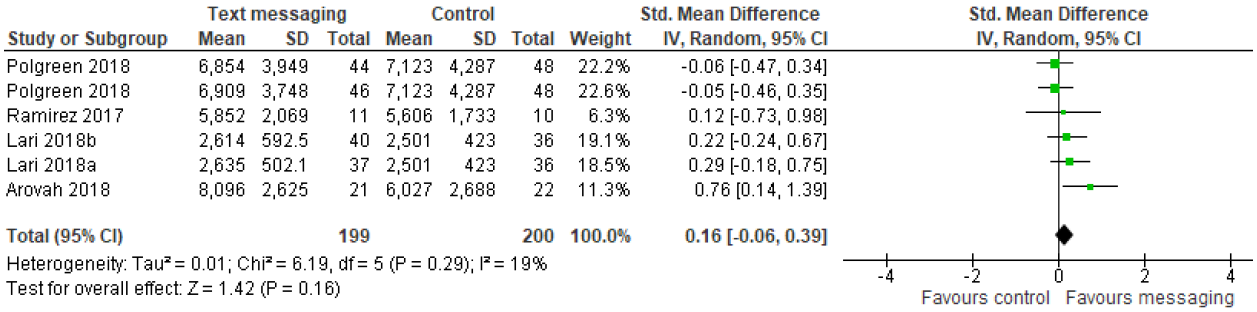


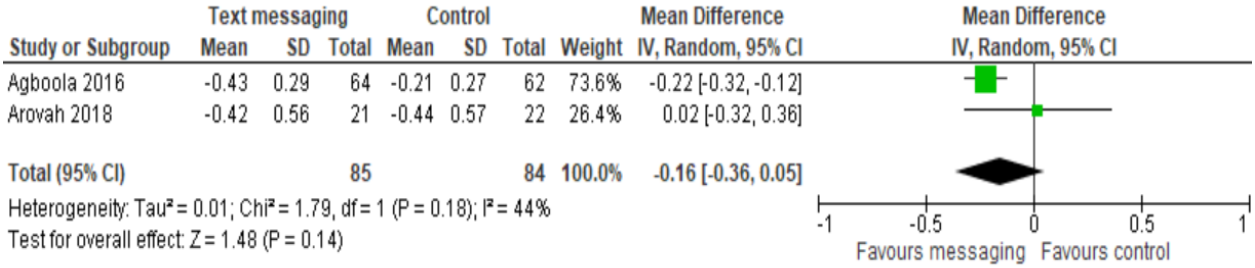

Figure 5: Forest plot of six studies assessing the effect of the text messaging on physical activity

The meta-analysis contained 6 comparisons as we included a comparison from each of 4 studies (Arovah et al., 2018, Ramirez and Wu, 2017, Lari et al., 2018a, Lari et al., 2018c) and 2 comparisons from the remaining study (Polgreen et al., 2018), which compared 2 types of text messages to no intervention. The meta-analysis showed no statistically significant difference in the physical activity (*P*=0.16) between text messages group and control group (SMD 0.16, 95% CI -0.06 to 0.39) (Figure 5). The heterogeneity of the evidence was not a concern (*P*=0.29; $I^2$= 19%). The quality of the evidence was very low due to the high risk of bias and impression (Appendix5).

### 2.6.2 Glycaemic Control

Two studies examined the effect of text messages on glycaemic control as assessed by HbA1C (Agboola et al., 2016, Arovah et al., 2018). The results of both studies were meta-analysed. The meta-analysis showed no statistically significant difference (*P*=.14) between intervention and control groups, with no difference observed between text messages plus pedometers and only pedometers on HbA1C (MD -0.16, 95% CI -0.36 to 0.05) (Figure 4). There was moderate heterogeneity of the evidence ($I^2$= 44%), but it was not statistically significant (*P*=.18) (Figure 4). The quality of evidence was low as it was downgraded by 1 level due to high risk of bias (Appendix 5). It is worth mentioning that one of the two studies compared the effect of text messages plus pedometers to only pedometers on glycaemic control as measured by fasting plasma glucose and 2-h plasma glucose (Arovah et al., 2018). The study did not find a statistically significant difference between the groups in terms of fasting plasma glucose (*P*=.18) and 2-h plasma glucose (*P*=.90) (Arovah et al., 2018).

Figure 6: Forest plot of two studies assessing the effect of the text messaging on HbA1C




### 2.6.3 Anthropometric Measures

Two studies assessed anthropometric measures as outcomes (weight and/or BMI) (Agboola et al., 2016, Polgreen et al., 2018). Results of the two studies could not be statistically synthesised as they assessed different outcomes. The first study showed no statistically significant difference between intervention and control groups, with no effect of text messages plus pedometers on weight (*P*=.77) in comparison with only pedometers (Agboola et al., 2016) . In the second study, Polgreen et al. compared the effect of two interventions to only pedometers on BMI (Polgreen et al., 2018). The first intervention was pedometers plus text-message reminders to wear the pedometers (reminders & pedometers) whereas the second intervention was the same as the first intervention plus text messages asking participants to set a step goal (goal setting, reminders & pedometers) (Polgreen et al., 2018). The study found no statistically significant difference in BMI between the three groups (Polgreen et al., 2018).

### *2.6.4 Other outcomes*

Secondary outcome measures reported in the examined studies included the following variables and parameters: reports of the usability, satisfaction and adherence to the intervention in (Agboola et al., 2016), quality of life and/or psychological outcomes (e.g. self-efficacy, outcome expectations, self-regulation, and social support) in (Arovah et al., 2018). Lari et al. assessed the Health Promotion Model (HPM) constructs (e.g., perceived benefits, perceived barriers, perceived social support and self-efficacy) (Lari et

al., 2018c, Hamideh Lari et al., 2018). Ramirez et al. also investigated the feasibility, perceived usefulness, and potential effectiveness (Ramirez and Wu, 2017)

## 2.7 Discussion

### 2.7.1 Principal Findings

This systematic review assessed the effectiveness of mobile text messaging as a method to promote solely physical activity in people with T2DM. The meta-analysis of results of 5 studies (6 comparisons) showed no statistically significant effect of mobile text messaging on physical activity in comparison with no intervention. The insignificant effect may be attributed to the fact that three studies showed a statistically significant effect of mobile text messaging on physical activity whereas two studies did not find any significant effect of text messages on physical activity. There are several potential reasons for the significant increase in physical activity in three studies. Firstly, the intervention in one study (Arovah et al., 2018) was combined with pedometers, and some studies have found greater effects when using objective measures compared with subjective measures (Silfee et al., 2018). It is possible that participants in these studies were more active as a result of knowledge that they are wearing the pedometer (Bravata et al., 2007). The remaining two RCTs (Lari et al., 2018a, Lari et al., 2018c) were rated high risk of bias because they used self-recall questionnaires to measure physical activity. However, these measures can present limitations in capturing physical activity due to poor reliability and validity, participant recall bias and differences in the interpretation of questions (Ainsworth et al., 2015). Our findings are consistent with previous reviews that assessed the effect of text messaging on physical activity in participants with different chronic conditions (Monroe et al., 2015).

Some studies observed only small improvements in daily steps and self-reported physical activity, other studies did not observe any statistically significant changes in physical activity despite the use of different physical activity measurement strategies (Monroe et al., 2015). Our review found no statistically significant effect of mobile text messaging on glycaemic control as assessed by HbA1C, fasting plasma glucose, and 2-h plasma glucose. Our findings are consistent with previous studies which showed no significant difference in HbA1c levels in people with T2DM following text messaging interventions (Valles-Ortiz et al., 2015). This could be contributed to the duration effect, our meta-analysis had short interventions and follow-up durations (median, 12 weeks), thus, outcomes such HbA1c are less likely to change over a short timescale (three months), in other words, it might take longer for the intervention effects to become apparent (Polonsky et al., 2011). The narrative synthesis in this review showed no statistically significant effect of mobile text messaging on either weight or BMI. We could not synthesise these measures in our meta-analysis due to high heterogeneity in the included studies. Our findings are consistent with previous reviews, a meta-analysis showed no statistically significant in BMI and weight following mobile messaging interventions in people with T2DM (Arambepola et al., 2016). However, it is important to be realistic about the period of interventions, a longer period is required to determine the desired improvements in such clinical outcomes (Bin Abbas et al., 2015). Aforementioned studies had short interventions (median, 12 weeks), thus, outcomes such weight and BMI are less likely to change on a short time scale (Polonsky et al., 2011).

## 2.8 Strengths and Limitations

### 2.8.1 Strengths

Our study is the first review and meta-analysis that focused on the effectiveness of text messages targeting only physical activity among T2DM patients. This enables us to ensure that the effect of text messaging on physical activity outcomes is attributed to physical activity-related message content, and no other contents such as diet, lifestyle, and general diabetic education. Our study is considered a robust and high-quality review given that we followed well-recommended guidelines (i.e., PRISMA) in developing, executing, and reporting it. To run as sensitive a search as possible, we searched the most popular databases in health and information technology fields using a very comprehensive list of search terms. The risk of publication bias is minimal in this review because we searched grey literature databases (i.e., Web of Science and Google Scholar) and conducted backward and forward reference list checking. We did not restrict our search to specific countries of publication, year of publication, comparators, nor settings; thus, this resulted in a more comprehensive review. The risk of selection bias is minimal in the current review as two authors independently selected studies, extracted data, and assessed the risk of bias and quality of evidence, and they had a very good interrater agreement in all processes. When possible, we meta-analysed results of the included studies, and this improved the power of studies and the estimates of the likely size of effect of text messaging on different outcomes.

### 2.8.2 Limitations

The intervention of interest in this review was restricted to physical activity-related text messaging, so we have not examined the impact of other digital interventions, such as mobile applications, wearables, or other e-health tools. We also focused on patients with T2DM rather than other types of diabetes. Accordingly, our results may not be generalisable to other e-health interventions nor patients with T1DM or gestational DM. In this review, we included only RCTs published in the English language, thus, it is possible that we missed results from some non-English RCTs. We applied these restrictions due to the high internal validity of RCTs over other study designs (Bhattacherjee, 2012) and lack of resources to translate non-English studies. The included studies were conducted in only 3 countries (USA, Iran, and Indonesia); therefore, the generalisability of our findings to other countries may be limited. The findings are based on a small number of studies that met review criteria. Although six studies were included in this review, two of the studies were from a single RCT where two separate analyses and had been undertaken with data taken from different arms. Only two studies were included in each of the two meta-analyses conducted in this review. This is attributed to the lack of reported data that were appropriate for the analysis, and incomparable outcome measures and comparators between studies. As such, it is not possible draw firm conclusions about effectiveness. The review did not conduct any sensitivity analysis; therefore, future studies should explore possible interventions for improving systematic review via conducting sensitivity analysis tools for study quality, and clearly specifying a threshold. This would ensure a better comparability of the study results.

## 2.9 Implications for Research

The current review found relatively few studies assessing the effectiveness of text messages in promoting physical activity in T2DM, thus, RTCs with larger sample sizes are needed. Future studies should seek to include objective outcome measures (e.g., physical activity, glycaemic control, and anthropometric measures), be consistent in terms of selected outcome measures, and measure outcomes after longer follow-up periods in order to be able to compare study findings and make firm conclusions about intervention effectiveness. More research is needed to determine what type of text message content, frequency of messaging and duration of intervention is most likely to have positive outcomes. Additional research needs to include an estimation of the cost-effectiveness of text messages and an examination of their long-term impact.

## Conclusion

We could not draw a definitive conclusion regarding the effectiveness of text messaging on physical activity, glycaemic control, weight, or BMI among patients with T2MD given the low number of the included studies and their high risk of bias. Thus, the findings of this study suggest that there is a pressing need for further RCTs with large sample sizes, low risk of bias, and more consistency in terms of intervention duration, outcome measures, the follow-up period, and comparator.

# Chapter 3: The Process of Developing a Theory Driven Text Messaging Intervention for Physical Activity (PA) in People with Type 2 Diabetes Mellitus (T2DM)

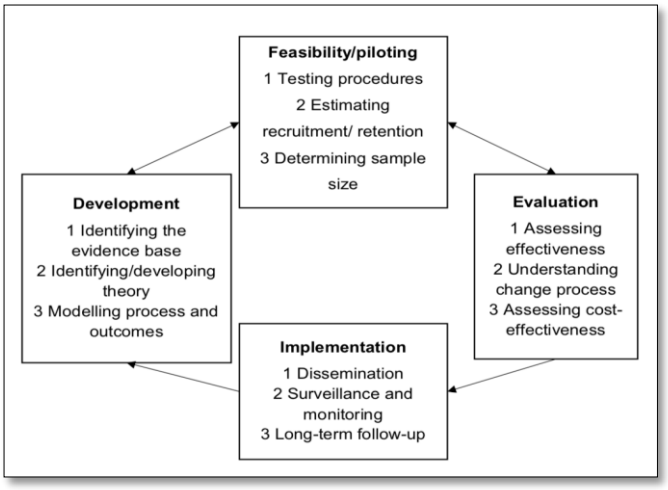
## 3. Introduction

The preceding chapters of this thesis have outlined the evidence basis for developing an intervention to promote physical activity (PA) in type 2 diabetes mellitus (T2DM) and have provided a rationale for the mode of delivery (Mobile Text messaging) that the intervention will take. This chapter describes how the Medical Research Council (MRC) framework, have helped developing the theory and processes which have been utilised to lead to the final development of the intervention content. A description of the SMS messages and the subsequent translation into the targeted population language (Arabic) is explicitly described throughout this chapter.

### 3.1. The MRC Stages Guidance of The Intervention Development

The UK MRC has produced an influential model of guidance on developing and evaluating complex health interventions, which presents a comprehensive framework for clinical researchers. The model consists of four phases: (1) development; (2) feasibility / piloting; (3) evaluation; and (4) implementation (see figure 7). Each stage is important, although they may not follow a linear sequence; rather, the stages can be conducted simultaneously and iteratively. Due to the restricted timescales of this study, the thesis has focused on the first two steps of the MRC guidance, the development stage (Chapters 1, 2 and 3) and the feasibility/piloting stage; the thesis concludes with recommendations for further research (Chapter 5,6 and 7).

Figure 7: The MRC Framework for Complex Interventions




### 3.2 The Importance of Theories in Interventions Development

Theories are a fundamental part of research and study design. They can provide guidance during the research questions development stage and generate explanations and predictions to specify the relationship between entities (West & Brown, 2013). The behaviour can be defined as "any response a person does to an internal or external event and the resulted action can be measurable or indirectly measurable. A behaviour can be seen through the body's reaction but controlled by the brain" (Michie et al., 2014). Theories are applied to behaviour change interventions to answer the when, why, and how questions for the targeted behaviour. There is a variety of theoretical frameworks identified as having an important influence on individuals' healthcare. These frameworks are derived from psychological approaches, and these include aspects such as skills, knowledge and beliefs on capabilities and motivations. Behaviour change concepts have provided enormous potential benefits to alter the current pattern of chronic diseases (Dombrowski et al., 2016).

There are plenty of models in practice addressing the intention-behaviour gap that could leave a positive impact on lifestyle behaviours, such as PA. Most known theories have been reviewed in this thesis: social cognitive theory (Bandura, 1989), self-efficacy theory (Bandura, 1977), the Theory Of Planned Behaviour (Ajzen, 1991), the transtheoretical model of change (Prochaska & Velicer, 1997) and the Behaviour Change Wheel (Michie et al 2014; (Dombrowski et al., 2016). However, the Behaviour Change Wheel (WBC) has been effectively applied in this thesis.

### 3.2.1 Social Cognitive Theory

Social cognitive theory (SCT) focuses on the reciprocal interaction between cognitive, behaviour and social processes. The SCT provides opportunities for social processes through establishing good expectations, self-efficacy and observing the behaviour of others to reinforce the targeted behaviour. Self-efficacy is a key term in this theoretical framework, it is defined as the degree to which an individual can perform a certain behaviour under a specific circumstance, in addition to the confidence that individuals have in performing the targeted health behaviour change. Self-efficacy belief is positively associated with someone's ability to perform a targeted behaviour (Bandura, 1977).

### 3.2.2 Self-Efficacy Theory

Self-efficacy refers to an individual's belief in his/her ability to execute new behaviours or challenges necessary to complete a task successfully (Bandura, 1977, 1986, 1997). Self-efficacy is also positively linked with confidence, as the stronger the sense of self-efficacy is, the more accomplishment and personal well-being an individual will have. Studies have shown that self-efficacy is strongly related to adherence to medical regimens and other health related behaviours. Self-efficacy is concerned with people's beliefs about

their capabilities to exercise control over their own lives. It can be improved through experiences, social persuasion and observing other people managing task demands successfully. Individuals must, therefore, have a strong sense of efficacy to sustain the targeted behaviour and maintain further development of self-efficacy skills throughout the course of the lifespan (Esopo et al., 2018).

### 3.2.3 The Theory of Planned Behaviour

The Theory of Planned Behaviour (TPB) has been widely applied in various health-related studies, especially in decision-making behaviours. The TPB model suggests that intentions are driven by three major constructs; 1) attitudes, 2) subjective norms, and 3) perceived behavioural control (PBC). In this theory, the stronger the intention, the more likely an individual will perform the behaviour. Attitude is known as to the degree to which an individual has a favourable or unfavourable evaluation of the targeted behaviour. A subjective norm is used to measure the value others hold about performing a certain behaviour and an individual's willingness to respond to it. The PBC describes the perceived ease or challenges an individual while performing a behaviour (Guerin et al., 2018). The TPB theory has been adopted in many studies to predict health related behaviours, such as physical activity, adherence to diets and the awareness of self-breast examination (Ferreira and Pereira, 2017). A study by White et al. (2007) showed that the usefulness of TPB in PA development. In this study, patients with T2DM were examined by their beliefs about adherence to low-fat diet and regular PA. Participants who did PA regularly from those who did not, were differentiated in their behavioural and control beliefs. Another study by Boudreau and Godin (2009) aimed to explain and predict patients' intents with T2DM to participate regularly in PA. The study showed evidence that attitudes, subjective

norms and PBC predicted their intention to do PA. This explained almost 60 percent of the variance (Ferreira and Pereira, 2017).

### 3.2.4 The Transtheoretical Model of Change

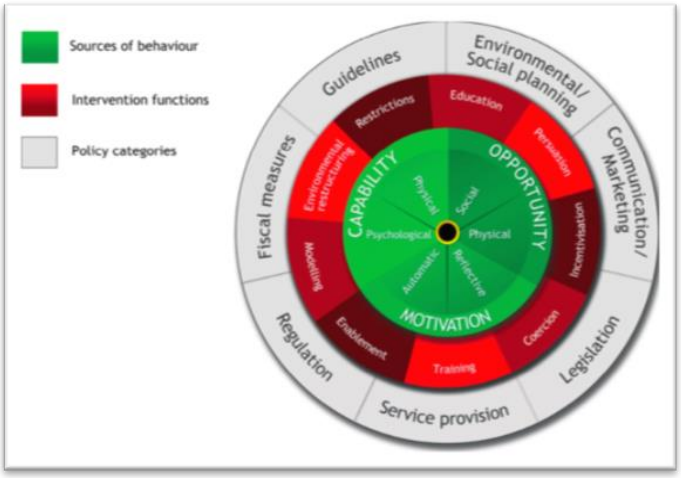
The Transtheoretical Model (TTM) is a stage-based model, it proposes that behaviour changes move through five sequential stages: precontemplation (not ready to change over the next 6 months), contemplation (thinking about change), preparation (taking steps towards the change), action (making an effort to change), and maintenance (being able to sustain the new behaviour for more than 6 months and working to prevent deterioration after a period of improvement) (Romain and Abdel-Baki, 2017). The TTM model was initially used in smoking cessation and other bad habits and addictions interventions. It was mainly applied to understand how people change their health behaviours over time. A meta-analysis, including clinical (e.g., T2DM) and non-clinical samples from adult's populations demonstrated that TTM based interventions are effective in increasing PA (Gourlan et al., 2016). In this model, individuals cannot change their targeted behaviour at once, but instead move through a series of five change stages. Each stage has its own temporal component. Research has shown that each stage occurs in a cyclical manner and can relapse at any stage of behaviour change (Prochaska et al., 1992). The TTM model demonstrates the importance of an individual's evaluation of the perceived benefits (pros) and disadvantages (cons) of the targeted behaviour, it would help them to understand why the new behaviour should be adopted (Prochaska and Velicer, 1997; Plotnikoff et al., 2001). The application of TTM as a theoretical framework to develop behaviour change interventions requires a full understanding of each dimension and their interactions with one another (Hutchison et al., 2009). The TTM was originally developed in the context of smoking cessation; therefore, there are limitations that should be

considered since the context of the targeted behaviour cannot be generalised to other health related behaviours (e.g., physical activity) (Nigg et al., 2011).

### 3.2.5 The Behaviour Change Wheel

The Behaviour Change Wheel (BCW) is made up of three main categories which address the important aspects of health-based interventions' design and development (Michie et al., 2014). The inner layer of this theory is classified as the main layer and includes three determinants of a behaviour; the middle layer consists of 9 functions which should be used to influence the new behaviour.

Figure 1: Behaviour Change Wheel (Michie et al., 2011).




The outer layer shows the different types of policies which could be utilised to promote the selected intervention functions (Michie et al., 2014). The inner layer of BCW has a COM-B model. The COM-B model has been widely used and implemented to identify most needed requirements to change for the new behaviour. The model describes that any new behaviour may be influenced by the individual's capability, motivation, and opportunity. According to the COM-B model, for every new behaviour to occur, it minimally requires a change in one of these main components. The first one means that the capability for an individual to adopt the new behaviour; the second one is having an opportunity to motivate the behaviour to happen; and last one is having the required motivation to

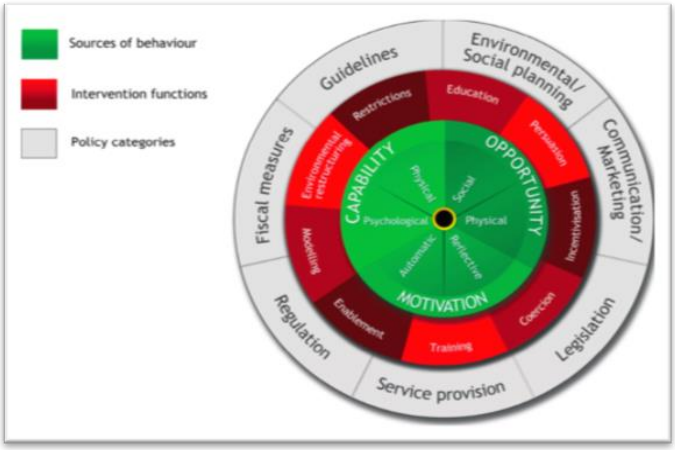
execute the new behaviour over a certain given time. Each one of these 3 components can be divided down into 2 types (Michie et al., 2011). The middle layer of this theory shows different 9 functions, they are designed to potentially create the intervention's options. These functions include the training, restrictions, persuasion, incentivisation, coercion, environmental restructuring, modelling and enablement. These functions can be used to perform or enable the new behaviour. Multiple functions can be used to promote the new behaviour. The Final layer of BCW theory recognise 7 different categories of policy which they can be used to deliver the selected functions. These policy include, the service provision, legislation, communication or marketing, environmental or social planning, guidelines, fiscal measures and regulations (Michie et al., 2014). The BCW theory integrates 12 theoretical frameworks which has been approved to be useful in assessing and intervening with health study implementations. The addressed above theories and models of behaviour change do not explicitly specify how these layers should be put into practice to initiate change in the new behaviour (Baranowski et al., 2003; Eliasson et al., 2011). The BCW framework has integrated multiple frames and been validated in different health contexts to underpin conditions and strategies to influence the targeted behaviour.

### 3.3 The Theoretical Framework of the Thesis

Several theories and frameworks have been largely identified and adapted in different health interventions. This can offer an efficient way of generalising findings across diverse settings within implemented interventions. However, given their potential benefits, the underuse, superficial use, and misuse of such theories represent a substantial scientific challenge for clinical researchers in real world practice.

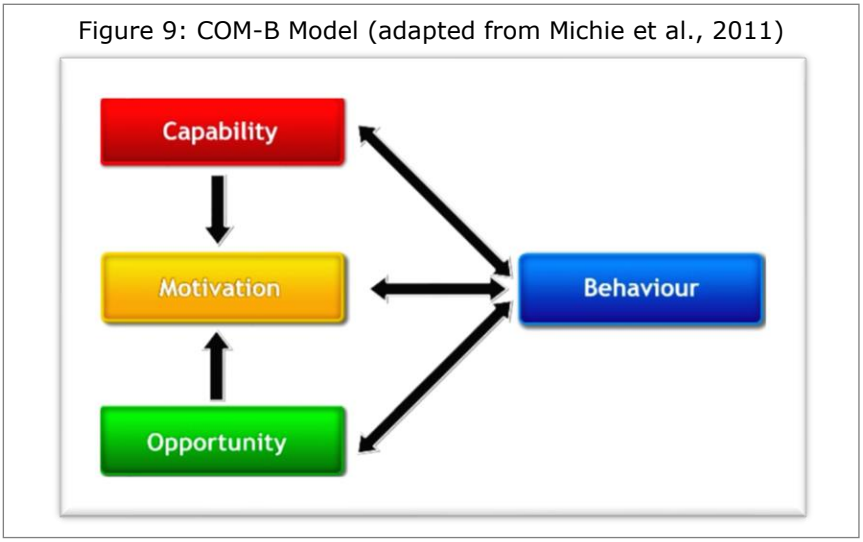
Successful behaviour change interventions draw on best available social and behavioural scientific theories, this would lead to understand both the targeted health behaviour and mechanisms for change (Guerin et al., 2018). The BCW theory was utilised as a practical guide to design the intervention content, using evidence from chapters (1, 2) to aid the selection during the decision-making process. The BCW framework encompass multiple theories and models which allow the researcher to draw upon a wide variety of constructs to map the change mechanisms into the real-world behaviours. The BCW is an integrated theory that pulls together 19 theoretical frameworks for designing, implementing and evaluating a behaviour change (Michie et al., 2014). The BCW is made up of three levels which address aspects of the intervention design and development (Michie et al., 2014). The inner layer of BCW is viewed as the main layer and contains three main determinants of behaviour; the middle layer consists of nine intervention functions which should influence behaviour change to occur. The outer layer describes the types of policy that could be used to deliver these intervention functions (Michie et al., 2014).

Figure 8: The Behaviour Change Wheel by Michie et al. (2014) showing the COM-B model, intervention functions, and policy categories.



**The Inner Layer** of BCW theory, as aforementioned, consists of a COM-B model of behaviour. This model identifies that any behaviour is influenced by the individual's capability, motivation, and opportunity (see figure 9).

Figure 9: COM-B Model (adapted from Michie et al., 2011)




The COM-B model suggests that for any behaviour change to occur, it requires a change in one of the previously mentioned components: the individual's capability to carry out the targeted behaviour; the opportunity for the behaviour to occur; and the motivation to perform the behaviour during that given time. Each of the three components can be broken down into two types. See table 5 for a summary of the model components.

| Table 5: COM-B Model Components | | |
|---|---|---|
| **COM-B** | **Influence** | **Example** |
| **Capability** | Physical | Having an ability to perform the behaviour demands |
| | Psychological | Ability to engage in thought process |
| **Motivation** | Reflective | Reflective conscious intentions, decisions, and plans |
| | Automatic | Emotional responses, impulses, or habit formation |
| **Opportunity** | Physical | External factors, physical opportunities |
| | Social environment | Thoughts and beliefs |

**The Middle Layer** of BCW theory provide nine intervention functions, it is designed to potentially inform the intervention options, including functions such as: training, restrictions, persuasion, incentivisation, coercion, environmental restructuring, modelling and enablement. These functions are performed to enable behavioural change. It is possible to perform more than one change function (see table 6 for definitions of each function).

| Table 6: BCW Intervention Functions | |
|---|---|
| **Intervention Function** | **Definition** |
| 1. Education | ○ To increase knowledge or understanding |
| 2. Persuasion | ○ To use communication to induce positive and convince |
| 3. Enablement | ○ To increase means/reducing barriers to increase chance availability |
| 4. Incentivisation | ○ To create an expectation of reward |
| 5. Coercion | ○ To create an expectation of punishment or cost |
| 6. Training | ○ To impart or teach new skills |
| 7. Restriction | ○ To use rules to reduce or restrain the opportunity to engage in the target behaviour |
| 8. Environmental restructuring | ○ To change the physical or social context, such as infrastructure development |
| 9. Modelling | ○ To provide an example for people to aspire to or imitate |

**The Outer Layer** of BCW theory identifies seven policy categories which allow the intervention to be delivered. It includes service provision, legislation, communication, or marketing, environmental or social planning, guidelines, fiscal measures, and regulation (please refer to table 3.6 for a definition of each category).

| Table 7: BCW Policy Categories | |
|---|---|
| **Policy Category** | **Definition** |
| Service provision | ○ To deliver a service |
| Regulation | ○ To establish rules or principles of behaviour or practice |
| Environmental/social planning | ○ To design and/or controlling the physical or social environment |
| Legislation | ○ To make changes in laws |
| Fiscal measures | ○ To use the tax system to reduce or increase the financial cost |
| Guidelines | ○ To create documents that recommend or mandate practice. Such as changes in service provision |
| Communication/marketing | ○ To use print, electronic, telephonic, or broadcast media |

Some of the policy categories can deliver the intervention in a wide scale, such as changes in legislation or fiscal measures; while some are specific in scale, such as service provision or communication and marketing. Not all intervention functions can be available to clinical researchers; for example, regulations that require government authority are not readily accessible for use. Therefore, some features of the BCW were bypassed if they were limited for implementation (Michie et al., 2014). It is important to carefully select from the BCWs' components for the target behaviour according to the social context. Therefore, the BCW theory outlines six criteria for consideration when choosing intervention functions and subsequent techniques, known as the APEASE criteria, see table (8).

The use of BCW recommended APEASE criteria to determine whether it was possible for the BCTs to be implemented within the targeted behaviour, target population, context and the study setting. Table 12 outlines the decisions from this process, which were made by the principal researcher and a panel of experts.

Table 8: APEASE Criteria (Michie et al. 2014)

| Level | Criteria | Meaning |
|---|---|---|
| **A** | **Affordability** | An intervention is affordable if it can be delivered and accessed by all those it would be relevant to or benefit, within an acceptable budget. |
| **P** | **Practicability** | An intervention is practicable if it can be delivered the way it was designed to the target population. |
| **E** | **Effectiveness & cost- effectiveness** | An intervention is deemed to be effective if the intended effect sizes are met on the objectives set. Cost-effectiveness examines the ratio of effect size to cost of implementing the intervention. |
| **A** | **Acceptability** | An intervention is acceptable if it is judged appropriate by relevant stakeholders including members of the public, health professionals and members of government. |
| **S** | **Side effects & safety** | An intervention needs to take into consideration participant safety and any side effects or unintended consequences which may exist. |

### 3.4 The Intervention Development Process

The BCW framework outlines three key stages for the intervention development process, and these are as follows: stage 1. understanding the behaviour and identifying what needs to change; stage 2. identifying intervention functions; and stage 3. identifying content and the relevant mode of delivery for the intervention. The key stages were further subdivided into more details. These were further subdivided into key steps including (i) defining the problem in behavioural terms; (ii) selecting the target behaviour; (iii) specifying the target behaviour; (iv) identifying what needs to change; (v) identifying appropriate intervention functions; (vi) identifying policy categories; (vii) identifying behaviour change techniques; and (viii) determining the mode of delivery. The text messages were then framed based on the BCW theory and the COM-B model (Cho et al., 2018).

- **Stage 1: Understand the Behaviour and Define the Problem**

The researcher reviewed the existing evidence on the importance of PA in people with T2DM in Saudi Arabia context and clearly defined the study of interest in order to select and specify the target behaviour for this intervention. For more information, see chapters 1 and 2.

- **Select the Target Behaviour**

The target behaviour of this intervention is PA in people with T2DM. The rationale of this intervention has been clearly justified in chapters 1 and 2. The preceding chapters have demonstrated the importance of delivering PA in people with T2DM in Saudi Arabia context. T2DM is a metabolic disorder that is characterised by high blood sugar due to insulin resistance. An increased risk of developing T2DM is associated with certain behavioural factors, such as unhealthy diet, poor sleep, stress, being overweight and

physical inactivity (NICE, 2019, ADA, 2018). In the Kingdom of Saudi Arabia (KSA), the epidemiologic transition of T2DM has been fast and complete, due to rapid economic growth that has led to a remarkable increase in living standards and a considerable change in lifestyle habits. Changing disease rates are almost certainly explained by changes in several behavioural risk factors, notably a reduction in PA (Robert et al., 2017). For more details, see chapters 1 and 2.

- **The Target Behaviour Specification**

The next step of this stage involved developing a clear specification of who will perform the target behaviour, what they need to do differently in order to achieve the change, where and when they need to do and, if necessary, how often and with whom they should perform it. Table 10 outlines the behavioural diagnosis as applied to PA behaviour, judgements as to the behavioural diagnosis were made by the principal researcher and reviewed with a panel of experts.

Table 10: Behaviour Specifications

| **Criteria** | **Specification** |
|---|---|
| Who | People with T2DM |
| What | Engage in any form of physical activity |
| When | During the day |
| Where | In any location or situation where, physical activity can occur |
| How often | Messages will be sent twice a week to encourage PA behaviour |
| With whom | Alone or with friends or family |

- **What Needs to Change to Achieve the Target Behaviour**

Michie et al. (2014) developed a COM-B model within the BCW theory to guide the understanding of a behaviour in the context and select behavioural targets as a basis for the intervention design. The COM-B model suggests that people need capability (C), opportunity (O) and motivation (M) to perform a new behaviour (B). The model is specifically designed to frame what needs to change for the targeted behaviour to be achieved. It helps to analyse whether the target of the intervention, patients with T2DM in this case, have the capability, opportunity, and motivation to carry out the new behaviour (PA). The behavioural diagnosis is presented in table 10, outlining the capability, opportunity and motivational factors that need to be assessed to bring about a change. The developed messages content was modified based upon COM-B model diagnosis.

| Table 11: Behavioral diagnosis using the COM-B model | | | |
|---|---|---|---|
| **COM-B criteria** | **COM-B component** | **What needs to happen for the target behaviour to occur** | **Is there a need for change?** |
| **Capability** | Physical capability | Have the physical capability to walk and engage in any form of physical movement. | **No**-The targeted people with T2DM should have the physical ability. |
| | Psychological capability | Knowledge of physical activity methods, potential side effects, how to engage in the target behaviour. | **Yes**-Patients with T2DM in this area may not have this knowledge as evidenced in Chapter 1. |
| **Opportunity** | Physical opportunity | Access to the physical activity methods. | **No**-Access is available through public services and health fitness facilities. |
| | Social opportunity | Inclusion of practices in cultural practices. | **No**-Lack of available programs, lifestyle culture and factors such as traditional and religious norms. |
| **Motivation** | Reflective motivation | Hold beliefs that PA can improve diabetes control. | **Yes**-Patients with T2DM need knowledge of the consequences of physical inactivity as evidenced in Chapter 1. |
| | Automatic motivation | Have established routines and habits. | **Yes**–Patients with T2DM need to have routines in place by repetition. |

- **Stage 2: Identify the Intervention Options and Polices**

  **Identify Intervention Functions**

The researcher selected the intervention functions that will most likely initiate the behaviour change in each COM-B component. The relevant intervention functions were graded using the APEASE criteria from the BCW framework guide.

These criteria are 1) affordability, 2) practicality, 3) effectiveness and cost-effectiveness, 4) acceptability, 5) side-effects /safety, and 6) equity. These factors were taken into consideration, especially concerning the fact that the mode of delivery is text

messages (SMS). Table 12 maps the intervention functions and their appropriateness for the target behaviour, population and the study setting

Table 12: Intervention functions vs. APEASE criteria (Michie et al., 2014)

| Intervention Function | APEASE criteria (affordability, practicability, effectiveness & cost-effectiveness, acceptability, side effects & safety and equity) |
|---|---|
| Education | • Yes |
| Persuasion | • Yes |
| Incentivisation | • Not practical, affordable, acceptable or equitable to implement this within context |
| Coercion | • Not acceptable, this is not a behaviour which has to be reinforced |
| Training | • Not affordable, practical or equitable to deliver training in the area or practical in terms of the workload of the health centre staff |
| Restriction | • Not possible within this context |
| Environmental restructuring | • Not practical to restructure the environment within this context, it is not required. It is not affordable, equitable or practical to make environmental restructuring options available to all individuals |
| Modelling | • Not practical in Saudi context |
| Enablement | • Not practical in Saudi context |

Therefore, the intervention functions education and persuasion are feasible to include in the text messaging intervention. After the messages content was informed and mapped to the COM-B components, opinions of the review panel were sought to identify the presence of BCTs in the sets of the text messages (see 3.1.7.2 section).

- **Identify Policy Categories**

As this intervention cannot have access to policy making, this step is bypassed as it is not relevant to the intervention design.

- **Stage 3: Identify the Content and Implementation Options**

**Identify Behaviour Change Techniques**

In this stage, the researcher has identified the frequently used behaviour change techniques taxonomy (BCTs) that are relevant to each of the considered intervention functions identified in stage 2 (Michie et al., 2014). Table 13 synthesises the most frequent used BCTs taxonomy. In effective interventions, 6 BCTs were identified from a systematic analysis conducted by Abraham and Michie (2008) in behaviour change interventions across behavioural domains, in particular PA (Abraham and Michie, 2008). Adopting a taxonomy of BCTs would help future researchers to facilitate theory testing through a meta-analytic review of interventions' effectiveness and accelerate the progress in the science of behaviour change.

Table 13: Mapping intervention functions and BCTS

| Intervention functions | Most frequently used BCTs | BCTs definition |
|---|---|---|
| **Education** | 1- Provide information about behaviour | General information about behavioural risk, for example, susceptibility to poor health outcomes or mortality risk in relation to the behaviour. |
| | 2- Provide information on consequences | Information about the benefits and costs of action or inaction, focusing on what will happen if the person does or does not perform the behaviour. |
| **Persuasion** | 3- Set graded tasks | Set easy tasks and increase difficulty until target behaviour is performed. |
| | 4- Provide instruction | Telling the person how to perform a behaviour and/or preparatory behaviours. |
| | 5- Prompt specific goal setting | Involves detailed planning of what the person will do, including a definition of the behaviour specifying frequency, intensity, or duration and specification of at least one context, that is, where, when, how, or with whom. |
| | 6- Provide general encouragement | Praising or rewarding the person for effort or performance without this being contingent on specified behaviours or standards of performance. |

### 3.5 Intervention Content Development

The text messages (SMS) content was developed rigorously applying the BCW theory and COM-B model process analysis. Each text message contained one or more BCTs as prompts and reminders to enhance delivery of the target behaviour in this study. The developed messages were limited to 160 characters, providing motivational, informational, and specifically to performing PA in people with T2DM. The characteristic of messages included the following: 1) general information about PA, recommended amounts of PA such as frequency, intensity, and duration; 2) information about the benefits of PA and outcomes

to T2DM; and 3) self-regulation strategies such as task achievement, goal setting, alternatives to achieve graded tasks or goals.

- **Text Messages Format (Phase I)**

A systematic process of intervention development was followed, advocated by the BCW guidance (Michie et al., 2014) (see section 3.1.6.1). This process was also underpinned not only by the literature, systematic review (see chapter 1, 2), but also a panel of experts and Patient and Public Involvement and Engagement (PPIE), (see 3.1.7.2 section). It was important to identify the evidence base for the determinants of the targeted behaviour and the intervention components that most likely will elicit the behaviour change (see section 3.1.6.1). The first series of text messages were developed by the primary researcher following the above processes and the message categories included educational, interventional and lifestyle change messages as follows:

- Physical activity knowledge and its effects on T2DM and personal life
- To set goals to do PA
- Reminders to not to give up
- Facts about habit change
- Tips to improve and increase self-efficacy
- Alternatives to perform PA

**In the first phase,** a total of 13 text messages were developed based on the literature and they were mapped to the BCW theory and the identifying BCTs, the second phase included several drafts shared with the main supervisors, the third phase included drafts shared with a panel of experts and PPIE group (see section 3.1.7.2). In the fourth phase, a final set of messages were prepared in English (see table 14), then were translated to the context's targeted language (Arabic Language) (see section 3.1.7.3).

The intervention development followed best practices and strategies to improve PA in people with T2DM. Although, the focus of this feasibility study was to find out if text messages are acceptable communication tool and practically feasible in Saudi Arabia context (see chapters 5, 6 and 7).

Table 14: Text Messages Content Mapped to BCW Theory

| The Behaviour Wheel Change Theory (BWC) | | Content Development |
|---|---|---|
| **BCW / COM-B components** | **Intervention Functions** | **Formatted Messages** |
| - | Start of Study | Asllam Alikum. Welcome to my study, I am proud of you that you decided to take this short challenge |
| Capability - Psychological | Education | Hi, do you know this fact, it takes up to 21 days to develop a habit? Find a physical activity you enjoy. Set your easy goals and start it now! |
| Capability - Psychological | Education | Hi, do you know that being active at any level can positively impact insulin action and blood glucose control acutely? |
| Motivation - Reflective | Persuasion | Hi, can you try to fit in 10 to 30 minutes physical activity every day this week? Remember this is hard at the start but will be your future habit. |
| Motivation - Reflective | Persuasion | Hi, allow yourself some time to build up to a steady, exercise routine. And be okay with going slow, it's better for your blood sugar in the long run. |
| Capability - Psychological | Education | Hi, do you know that physical activity can be in many forms, like taking the stairs not the lift, walk further away to mosques or shops. Small effort counts. |
| Capability - Psychological | Education | Hi, exercise actually makes your insulin more effective, your body burns glucose; therefore, you may be able to take fewer diabetes pills. |
| Motivation - Reflective | Persuasion | Hi, how did you get on with your physical activity last week? Don't feel bad if nothing went well, set a new achievable goal for this week. |
| Motivation - Reflective | Persuasion | Hi, have you set your goals yet? Your health is more important than anything, be healthy and all good comes with that. Write them today as a note. |
| Capability - Psychological | Education | Hi, have you decided what physical activity can you do this week? Click on this link () to decide. |
| Social - Opportunity | Persuasion | Hi, what do you think if you ask someone of your favourable people to go for a short walk with? It would be good to talk and be active. |
| - | - | Hi, if you think these messages have not been helpful and did not make any difference, please talk to me on this number (). |
| - | - | Hi, I am happy to tell you that you have come to the end of this challenge, but I am sure it's the beginning of a more active lifestyle. Please Keep it up. |

- **Text Messages Validation (Phase II)**

**Experts Panel**

The messages content was developed by a multidisciplinary team (7 people), led by the principal researcher (PR) and project supervisors (PS). The panel of experts in this study were selected based on their research interests of behaviour change interventions, digital health-based studies, and diabetes related management interventions. They were reached by references and contacted via email communications and telephone calls. The second and third group were fluent in the Arabic and English languages; however, due to the restricted time of this study they were only consulted in the English language. The first expert group for behaviour change included: the primary supervisor (she is a behavioural science researcher, with research expertise in wellbeing, the development, delivery, and evaluation of digital health interventions), the second supervisor (he is a researcher in e-Learning and health and education informatics). The second expert group for diabetes care included: a clinical nurse (she is working in outpatient care for endocrine department), a clinical nurse (he is a PhD holder in nursing, his expertise in diabetes management, patients' safety, and quality of health care). The third expert group for health informatics included: an academic researcher (he is a PhD holder in health informatics, with research expertise in mHealth, eHealth and diabetes management), a clinical informatics specialist (he holds a master's degree in health informatics and his expertise involves end user testing of clinical systems, training, and on-going support of clinical staff in acute healthcare settings).

A toolkit was adopted by Model Systems Knowledge Translation Centre (MSKTC) to test the developed text messages against the following criteria: the content relevance (appropriateness of each message to the theoretical constructs), readability (appropriate reading level), and tone (matching of the messages to the response level) (MSKTC, 2018). Suggested revisions centred on appropriately structuring messages, mapping messages to the behaviour change techniques (BCTs), simplifying the language and to avoid negative stereotyping (see Table 15 for examples, check appendix for full texts).

Table 15: The MSKTC criteria used to validate the messages

| **Guidance Tool** | **Overall Feedback (Developed Messages)** |
|---|---|
| Are messages consistent and accurate? | I feel the order would be better if it went 7, 6, 8. |
| Are messages relevant to type 2 diabetes? | Yes. |
| Are messages simple language to understand? | Yes, just concern if the Arabic translation would change the sentence structure and phrases. Overall is okay for most levels of education. |
| Is there any main information missing in the messages? | I did not notice any missing information. |
| Should I simplify the language or make it more concise? | It looks good enough. |
| Any comments? | Unless you are going to send these messages in English. You may still need to do another evaluation after translating these messages into Arabic |

The toolkit provided step-by-step guidance and tools for validating the key messages that were used to promote PA in people with T2DM. The experts had to follow the guidance tool in the first column and make sure each developed text message had fulfilled the guidance model. Due to time constraints, the consultation with experts and the PPIE group was happening spontaneously and smoothly. The study constraints will be discussed in detail in the discussion chapter, (see chapter 7).

- **Patient and Public Involvement and Engagement (PPIE).**

  The PPIE group is currently considered a key element of health care research in the United Kingdom (UK) and is acknowledged internationally. A systematic review has found that involving PPIE in research has the potential to develop a better understanding and awareness of the area of interest with the target population (Brett et al., 2014). Patient representatives were consulted on each text message created. Those patient representatives are people living with T2DM in with varying ages in Saudi Arabia. They were asked to evaluate if the messages content tone is understandable, clear, and as intended to promote the target behaviour. A total of 13 potential, theory-based messages were included in the final library. The PPIE group in Saudi is a new learning process and it is never done before with the group, so representatives were only asked very plain questions if the messages tone was simple and clear language as intended.

- **Translation of the Intervention Content (Phase III)**

  The first content was created in English adhering to the 160-character limit and were evaluated for content validity by the expert panel. An expert translation agency was hired to ensure that there are no errors in the original language, and the translations were checked against the source file. The agent was selected based

upon their large pool of linguists with different language combinations and fields of expertise, all of whom have translation qualifications and/or several years of professional experience. There are various stages of the translation process, the main approach as following: forward translation and back-translation. The forward translation was conducted by one bilingual translator of Arab descent, who speaks, reads, and writes both English and Arabic fluently. The back-translation method eventually was applied by two bilingual translators who were asked to translate back to the original language without having seen the original text (Son, 2018).

- **Text Messages Delivery (Phase IIII)**

The text messages were programmed for a one-way transmission using a commercial SMS provider (https://www.mobily.ws/en/); it is the only authorised provider in Saudi Arabia, the system limitations will be discussed in detail in the discussion chapter (see chapter 7). The system was composed of an SMS data collection tool which uses an in-built SMS gateway to send one-way structured messages that are then stored in a local database and utilise an enabled analytics tool that presents data visualisation to track the trial progress of sent messages. The one-way communication was selected due to various reasons, firstly to lower the costs of intervention and the sent messages were factual information and did not require participant's interactivity (Orr, 2015). Text messages were limited to 160-characters to prevent them from being automatically converted to MMS.

- **Frequency and Time of Day**

Text messages frequency varied across studies, from daily to weekly texting seemed to increase program retention (Eysenbach et al., 2019, Sahin et al., 2019a). Two text messages were sent within each week, over a six-week period. This study’s

design was selected based on evidence-based healthcare and behaviour change interventions (Eysenbach et al., 2017, Saffari et al., 2014a, Leahy et al., 2017). According to the literature, an average of 18 to 60 days is required to inform a new behaviour and becomes as much of a habit (Carden and Wood, 2018). Text messages were sent at various times per day (i.e., morning|9:30 am and evening|7:30 pm), on Mondays, Wednesdays, and Thursdays. The schedule for text message delivery was determined by the primary researcher, considering Saudi Arabia context's lifestyle (i.e., people pray five times throughout the day). One of the PPIE group was asked to indicate the preferred timing to receive the messages during morning hours, or during the early night hours. Prior studies using text messaging to promote behaviour change in various medical conditions have also supported the early morning and early night hours (Reese et al., 2017). However, this is a feasibility study, and it should inform the bases evidence for main studies.

- **Message Signature**

  Similar to the findings of previous studies, participants preferred text messages to end with the intervention signature so that they knew who the message was being sent from (Reese et al., 2017), However, the current study could not change the signature as the service provider did not enable this tool and this is one of the limitations that been discussed in chapter 7.

### 3.6 Chapter Summary

The BCW was utilised as a theoretical framework to develop the SMS based PA behaviour change intervention. The SMS messages aimed to include BCTs which were identified in the BCW process, their reliability was judged by a panel of experts to allow a level of certainty and the theoretical components intended to be present in the intervention

content. Finally, the final step outlined the processes to ensure accuracy within the translation of the text messages from English to Arabic. After the intervention development, the next step was delivering the intervention to determine both the feasibility and acceptability of using text messages to promote PA among people with T2DM in Saudi Arabia context, the next chapters presented results of this study.

# Chapter 4: The Methodology for Developing and Implementing Mobile-Messaging Based Intervention

## Introduction

The previous chapter aimed to develop a theory-based mobile text messaging to promote physical activity (PA) for people with type 2 diabetes mellitus (T2DM). This chapter provides an overview of the methodology implemented to achieve the aims of this research. It outlines the methods used and describes the many steps undertaken to complete the feasibility and acceptability phases of this study. The researcher used a mixed method approach, whereby quantitative and qualitative approaches were eventually combined. Subsequently, a description of data collection process, data analysis techniques and the main ethical considerations are justified in detail throughout this chapter.

## 4.1 Study Method Rationale

There are challenges in undertaking any research study; the major one is often choosing the appropriate methodology to answer the proposed research questions. In 2000, the Medical Research Council (MRC) published a framework to help researchers to recognise and guide the research processes. The MRC framework is been well-known and cited in the literature for developing and evaluating complex health interventions (Moore et al., 2015). This study has utilised the four phases of MRC framework which included: identifying the best available evidence (see chapter 1 and 2) and identifying the appropriate theory (see chapter 3) and modelling of the intervention (see chapters 5 and 6). A mix method approach was undertaken using a parallel design that consisted of qualitative and quantitative obtained in different stages to report the intervention results.

## 4.2 Aims and Objectives

The overall aim of this study is to explore the feasibility and acceptability of a theory-based text messaging intervention to promote PA in people with T2DM in Saudi Arabia.

### Primary objectives

To provide preliminary evidence regarding the feasibility and acceptability of delivering and evaluating a text messaging-based intervention for people with T2DM in Saudi Arabia context. Specifically, to:

- Explore recruitment, attrition, engagement, and adherence to the intervention.
- Evaluate patient's perception and satisfaction with the text-messaging intervention.

### Secondary objectives

To determine if certain health outcomes are sensitive to change following the text message intervention. Specifically, to:

- Measure the effects of the intervention on self-efficacy and physical activity levels before and after the intervention.
- Identify the barriers to physical activity.
- Measure the effects of the intervention on glycated haemoglobin (HbA1c) levels, the body mass index (BMI) before and after the intervention.

## 4.3 Background to Methodological Approach

- **Quantitative methods**

The feasibility objectives were achieved using the quantitative data collected at pre- and post-intervention surveys. The strength of quantitative methodology was used to explore participant's experience of the intervention engagement using descriptive

statistical data (Shorten and Smith, 2017). The quantitative method uses a deductive approach whereby the relationship between variables is assessed and analysed in numbers using statistical procedures (see Table 16: Strength and weakness of data-driven methods).

- **Qualitative methods**

The acceptability objective was achieved using the qualitative interviews collected at the end of the intervention. The aim of qualitative research was to explore patients' and health care worker's perspectives and opinions towards the delivered intervention and suggestions for improvement. The conducted interviews focused specifically on the use of text messages for the delivered intervention, also including study processes and procedures. The researcher used semi-structured interviews with open-ended questions to ensure the same areas were covered across all interviews (Dowding, 2013). The interview questions were developed in line with the study aims and pilot tested with T2DM patients.

- **Mixed methods design**

A mixed method using a parallel design was chosen as an appropriate method in this study to address the aim and objectives of this thesis (Onwuegbuzie and Leech, 2005, Creswell, 2018). The development and evaluation processes of text messaging is complex and involves several interacting components, including tailoring to the study context, the targeted behaviour change and assessment of a range of health-related outcomes, for which both quantitative and qualitative methods are needed (Evans et al., 2013). The current study has combined the strengths of quantitative and qualitative methodologies to achieve a comprehensive understanding of text messaging technology, the promoted

behaviour among people with T2DM, by exploring their experiences alongside health-related outcomes (Plano Clark, 2010).

The advantages and disadvantages of mixed-methods in health-related research have been argued, summarised in the following table (4). Quantitative data was collected at the baseline and follow up phase of the feasibility study, whereas qualitative data was collected at the end of the intervention. However, both quantitative and qualitative data were given equal priority and integrated during data analysis.

- **Rationale for combining quantitative and qualitative methods**

1. Seeking convergence and confirmation of results from various approaches exploring the same phenomena (triangulation).
2. Elaboration on results from each method can produce a richer and more comprehensive understanding of the intervention (complementarities).
3. Qualitative data is used for uncovering the way people feel, the emotions and motivations behind their behaviour.

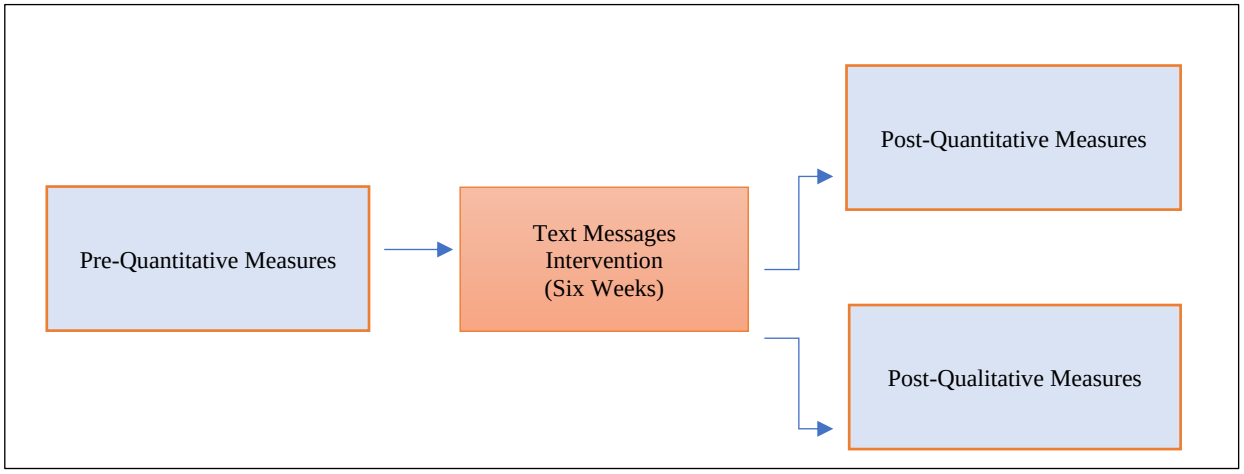
Table 16: Strengths and weaknesses of MMR (Johnson and Onwuegbuzie, 2016).

| Strengths | Weaknesses |
|---|---|
| • The MMR approach answers a broader and more complete range of research objectives because the researcher is not confined to a single method or approach.<br>• The MMR approach uses the strengths of an additional method to overcome the weaknesses in another method by using both methods in one research study.<br>• The MMR approach can provide stronger evidence for a conclusion through the convergence and corroboration of findings.<br>• The MMR approach can add insights and understanding that might be missed when only a single method is used.<br>• The MMR approach increases the generalisability of results which produces more complete knowledge. | • The researcher learns about multiple methods and approaches and understand how to integrate them appropriately.<br>• More expensive.<br>• More time consuming.<br>• Some of the details of conducting mixed research remain to be worked out fully by research methodologists. |

### 4.4 The Study Design

The current study used a single group design in order to achieve the aim and objectives of this study (Ip et al., 2013). The single group design is a design in which a group of subjects are administered a new behaviour and then measured pre and after the intervention. The rationale for not choosing a feasibility randomised control trial was because of the time limit of this PhD timeframe by the sponsor. However, the single group design fulfilled the main aim which to explore the magnitude of the intervention effects and the workings of the study components prior to developing a randomized controlled trial (Julie Wambaugh, 2014). The study protocol was prepared according to the National Institute of Health Research (NIHR) for feasibility design studies (NIHR, 2018). The feasibility study ran across three strands as follows: 1) text messages intervention delivery, 2) pre-post quantitative test and 3) and post-qualitative test (see Figure 10).

Figure 10: Flow of study strands



### 4.5 Sample Size

Identifying the sample size is a crucial step that should be carefully taken into account (Malhotra, 2017). The researcher followed the NIHR guideline for feasibility studies; therefore, 40-50 participants was the targeted sample size. According to the literature, sample sizes between 24 and 50 have been the average sample size in feasibility studies and can fulfil the nature of PhD studies (Vasileiou et al., 2018, Lancaster et al., 2004, Arain et al., 2010, Mark and Mason, 2010). The researcher anticipated an attrition rate of 10% at six weeks, based on attrition rates found in similar studies (Billingham et al., 2013). Adults with T2DM who could participate in this study were selected according to the eligibility criteria. The following sections explain the inclusion and exclusion strategy.

#### 4.5.1 Inclusion Criteria

Participants were included if they:

1. Clinician diagnosis of T2DM, according to the American Diabetes Association (ADA) criteria.
2. Over 18 years of age.
3. Possession of a cell phone with text messaging capability.
4. Ability to read and understand Arabic.

#### 4.5.2 Exclusion Criteria

The justification for the exclusion of this group was to minimise the likelihood of harm to participants, and guards against exploitation of any vulnerable people or if the study might increase their risk for adverse events (Patino and Ferreira, 2018). Participants were excluded if they:

1. Treatment with insulin adjustment.
2. Unable to understand the study requirements or give informed consent.
3. Visual impairment.
4. Diabetes-related complications.
5. Physicians were asked to confirm whether eligible participants can be medically capable of performing PA at the recommended level advised by National Institute for Health and Care Excellence (NICE, 2013).

### 4.6 Study Setting

Participants were recruited from the Ministry of Health (MOH), particularly King Fahd Medical City (KFMC), in the capital city of Riyadh. The MOH provides health services at three levels: primary, secondary, and tertiary. Patients diagnosed with type 2 diabetes mellitus (T2DM) or prediabetic are referred to the secondary level of service (e.g. KFMC), whereas complex cases that need more levels of management are transferred to the tertiary centres (Robert et al., 2017). This setting has been purposely selected as it is one of the largest public hospitals in Saudi Arabia and considered as one of the largest healthcare facilities in the Gulf Region, with a total capacity of 1,200 beds. The KFMC contains various primary care clinics; in particular, the diabetes and endocrinology centre. This centre comprises several divisions, including nursing, health education and nutrition. All patients with T2DM are scheduled for education support after their first appointment with their health providers. The diabetes centre provides them with full treatment and self-management education support through face-to-face sessions, group sessions or videos, pamphlets and phone conversations, these sessions usually conducted by trained health team members, which include nurses, clinical educators, and dietitians. In 2018, KDMC's

referrals of patients with T2DM were around 20 to 30 patients seen per day and have to attend at least 3 clinic visits per year (Alharbi, 2018).

### 4.7 Recruitment Process

Prior to inviting participants to the intervention, it was important to determine whether participants were interested, and what changes needed for the recruitment process. Personal face-to-face communication was considered as an effective way and more respectable approach in Saudi Arabia culture.

According to similar studies, patients are more likely to participate if they are invited verbally rather than other written invitations (Alabdulbaqi, 2019). Prospective patients were approached by a nurse's assistant at the time of a routine clinic visit either in the waiting room, or after they seen their endocrinology health providers. Health providers were also asked to refer interested T2DM patients to the diabetes education room if the inclusion criteria of participation were met.

The researcher and two trained nurses distributed the recruitment materials: (1) an information sheet in the Arabic language - which describes the study purpose, length, perceived benefits and contact details of the primary researcher if anyone wish to discuss the study in more detail; (2) consent forms – one for each participant to make sure that they understand what their participation in the study involves and, once anyone agreed, they were instantly asked to complete the consent form (see Appendix 1). For ethical purposes, participants were given 24 hours to take the study information home if needed for family consultation. This was then afterwards followed-up by WhatsApp message (with prior consent) (Kelly et al., 2015). The WhatsApp messages were used also to monitor participant's engagement, see section 5.4 for more details. Participants were informed that they can withdraw anytime during the study if they are unwilling to participate or unable

to give the written consent. The researcher facilitated the whole recruitment process for any raised enquiries about the study and responded thoroughly to any questions or concerns that they may have. The number of approached and recruited participants is presented in the following chapters (see chapter 5, section 5.2).

### 4.8 Data Collection and Intervention Delivery

Participants were recruited through convenience sampling. This is the most popular method of research subjects' recruitment in feasibility studies, pilot studies and randomized clinical trials (Martínez-Mesa et al., 2016). After eligibility exclusions and patient declinations, a total of 57 were included in the study (see section 5.2 for details). Participants were excluded primarily for not meeting eligibility criteria or declined to participate due to various reasons, but the common ones were concern about health issues, functional illiteracy, confidentiality related matters, lack of interest, family refusal and uncertainty or unwilling to follow up procedures (see chapter 5 for details). Following the recruitment and consent procedures, included participants were asked to complete the pre-assessment measures (physical activity, self-efficacy, and barriers to physical activity), demographic and health related outcome measures (HbA1c and BMI). By the end of the study, participants were invited again to complete the same measures. In addition to that, a semi-structured interview was conducted and audio-recorded, and transcribed verbatim (see chapter 6 for details). Further, incentive coupons were provided upon completion of the study, (it was non-financial targets). Incentivising has shown to improve participation in clinical trials (Vellinga et al., 2020).

### 4.8.1 Quantitative Method

- **Main Objective**

The purpose of quantitative data was to generate knowledge, determine the likelihood of changes in T2DM related health outcome measures and explore the feasibility main outcomes. The outcome measures were adopted based on the literature and similar conducted studies; this is clearly justified in chapter 1 (see section 1.6.4). The feasibility main outcomes were conducted to explore the numbers of eligible participants seen over the recruitment period, and the resulting rates of recruitment, adherence to the intervention, retention rate, text messages sent, received by participants and data completion (see chapter 5 for quantitative results).

- **Data Collection Method**

The outcome measures were collected via questionnaires to compare physical activity, self-efficacy, and barriers to physical activity. They were conducted before-and-after the intervention (pre-post questionnaires), to explore whether these outcomes are sensitive to change. The feasibility main outcomes were collected during data collection and stored in an excel sheet.

- **Outcome Measures**

- **The Arabic version of International Physical Activity Questionnaire (IPAQ)**

There are two main ways of measuring physical activity, mainly subjective and the objective methods. Subjective methods consist of physical activity diaries and questionnaires, whereas the objective method is predominantly measured via wearable monitors that measure indicators such as bio signals, heart rate and energy expenditure. Subjective methods are the most broadly adopted monitoring tools in multinational studies. One example of this is the International Physical Activity Questionnaire (IPAQ); this tool has been used in many studies, different contexts, and languages. The related IPAQ short

questionnaires were validated for international application and designed to be used by adults aged 18 – 65 years of age. The short version (9 items) was validated in Lebanon on the scale of time spent walking, in vigorous- and moderate- intensity activity and sedentary activity (Helou et al., 2017). The validated Arabic version of IPAQ showed a high internal consistency reliability with Cronbach's alpha ranging from 0.769-1.00 ($p < 0.001$) and intraclass correlation coefficient (ICC) ranging from 0.625-0.999 ($p < 0.001$), except for a moderate agreement with the moderate garden/yard activity (alpha = 0.682; ICC = 0.518; $p < 0.001$) (Helou et al., 2017).

- **The Arabic version of CDC questionnaire on Barriers to Physical Activity**

Several studies have demonstrated that lifestyle change is related to different factors, including social, psychological, cultural, and environmental factors (Harris et al., 2007, Atlantis et al., 2008, AlQuaiz and Tayel, 2009). Great benefits and hopefully improvements of these barriers can be acquired only if these barriers are identified and apprehended (Samara et al., 2015). Barriers to being active questionnaire of the Centres for Disease Control and Prevention (CDC) questionnaire was adopted. The instrument uses 27 questions on seven barriers (lack of time, lack of social support, lack of energy, lack of willpower, fear of injury, lack of skill and lack of resources). Each barrier category was represented by a set of three related questions (total of 27 questions), presented in a random order within the questionnaire. The scoring system was used to indicate how likely each statement/item was considered to be a barrier (very likely=3, somewhat likely=2, somewhat unlikely=1, very unlikely=0). The CDC questionnaire has been examined for validity evidence and used in various Arabic contexts. The Cronbach’s alpha was used to calculate the reliability of the questionnaire. The internal consistency (alpha) scale was

0.79 indicating good consistency and reliability (Samara et al., 2015). Permission to reuse the Arabic version questionnaire was obtained from researchers prior to data collection.

- **The Arabic version of Exercise Self-Efficacy scale (ESE)**

It has been proven that self-efficacy may increase the success rate in the process of lifestyle change and this can be an effective mechanism to health promotion in diabetes management (Daniali et al., 2017). Self-efficacy is known as "the beliefs in the ability to successfully perform an action or specific task by having the confidence and ability, the higher level of self-efficacy is more likely to overcome related obstacles (for more details, see chapter 1).

Many self-efficacy instruments have been developed; however, the ESE is most widely used measure and has been validated in different contexts. The Arabic version of the ESE scale was tested for validity and reliability in similar context, the construct validity was tested using exploratory factor analysis and Cronbach's alpha. The results showed a meaningful factor with an eigenvalue of 10.38 and an explained variance of 57.7%, and the alpha was .89 and split-half coefficient was .83 indicating that the ESE-A is a reliable scale (Darawad et al., 2018).

- **Quantitative Data Analysis Strategy**

Quantitative data were analysed using the Statistical Package for the Social Science Version 25.0 (IBM SPSS 27.0). The tests were conducted to compare the differences between baseline and post-intervention scores of self-reported physical activities, barriers to physical activity and exercise self-efficacy. For that, descriptive analysis was used to summarise the standard deviation (SD), frequencies, means, standard deviations, and ranges. See chapter (5).

### 4.8.2 Qualitative Method

- **The Main Objective**

The purpose of qualitative data was to explore patients and healthcare worker's experience towards the use of text messages in promoting physical activity and suggestions for improvements.

- **Collection Method**

Qualitative data was collected using a semi-structured interview guide formed of open-ended questions. These questions were developed based on the main objectives of this study. Using open-ended questions is, as opposed to closed-ended questions, non-directive and allowed interviewee to express their opinions using their native language and provide them with more flexibility to introduce aspects of the intervention at their convenience (Irvine et al., 2013). The topic guides were developed by the principal researcher and the main supervisors. These both ensured that the interview guide of the topic was relevant to the study's aims and objectives. The questions were generally created to explore the big picture of the intervention as to open the door for the main studies to understand the surrounding patterns of the interventions. More importantly Saudi context is unique in its structure and culture, so we avoided questions to be theoretically framed to avoid any conflicts and future studies should consider these limitations.

Table 17: Topic guides for interviews

| Topic Guide for Patients | Topic Guide for Healthcare Workers |
|---|---|
| • Generally, what do you think of mobile phone text messaging ?<br>• What do you think of the recruitment process ?<br>• What made you participate in this research study ?<br>• Did you experience any issues with receiving the SMS messages ?<br>• Did you notice any change in your lifestyle because of the SMS messages?<br>• Do you suggest those SMS messages should be combined with others ?<br>• Do you have any questions or comments? | • Overall, what do you think about the study?<br>• What should we do differently if we were starting over with this program?<br>• Have you learned anything from being involved in this project?<br>• Would you recommend this intervention to other clinical settings ?<br>• Do you have any questions or something to add or suggest?<br>• What do you think about the SMS messaging as a communication tool used in this study? |

- **Qualitative Data Analysis Strategy**

The collected qualitative data was transcribed verbatim; two bilingual independent reviewers were hired to conduct a forward-translation and back-translation (Toma et al., 2017). The main supervisors were also consulted to review the interview content and to provide constant feedback throughout all the data analysis stages. A thematic analysis approach was conducted following Braun and Clarke's (2006) guidelines; these include six phases: familiarisation with the data; generation of initial codes; searching for themes; reviewing themes; defining and naming themes in a code book; and producing the report. This inductive approach led to a richer and more participant-driven analysis that shed light

on the principles and practices that can enhance physical activity to type 2 diabetes mellitus patients in KSA.

This method was used to identify the key themes and generate common codes. If any overlapping occurred during this stage, they were categorised under similar themes, and uncoded texts were evaluated to ensure that they are relevant to the research aims. Finally, generated codes were revised and refined by the principal researcher and expert researchers in mixed method research from the University of Nottingham (HB, ST). NVivo (version 12) software program was used throughout to aid in this analytical process.

### 4.8.3 Demonstrating Rigour in Qualitative Data

Qualitative data requires a soulful and imaginative approach to assessing its quality (Maher et al., 2018). Different criteria are used to assess the rigour of qualitative studies but the most common are those proposed by Lincoln and Guba (1985): credibility, dependability, confirmability, and transferability. The four aspects of criteria are explained in further detail in the following subsections. These steps were attempted by the researcher to ensure the generated data was conducted to uphold qualitative rigour.

### 4.8.4 Credibility

Credibility in qualitative research can be enhanced via prolonged engagement and persistent observation on the study. The researcher made sure sufficient time was spent with participants prior to their interviews, to learn more about the social context and develop a harmonious relationship. A close observation was also spontaneously applied to ensure the phenomena was covered in depth, and the findings accurately represents the views of the participants.

More strategies have been used such as peer debriefing where the researcher discussed the methods used, data collection and analysis processes continuously throughout all research stages with main supervisors and two clinical researchers in the study setting.

### 4.8.5 Dependability and Confirmability

Dependability involves ensuring that the qualitative findings are consistent and repeatable, and confirmability refers to the neutrality and accuracy of the data; however, it is closely linked to dependability and the processes for establishing both are similar (Houghton et al., 2013). There are several techniques which can be used to establish dependability, one of the best ways to establish dependability is to have an outside reviewer conduct an inquiry audit on the study. The researcher verified findings by including the main supervisors, and two clinical researchers in the same field. This is important to make sure that nothing is missed in the research study, or that the researcher was not sloppy or misguided in final report. All interpretations and conclusions were examined to determine whether they are supported by the data itself. The researcher also followed the triangulation method by verifying findings through: 1) referring to multiple sources of information (including literature), 2) using multiple methods of data collection, and often 3) acquiring observations from multiple inquirers (Salkind, 2010). The focus of following these processes was to avoid any interpretations based on one's own preferences and viewpoints but needs to be grounded in the data.

### 4.8.6 Transferability

Transferability relates to the ability of the findings to be transferred to other contexts or settings. To determine transferability, the original context of the research must be adequately described so that judgements can be made (Koch 1994). The researcher provided a rich account of the descriptive data, such as the context in which the research was carried out, its setting, sample size, sample strategy, demographic, socio-economic, and clinical characteristics, inclusion and exclusion criteria, interview procedure and topics. In providing this information, the aim was to allow future researchers to determine whether the findings of the study were applicable in other settings or contexts (Morse, 2015).

## 4.9 Data Synthesis

Qualitative and quantitative data were collected concurrently and analysed independently. Merging data analysis through data comparison was applied in this study. The integration process consisted of combining quantitative data in the form of numeric information and qualitative data in the form of texts. The integration was achieved through reporting results together in a discussion section; such as reporting first the quantitative statistical result, followed by qualitative quotes or themes that supported the quantitative results (Dowding, 2013).

## 4.10 Ethical Approval

The project was approved by both the Faculty of Medicine and Health Sciences Research Ethics Committee at the University of Nottingham on [25-10-2019] (Ref: 414-1910), and the hospital setting in Saudi Arabia on [03-11-2019] (Ref: H-01-R-012).

- **Ethical Considerations**

All participants were administered participant information sheets and consent forms prior to taking part in the study (see appendix). The researcher and two nurses distributed

the information sheet and consent forms, see section 4.7 for details. The information sheet offered a clear statement of all those aspects of the research that are relevant for their decision about whether to agree to participation, they were given an option to withdraw or modify her/his consent or ask for the destruction of all or part of the data gathered. All information sheets, consent forms and surveys were stored safely in a locked draw of a desk situated in the recruitment setting. The interview recordings were saved in an iPhone cloud configured with a passcode and 2-Step Verifications (It Governance Privacy Team, 2017).

- **Confidentiality and Data Protection**

Anonymity and confidentiality of the reported participant data is central; the researcher assured that the data provided cannot be traced back to the participants in reports, presentations, or other forms of dissemination. The researcher preserved anonymity and confidentiality using pseudonyms for participants, such as changing the reported characteristics of participants (such as female, male). General Data Protection Regulation (GDPR) does not define for how long personal data should be kept; however, for the nature of this PhD research, data will be kept for a minimum of 10 years (Spencer and Patel, 2019). The researcher is the only person who have access to all participants' personal information. Data obtained from participants were only used for academic purposes, including discussion during supervision, informal meetings, or conferences.

### 4.11 Chapter Summary

This chapter provided an overview of the methods followed to achieve the overall aim and objectives of this thesis. The study aimed to develop and evaluate a text messaging-based intervention to promote PA in people with T2DM in Saudi Arabia. The study phases were developed based on the MRC Framework on the development and

evaluation of complex interventions. Quantitative and qualitative data were collected concurrently and were analysed independently, and both approaches were combined in order to inform a future definitive RCT. The following chapters will present the results of both quantitative and qualitative analysis described in this chapter.

# Chapter 5: Quantitative Results

## 5. Introduction

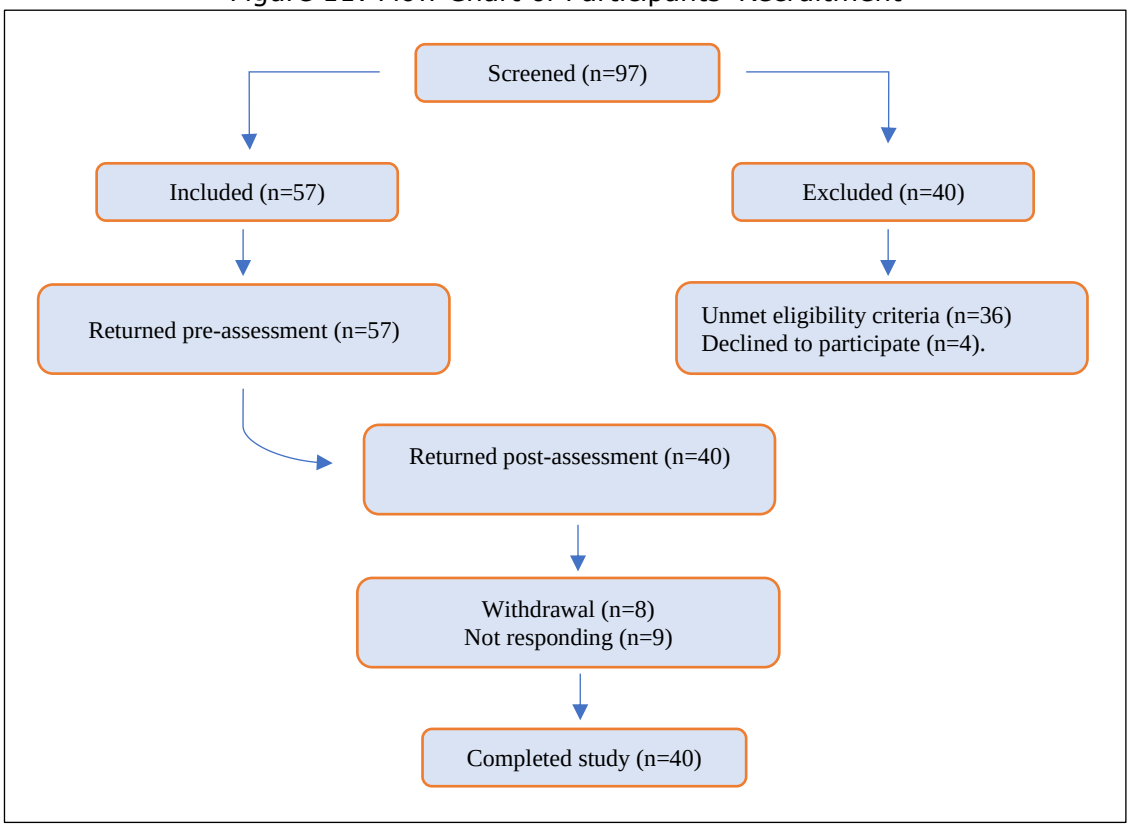
The aim of this chapter is to present the findings of the feasibility of mobile text message-based intervention to promote physical activity (PA) among people with type 2 diabetes (T2DM). Baseline demographic and clinical data were analysed using a descriptive statistic. Categorical data were presented as frequencies and percentages, while continuous data were presented as means and standard deviations. The following sections report a set of feasibility criteria to assess the potential pre-defined success rate. Results of the assessment are shown in table 18.

## 5.1 Recruitment and Response Rate

Participants were recruited from the Ministry of Health (MOH), particularly King Fahad Medical City (KFMC), in the capital city of Riyadh. A convenience sample of participants were recruited from an adult population (aged 18 or over) with T2DM, (see section 4.5.1 for eligibility criteria). During the initial stages of studies, researchers usually prefer using convenience sampling as it's quick and easy to deliver results especially in feasibility studies (Stratton, 2021). The recruiting process started on the 26$^{th}$ of December 2019 and ended on the 3$^{rd}$ of March 2020. The principal researcher with a nurse's assistant who approached 97 patients with T2DM during their routine clinic visit. Those who have met our inclusion criteria were invited to the study. Of those eligible 97 participants, only 57 (58%) (26 women and 31 men) agreed to participate in in the study. Participants who did not wish to participate in the study (n=97) cited different reasons for their decision including PA related health risks determined by their health care providers (n=9 patients), diagnosed with T2DM but they have TDM1 (n=6 patients), family refusal who appointed someone else to act on their behalf (n=4 patients), health related complications determined by their health care providers (n=12 patients), not interested in the study (n=9

patients). Recruited participants were asked to complete a set of baseline questionnaires and all 57 participants (100%) returned the questionnaires back to the research team.

Figure 11: Flow Chart of Participants' Recruitment




**5.3 Follow-up Rate**

Of the 57 participants who consented to take part in the study, 40 (70%) participants were available for follow-up at 3 months. Of those not eligible, 8 (15%) had withdrawn before the outcome measures and 9 (16%) were not responding to the final 3-month follow-up data collection. Data collection was monitored in real time by the principal researcher, the online methods used to complete the post outcome measures were tested to make sure it works and changed it if necessary. Throughout the intervention, there was a set of messages which reminded participants to reach out to the researcher when needed and 2 messages emphasising the importance of follow up, including the survey links to complete the post-outcome measures; this was achieved via the WhatsApp application.

We created a broadcast list on WhatsApp and then 3 reminder messages were sent to the whole group, but participants received these messages as private messages, by means of a direct message from the principal researcher. This way it was possible to increase the rate of the messages being open and read because people rarely ignore private messages (De Benedictis et al., 2019). We used incentives as a reward to encourage participation and complete the follow-up outcome measurements (57 coupons were reimbursed). Incentivising has shown to improve and encourage participation in clinical trials (Smith et al., 2019).

The rate of follow up in this study was 70% (40/57), this rate is deemed good and an acceptable rate according to the literature, the response rate for clinical studies range between 68% and 75% (Neuman, 2013). The results of this feasibility study are summarised in table 5.1 and are compared with the pre-defined criteria which is based on the literature and UK's National Institute for Health Research (NIHR) and Health Technology Assessment (HTA) Programme (Lavoie et al., 2018). These rates will be interpreted and discussed in chapter (7).

Table 18: Pre-defined success rate

| Assessment Type | Results (%) | Pre-define success rate (%) |
|---|---|---|
| Recruitment Rate | n=57 (58%) | > 54% |
| Response Rate | n=40 (70%) | > 65% |
| Follow up Rate | n=40 (70%) | > 65% |
| Engagement Rate | n=15 (40%) | > 55 % |

### 5.4 Intervention Engagement

Evidence suggests that a certain level of engagement is necessary for intervention effectiveness. However, it is not clear how to conceptualise engagement in complex health interventions (Walton et al., 2017). The system we used for the main intervention did not provide us with tools to measure participant's engagement. Therefore, we examined the rate of engagement by utilising the follow up messages sent via the WhatsApp application. The system we used for the main intervention did not provide us with tools to measure participant's engagement. The generated responses were used and reported in percentages. The system usage data are the most commonly collected and reported measures of engagement in eHealth and mHealth interventions (Perski et al., 2017). As mentioned earlier, participants were added to a broadcast list, and they received 3 messages divided into 3 categories, see table 5.2. At the end of each group of messages, participants were prompted to verify that they received the messages. Engagement was reported as the percent of messages to which the participant responded, categorised as high (≥90%), good (≥70–<90%), and low (<70%) engagement levels (Short et al., 2018). Table 12 describes the different types of the WhatsApp interactions measured as the number of comments that every participant made in response to each of the sent message. Further discussion of these engagement rates will be made, followed by recommendations for further research (please see chapter 7).

Table 19: Number and percentage of engaged participants (Short et al., 2018)

| Type of Engagement | Description | Engagement Measurement | Results |
|---|---|---|---|
| **Active Engagement** | Hi, I am Mohammed AlSahli, the PhD researcher who met you at King Fahd Medical City. Please if you need any support or help for my study, feel free text me back. | • This was measured as the number of comments that every participant made in response to each message (Short et al., 2018). | **n=6 (10%)** |
| **Active Engagement** | Hi, I hope the SMS messages that were sent benefited you and encouraged you to exercise, please can you complete the online questionnaires? | | **n=18 (31%)** |
| **Active Engagement** | Good evening, I would like to gift you a free coupon, please make sure that your online questionnaires are completed and thank you for your efforts during my study, I wish you all the best and good health. Can you confirm if you completed the online questionnaires? | | **n=8 (14%)** |
| **Overall Engagement Rate (%)** | | | **56%** |

### 5.5. Baseline Characteristic of Participants

The current study included 40 participants in the final analysis. As depicted in table 6, the mean age of respondents was 51.9 years (SD=11.5). More than half of participants were males (n=21, 51.3 %). Regarding ethnicity, all respondents were of the Saudi Arabian nationality (100%). More than half of the sample (66.7%) were from a middle-income background, the three most prominent education levels among respondents were high school's degree (30.8%), postgraduate (25.6%), and undergraduate (23.1%). All participants had an average mean of glycated haemoglobin HbA1c (7.46%) and body mass index (BMI) (30.80%). For characteristics of participants, see table (20).

- **Health Related Information**

Our clinical data included (HbA1c, BMI and medical history). Their collection was planned at week 0 (pre-test) and at week 6 (post-test). However, clinical data was only collected at bassline, this was due to long clinical appointments and study limitations. For more details, see chapter 7.

Table 20: Baseline participants' characteristics with T2DM

| Variables | Frequency | Percentage % |
|---|---|---|
| **Gender** | | |
| **Male** | 21 | 51.3 |
| **Female** | 19 | 48.7 |
| **Medical history** | | |
| **Diagnosed with T2DM** | 39 | 100.0 |
| **Hypertension** | 17 | 43.6 |
| **Other** | 13 | 33.3 |
| **Education level** | | |
| **No education** | 2 | 5.1 |
| **Middle school** | 6 | 15.4 |
| **High school** | 12 | 30.8 |
| **Undergraduate** | 9 | 23.1 |
| **Postgraduate** | 10 | 25.6 |
| **Marital status** | | |
| **Single** | 2 | 5.1 |
| **Married** | 34 | 87.2 |
| **Divorced** | 1 | 2.6 |
| **Widowed** | 2 | 5.1 |
| **Income level** | | |
| **Low** | 1 | 2.6 |
| **Moderate** | 26 | 66.7 |
| **High** | 12 | 30.8 |
| **Total** | 40 | 100.0 |

**Clinical outcomes**

| The variable | Mean | Std. Dev | Min | Max |
|---|---|---|---|---|
| **The age** | 51.92 | 11.52 | 29 | 71 |
| **BMI** | 30.80 | 5.09 | 22.60 | 44.05 |
| **HbA1c** | 7.46 | 1.18 | 5.6 | 12.1 |
| **Total** | | | 40 | |

### 5.6. Process Evaluation

The Medical Research Council (MRC) guidance for developing and evaluating complex interventions recognises the importance of process evaluation within trials but did not provide guidance for its conduct (Moore et al., 2015). The process evaluation focuses on the used research methods and the implementation process to determine how successfully the study answered the aim and objectives laid out in the study protocol. The current study used the most common framework presented by Reelick and colleagues (2011). This encompasses the following three process components: (1) success rate of recruitment; (2) the quality of execution of the complex intervention; and (3) the process of acquisition of the data. The intervention process was assessed through the framework

presented by Irvine and his colleagues (Irvine et al., 2012). The different frameworks were conducted to produce in-depth insight into the study processes, to prevent drawing inappropriate conclusions and to formulate firm recommendations for future studies.

Table 21: Process evaluation (Reelick at al., 2011)

| Process Measures | Process Measures | Process Variables |
|---|---|---|
| **Research Processes: Study Sample** | Recruitment rate | • Number of potentially eligible participants in target population<br>• Number of participants met the inclusion criteria<br>• Number of participants recruited |
| | Barriers and facilitators to recruitment process | • Motivation for participation<br>• Reasons for non-participation<br>• Time spent to recruit participants |
| | Follow-up rate | • Number of participants completing pre-post assessments |
| | Barriers and facilitators for follow-up | • Reasons for not completing the study<br>• What motivated participants to complete the intervention |
| **Research Processes: Data Collection** | Completeness of data collection | • Number and characteristics of missing data<br>• Feasibility of outcome measures to detect change over time<br>• Reasons for missing data |
| | Barriers and facilitators for data collection | • Burden of completing outcome measures<br>• Rate of questionnaire completion<br>• Geographical spread of where participants live<br>• Time needed to collect and analyse data |

- **Research Process Evaluation**

**The Study Sample**

The study sample has been described in detail in chapter 5, section 5.2. The following sub-sections has described the same sample and related details in accordance to the process evaluation framework (Reelick et al., 2011). The process evaluation has included some quotations from participants' interviews, all interviews are presented elsewhere (see chapter 6).

**The Recruitment and Follow up Rate**

Fifty-seven participants consented to take part in the study, of these, 40 (70%) participants were eligible for a follow-up at 3 months. Eligible participants were screened between the 22nd of December 2019 and the 5th of January 2020 (planned duration was 2 weeks). The study successfully achieved enrolment of the study in a timely and efficient manner, with a recruitment rate of 4 participants per day. Recruitment rates in previously published studies in these populations vary from 65-74% (Lavoie et al., 2018). Recruiting the required number of participants is vital to the success of clinical research, this is one of our main outcomes in this feasibility study. The findings will be interpreted and discussed in more detail in the context of some prior studies (see chapter 7).

**The Barriers and Facilitators to Recruitment**

Understanding the barriers and facilitators to recruitment of subjects could improve the recruitment rate and increase the maximum study success (Adams et al., 2015). The current study utilised different strategies to ensure the required sample size is reached. The research team made sure that every enquiry raised was answered during the recruiting process.

The perceived support and expertise offered by the research team were an added level of motivation to potential participants. The in-person approach was very helpful and motivated participants to freely exchange questions.

Participant No. 55, shared her views about the research team's approach:

> **Your explanation why we need exercise and my sugar control, I want to do this, but it is very hard because of my life challenges.**

Participant No. 31, expressed a similar viewpoint that knowing that there is no required tasks to do made them feel encouraged:

> ***I like your study when you told me I have no commitment.***

As mentioned, recruiting through face-to-face interaction is a more respectable way to communicate in Saudi culture. Therefore, participants were invited verbally rather than through a written invitation. Participants reported different opinions related to being approached during the clinic appointment. Some participants quoted that they were happy and comfortable being approached during their routine clinic time and others felt uncomfortable for various reasons:

Participant No. 33, described her preference for this approach:

> ***It was good timing, but I wasn't in a good mood to talk to anyone. I was tired and worried about my lab results.***

Participant No. 07:

> ***It was suitable time, I made use of it while I was waiting for my turn, and I completed the questionnaires.***

Participant No. 29:

> ***It was fine, but I felt embarrassed when I talked in front of nurses about my private life, I have friends working here, I do not want they know about my health.***

These findings may help future studies to understand which facilitators and barriers increased patients' participation and engaged those who were less likely to enrol onto the study.

**The Barriers and Facilitators to Follow Up**

Loss to follow-up in clinical trials could bias results for unavailability of participant data that is associated with an absolute outcome measure (Akl et al., 2012). Of the 57 participants included in the study, 40 (70%) of them were retrieved for 3 months follow-up. Reasons for non-completion of post outcome measures were recorded, 8 (15%) had withdrawn during the intervention and 9 (16%) were not responding to the follow-up data collection. Although, the current study adopted several strategies to improve retention and generate maximum data return to follow-up. These recruitment strategies included: a telephone call and WhatsApp messages. Participants were offered to complete post-assessment tools via (online surveys or scanned surveys). 57 free coupons were offered to encourage completion or maximise completion. Most of participants described the social support and motivation they felt during the intervention as facilitating their return for follow up.

Patient no. (13)

> ***Honestly, these messages made me feel as if there is someone supporting and encouraging me.***

*Patient no. (23)*

> ***For me, any word of support is like a medicine to me. We human beings need to hear such nice and encouraging words, when you sent to me those messages, it means you cared about me.***

Understanding what motivated or discouraged participants to complete the study can help future studies maintain high follow-up rates. Although, this was not the primary focus of this feasibility study, but it should be carefully thought out to design the future definitive trial. These findings will be interpreted and compared with previous studies (please see chapter 7).

**Data Collection**

The process evaluation of data collection offers a valuable insight into the reasons why the intervention may have been effective in achieving its aim and objectives. Our data collection was assessed against the appropriateness of the outcome measures, the completeness of data and the detection of sensitivity in the included outcome measures.

**Completeness of Data Collection**

Missing data is a common issue in all types of research but varies on how much data is missing, (e.g., single items, a full questionnaire, a measurement wave), and why it is missing (Reelick et al., 2011). The research team made sure that there was no missing data in the pre-assessment questionnaires completed in their presence; however, in the post-assessment questionnaires, participants were encouraged for the data to be completed in order to win the free coupons that were offered. Moreover, they were offered continuous and instant support in case anything needed more clarification. Online papers were completed, and no missing data was reported. The preferred mode for collecting data in research has traditionally been the paper questionnaire; however, we could not meet patients again as their clinical appointments could not be scheduled to fit it in a practical timeframe for the PhD project.

**Burden of Completing Outcome Measures**

The burden of participation in a clinical trial is a holistic composite of multiple factors that include direct risk of participation, treatment side effects, adverse events and aspects of inconvenience (study duration, location, frequency and duration of clinic visits) (Bodart et al., 2018). These aspects were not either subjectively or objectively measured; meanwhile, participants did not report any burden of the above-mentioned factors.

**Data Collection and Analysis Time Scale**

Participants were given the option to complete the study tools via online or paper-based versions. The required sample size was fulfilled over 2 weeks including the pre-intervention assessments. The post-intervention assessment was completed within the last 3 weeks of the study. The duration of data analysis was 3 months, no issues were reported during all study phases, for the study timetable (please see the appendix for more information).

**The Feasibility of Selected Outcome Measures**

The outcome measures were collected via questionnaires from each participant at 2 points, baseline and in the end of the study. Pre-test data was collected during the same 2 weeks of recruitment, post-test data were gathered within 3 weeks of the final week of the intervention. In total, 57 participants completed the pre-test data and only 40 participants' data were included in the final analysis, (70% completion rate); for details, see section 5.3. The independent t-test was conducted to compare the scores of the outcomes, and the repeated measure t-test (the non-parametric equivalent Wilcoxon test) was also conducted to compare the mean score of the measures in the intervention (Fagerland, 2012).

**Results of Outcome Measures**

The current study used a descriptive statistic to describe the basic features of data. They provide simple summaries about the sample and the measures. Almost, half of the used statistical tests require that one or more assumption is met and any violations to the assumptions can cause the tests to produce an overestimation or underestimation of the inferential measures and effects (Hoekstra et al., 2012). For parametric statistical analyses, normality of each outcome measure was assessed through visual inspection of residuals in a normal quantile (QQ) plot and histogram (see the appendix for more information). Non-parametric analyses were used if data were deemed to depart from normality. Several studies suggest that the analysis of feasibility studies should mainly be descriptive, as hypothesis testing requires a powered sample size which is usually not available in feasibility studies. In addition, inferential statistics for effectiveness requires a control arm which may not be present in feasibility studies (Arain et al., 2010). The analysis strategy was discussed with Dr. Andrea Venn, a medical statistician, and she agreed that the approaches were convenient for the research aims and objectives.

- **The Paired Samples T-Test**

This was done to explore whether the primary outcome measures were sensitive to change over 6 weeks, the researcher used the (T) test to indicate the difference between pre- and post-scores. It was also used to identify the significant difference between the mean levels of the pre- and post-scores of the intervention sample in each of the 3 research tools. These tools are as follows: the barriers to physical activity, exercise self-efficacy and the physical activity questionnaire (refer to the appendix for more information).

- **Barriers to Physical Activity**

Table 22: Paired samples T-test

| The Factor | Pre | | Post | | t-value | Sig. (2-tailed) |
|---|---|---|---|---|---|---|
| | Mean | Std. Deviation | Mean | Std. Deviation | | |
| **Lack of Time** | 5.03 | 2.54 | 5.21 | 1.84 | 0.44 | 0.662 (N. S.) |
| **Social Influence** | 4.31 | 1.76 | 5.21 | 1.42 | 3.08 | 0.004 (0.01) |
| **Lack of Energy** | 4.54 | 2.78 | 5.13 | 1.81 | 1.07 | 0.293 (N. S.) |
| **Lack of Willpower** | 5.23 | 2.40 | 4.90 | 1.90 | 0.63 | 0.531 (N. S.) |
| **Fear of Injury** | 1.87 | 1.73 | 3.56 | 1.96 | 4.33 | 0.000 (0.01) |
| **Lack of Skill** | 2.92 | 2.41 | 4.10 | 1.67 | 2.78 | 0.009 (0.01) |
| **Lack of Resources** | 4.49 | 2.55 | 4.10 | 1.60 | 0.86 | 0.394 (N. S.) |
| **Total Score of Barriers to Being Physically Active** | 28.38 | 10.56 | 32.21 | 7.52 | 2.01 | 0.052 (0.05) |

As shown in table No. 22, the values of (t) are non-significant in the factors: lack of time, lack of energy, lack of willpower, lack of resources. This indicates that there is no statistically significant difference between the average pre- and post-measurements in these factors in the study sample. As shown in table No. 8, the values of (t) are significant at the 0.05 level or less in factors: social influence, fear of injury, lack of skill; as well as in the total score of barriers to physical activity. This indicates the existence of statistically significant differences between the average pre- and post-measurements in these factors in the study sample, and those differences were in favour of post-test.

- **Exercise Self-Efficacy (ESE)**

Table 23: Paired samples T-test

| Pre | | Post | | | |
|---|---|---|---|---|---|
| **Mean** | **Std. Deviation** | **Mean** | **Std. Deviation** | **t-value** | **Sig. (2-tailed)** |
| 731.03 | 401.92 | 1023.59 | 400.87 | 5.09 | 0.000 (0.01) |

As shown in table No. 23, the value of (t) is significant at the 0.01 level, which indicates the existence of statistically significant differences between the average pre- and post-measurements in exercise self-efficacy in the study sample. Those differences were in favour of the post-test. Our findings are consistent with the literature; prior research has demonstrated a positive relationship between self-efficacy and physical activity in T2DM (Dutton et al., 2009, Guicciardi et al., 2014, Siregar et al., 2018).

- **The International Physical Activity Questionnaire (IPAQ):**

Table 24: Paired Samples T-test

| | Pre | | Post | | | |
|---|---|---|---|---|---|---|
| **The Variable** | **Mean** | **Std. Deviation** | **Mean** | **Std. Deviation** | **t-value** | **Sig. (2-tailed)** |
| **MET- Vigorous Physical Activity** | 774.36 | 2212.36 | 1913.85 | 2461.42 | 2.06 | 0.046 (0.05) |
| **MET- Moderate Physical Activity** | 295.38 | 559.44 | 920.62 | 1247.81 | 2.74 | 0.009 (0.01) |
| **MET- Walking** | 492.04 | 763.91 | 568.19 | 749.11 | 0.52 | 0.609 (N. S.) |
| **MET- Total** | 1561.78 | 2922.88 | 3402.65 | 3389.21 | 2.58 | 0.014 (0.01) |

As shown in table 24, the value of (t) is significant at the 0.05 level or less in the variables: MET- Vigorous physical activity, MET- Moderate physical activity; as well as in the total of the MET value. This indicates the existence of statistically significant differences between the average pre- and post-measurements in these variables in the study sample,

and those differences were in favour of the post-test. The value of (t) is non-significant in the variable: MET- Walking. This indicates that there were no statistically significant differences between the average pre- and post-measurements in this variable in the study sample. However, there was a non-significant trend apparent, in that mean scores for walking were higher at post-test than pre-test.

- **The Non-Parametric Wilcoxon Test**

The following tables show the results of the Wilcoxon test, as an alternative to the (T) test. This was used to identify the significance of the difference between the pre- and post-intervention with the research sample. The non-parametric test can show the numbers of the sample subjects according to the change in their degrees between the two measurements.

- **Barriers to Physical Activity**

Table 25: Wilcoxon Test for Paired Samples Test

| The factor | Group | N | % | Sum of Ranks | Mean Rank | Z-value | Sig. |
|---|---|---|---|---|---|---|---|
| **Lack of Time** | Negative Ranks | 13 | 33.3 | 15.12 | 196.50 | 0.46 | 0.647 (N. S.) |
| | Positive Ranks | 16 | 41.0 | 14.91 | 238.50 | | |
| | Ties | 10 | 25.6 | | | | |
| **Social Influence** | Negative Ranks | 7 | 17.9 | 16.07 | 112.50 | 2.69 | 0.007 (0.01) |
| | Positive Ranks | 24 | 61.5 | 15.98 | 383.50 | | |
| | Ties | 8 | 20.5 | | | | |
| **Lack of Energy** | Negative Ranks | 13 | 33.3 | 18.73 | 243.50 | 1.18 | 0.239 (N. S.) |
| | Positive Ranks | 22 | 33.8 | 17.57 | 386.50 | | |
| | Ties | 4 | 6.5 | | | | |
| **Lack of Willpower** | Negative Ranks | 19 | 48.7 | 18.95 | 360.00 | 0.74 | 0.459 (N. S.) |
| | Positive Ranks | 16 | 27.1 | 16.88 | 270.00 | | |
| | Ties | 4 | 8.0 | | | | |
| **Fear of Injury** | Negative Ranks | 7 | 17.9 | 12.29 | 86.00 | 3.64 | 0.000 (0.01) |
| | Positive Ranks | 27 | 38.0 | 18.85 | 509.00 | | |
| | Ties | 5 | 9.6 | | | | |
| **Lack of Skill** | Negative Ranks | 8 | 20.5 | 15.88 | 127.00 | 2.58 | 0.010 (0.01) |
| | Positive Ranks | 24 | 34.3 | 16.71 | 401.00 | | |
| | Ties | 7 | 10.3 | | | | |
| **Lack of Resources** | Negative Ranks | 22 | 56.4 | 17.68 | 389.00 | 0.89 | 0.375 (N. S.) |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Total Score of Barriers to Being Physically Active** | Positive Ranks | 14 | 25.0 | 19.79 | 277.00 | 1.89 | 0.059 (N. S.) |
| | Ties | 3 | 5.4 | | | | |
| | Negative Ranks | 14 | 35.9 | 18.21 | 255.00 | | |
| | Positive Ranks | 25 | 39.1 | 21.00 | 525.00 | | |
| | Ties | 0 | 0.0 | | | | |

As shown in table no. 25, the values of (z) is non-significant in the factors: lack of time, lack of energy, lack of willpower, lack of resources; as well as in total score of barriers to physical activity of the test. This indicates that there is no statistically significant difference between the average pre- and post-measurements in these factors. The value of (z) is significant at the 0.05 level or less in the following factors: social influence, fear of injury, lack of skill. This indicates the existence of statistically significant differences between the average pre- and post-measurements in these factors in the study sample, and those differences were in favour of the post-test.

**Exercise Self-Efficacy**

Table 26: Wilcoxon test for paired samples test

| Group | N | % | Sum of Ranks | Mean Rank | Z-value | Sig. |
|---|---|---|---|---|---|---|
| **Negative Ranks** | 7 | 17.9 | 16.21 | 113.50 | 3.86 | 0.000 (0.01) |
| **Positive Ranks** | 32 | 45.1 | 20.83 | 666.50 | | |
| **Ties** | 0 | 0.0 | | | | |

As shown in Table No. 26, that the value of (z) is significant at the 0.01 level, which indicates the existence of statistically significant differences between the average pre- and post-measurements in exercise self-efficacy in the study sample, and those differences were in favour of the post-test.

**The International Physical Activity Questionnaire (IPAQ):**

Table 27: Wilcoxon test for paired samples test

| The Variable | Group | N | % | Sum of Ranks | Mean Rank | Z-value | Sig. |
|---|---|---|---|---|---|---|---|
| **MET- Vigorous Physical Activity** | Negative Ranks | 5 | 12.8 | 14.30 | 71.50 | 2.83 | 0.005 (0.01) |
| | Positive Ranks | 22 | 30.1 | 13.93 | 306.50 | | |
| | Ties | 12 | 20.3 | | | | |
| **MET- Moderate Physical Activity** | Negative Ranks | 8 | 20.5 | 12.81 | 102.50 | 2.85 | 0.004 (0.01) |
| | Positive Ranks | 23 | 32.9 | 17.11 | 393.50 | | |
| | Ties | 8 | 13.1 | | | | |
| **MET- Walking** | Negative Ranks | 14 | 35.9 | 14.46 | 202.50 | 0.62 | 0.537 (N. S.) |
| | Positive Ranks | 16 | 25.0 | 16.41 | 262.50 | | |
| | Ties | 9 | 16.4 | | | | |
| **MET- Total** | Negative Ranks | 7 | 17.9 | 13.57 | 95.00 | 3.31 | 0.001 (0.01) |
| | Positive Ranks | 26 | 36.6 | 17.92 | 466.00 | | |
| | Ties | 6 | 13.3 | | | | |

As shown in Table No. 27, the values of (z) are significant at the 0.0 level in variables: MET- Vigorous physical activity, MET- Moderate physical activity. As well as in the total of MET value, which indicates the existence of statistically significant differences between the average pre- and post-measurements in these variables in the study sample, and those differences were in favour of post-test. The value of (z) is non-significant in the variables: MET- Walking. This indicates that there are no statistically significant differences between the average pre- and post-measurements in this variable in the study sample.

### 5.7. The Messages Implementation Evaluation

The purpose of this evaluation was to assess the intervention delivered via the text messages using the Irvine's framework (Irvine et al., 2012). The evaluation framework provided a method of assessing participants' engagement with the sent messages which is mainly required in feasibility studies. The framework has been used in several studies (Fjeldsoe et al., 2009a, Cole-Lewis and Kershaw, 2010, Irvine et al., 2017).

- **The Fidelity of Text Messages**

A total of 697 text messages were sent to participants over a period of 6 weeks. of the 697 text messages, 668 (96 %) were recorded as being successfully sent, 29 text messages were not delivered, and the automated system did not report their reasons for being missing. However, this will be discussed in the coming chapters regarding the learned lessons, the study limitations, and implications for future studies. The functionality of the text messages delivery was checked during the intervention. The text message system provider was asked for a report of successfully sent text messages. Also, every time prior to sending the messages, three mobile phone numbers were included (the main researcher and two members of the PPIE group) to confirm whether the sent messages have been delivered to the recruited participants.

- **Engagement with the Text Messages and Attenuation**

To assess whether participants had engaged with the delivered test messages, a summary of the sent messages was reported. Of the 696 messages sent, 690 text messages were successfully delivered and opened. The remining 6 text messages could not be sent for unknown reasons. 150 WhatsApp messages were sent during weeks 1 and 4. These messages asked participants if the text messages were not received, encountered any issues, or had any questions, participants were not required to respond. Attenuation was determined through a mixed of approaches (the behavioural components of the delivered intervention) (O'Brien and McLean, 2009). The attrition rate in this study was 70% based on the number of participants who completed baseline and follow-up questionnaires. The level of engagement was established merely from attending or compliance to the promoted text messages (Lee et al., 2011). For this context, participants reported improvements in their physical activity, self-efficacy, and barriers to physical

activity. The findings of these outcome measures are discussed and interpreted in chapter (7).

- **Engagement with the Behaviour Change Strategies**

The current study cannot conclude which one of the BCW components had a more profound influence on behaviour change, some participants reported positive feedback about their thoughts and the text messages helped them improved their self-efficacy (please see chapter 6, section 6.6.3). Our study outcome measures at pre- and post-intervention demonstrated statistical improvements in barriers to physical activity, self-efficacy, and physical activity questionnaire. This could explain that participants engaged with the tasks and information shared within the text messages. Participants also enjoyed the text messages intervention and reported a positive experience (for the full qualitative results, see chapter 6).

## 5.8 Chapter Summary

This is the first study to evaluate the feasibility and acceptability of text messages to promote PA in people with T2DM in Saudi Arabia. The current study has used two different frameworks (Reelick et al., 2011), the first one to evaluate the research processes, and the second one developed by (Irvine et al., 2012) to evaluate the delivery of the text messages intervention. Our findings have shown statistically significant improvements in scores of barriers to physical activity, the exercise self-efficacy and physical activity prior to the text messages. The quantitative findings will be discussed and compared to the results of previous studies (see chapter 7). The following chapter will present the qualitative results (refer to chapter 6).

# Chapter 6: Qualitative Findings

## 6.1 Introduction

In this study, the utilisation of a qualitative process evaluation of randomised controlled trials has been an important contributor in providing a deeper understanding of the disease condition; in addition to issues and mechanisms of the intervention implementation (O'Cathain et al., 2014). It is recognised by the UK Medical Research Council (MRC) that using qualitative and quantitative data (mixed methods) can help facilitate the trial implementation and research findings (Liu et al., 2016, Evans et al., 2013). The MRC framework highlights the importance of using qualitative methods in health research to thereby offer a better understanding of the important aspects of the trial, which are as follows: the intervention being studied, the design processes and conduct of the trial, and the outcomes of the trial (O'Cathain et al., 2013); for more details, please refer to chapter (4). The current chapter will present the qualitative findings, which begins by first providing details about the aim and objectives of the study; then by outlining the characteristics of participants who took part in the interviews; and finally, presenting the main themes and sub-themes that emerged in the analysis processes.

## 6.2 Study Aim and Objectives

The aim of this study is to explore the experience and attitude of participants (patients with T2DM) and healthcare professionals (nurses), towards the use of mobile text messaging to promote PA. The chapter which ensues addresses the following research objectives:

a) What are the experiences and attitudes of people with T2DM towards the use of text messages, research processes and delivered intervention?

b) What are the experiences and attitudes of health care professionals towards the use of text messages, research processes and delivered intervention?

### 6.3 Study Design

A convenience sample of 19 participants was targeted for recruitment. Semi-structured interviews were carried out with participants in the week following the end of the 6-week intervention period (week 7). All interviews were carried out over the phone; furthermore, these interviews were conducted by the PhD researcher. All study participants were eligible to take part in the interviews; in addition to this, no exclusion criterion was cited to prevent participation in the interview process. All participants consented at the start of the study to an additional an interview at the end of the study. Our sample size was selected based on the published literature, which states that sample sizes in qualitative research for feasibility studies are usually small, with ranges between 5 and 20 individuals (O'Cathain et al., 2015). The interviews lasted between 5-10 minutes, this is considered short in comparison with literature, this could have been impacted by Saudi People's communication patterns, see chapter (8) for the study's limitation. There were 7 open-ended questions exploring the views of individuals and their experiences using text messages in physical activity promotion. The interview guide was piloted on the PPIE group, which allowed testing of the interview questions and identified areas for improvement. As a result of the pilot study, some questions were re-worded to make them easier and clearer for participants to understand.

### 6.4 Interviewee Characteristics

Qualitative interviews were conducted with 19 participants from King Fahd Medical City (KFMC) in Saudi Arabia. Eleven participants were patients with T2DM, and eight participants were nurses from the diabetes centre of the KFMC. More than half of the T2DM participants were male (7/11). Their mean age was 54.54 years (SD = 4.5 range 36-66 years). The mean age of the nurse's participants was 54.54 years (SD = 4.5 range 36-66 years). The descriptive information of the participants is presented in table 28. All names used for both the patients and the staff participants have been changed to pseudonyms.

Table 28: Characteristics of participants

| Participant ID | Gender | Age | Occupation |
|---|---|---|---|
| **Patients** | | | |
| Patient (31) | Male | 65 | Trader |
| Patient (07) | Male | 38 | Salesman |
| Patient (22) | Male | 36 | Engineer |
| Patient (29) | Male | 64 | Academic researcher |
| Patient (28) | Female | 66 | Housewife |
| Patient (13) | Male | 58 | Retired teacher |
| Patient (55) | Female | 61 | Housewife |
| Patient (42) | Male | 59 | Retired soldier |
| Patient (40) | Female | 39 | Housewife |
| Patient (60) | Male | 45 | Retired man |
| Patient (23) | Female | 69 | Social media influencer |
| **Professionals** | | | |
| Nurse (1) | Female | 34 | Ward nurse |

| | | | |
|---|---|---|---|
| Nurse (2) | Female | 29 | Nurse educator |
| Nurse (3) | Female | 30 | Charge nurse |
| Nurse (4) | Female | 36 | Head nurse |
| Nurse (5) | Female | 33 | Ward nurse |
| Nurse (6) | Female | 27 | Ward nurse |
| Nurse (7) | Female | 34 | Nurse administrator |
| Nurse (8) | Female | 31 | Ward nurse |

### 6.5 Data Analysis

All interviews with participants were recorded and transcribed in the Arabic language and were translated into English by the main researcher. The back translation process was carried out by a professional translator (who is fluent in English and Arabic), the back-translation was applied to compare the original transcripts for inconsistencies and unreliability; if none were found, the translation was considered equivalent (Son, 2018). Once the translations were done, both patient and nurse data were imported into the NVivo software system (version 12); these were then organised and analysed using thematic analysis (Braun and Clarke, 2006). Each transcript was repeatedly read by the main researcher and main supervisors, in addition to a reading by one expert in qualitative research to identify the common theme. Emergent themes and codes were then discussed among all experts involved to refine the analysis. The thematic analysis involved identifying themes, codes, and common patterns of meaning that come up repeatedly in the interviews. The approach for thematic analysis was inductive (data-driven), semantic (based on explicit content), and realist (report of reality as found in the generated data) (Azungah, 2018). For more details, see chapter (4), section (3.8.2.3).

The thematic analysis outlines a guide through the six phases of analysis, with the focus of the first phase on the researcher's absorption in the depth and breadth of the interviews. The second stage involved the production of initial codes from the data. The third step involved the identification of reoccurring data that generated the initial codes. The fourth step involved reviewing the collated extracts for each theme, in addition to the assurance of a coherent pattern between the themes. The fifth phase finalised the selected themes and prepared the final themes for the write-up of the report. The sixth and final phase involved putting together the analytic narrative and writing the final analysis report (Braun and Clarke, 2006).

Figure 12: The six phases of thematic analysis adapted from Braun and Clarke (2006)

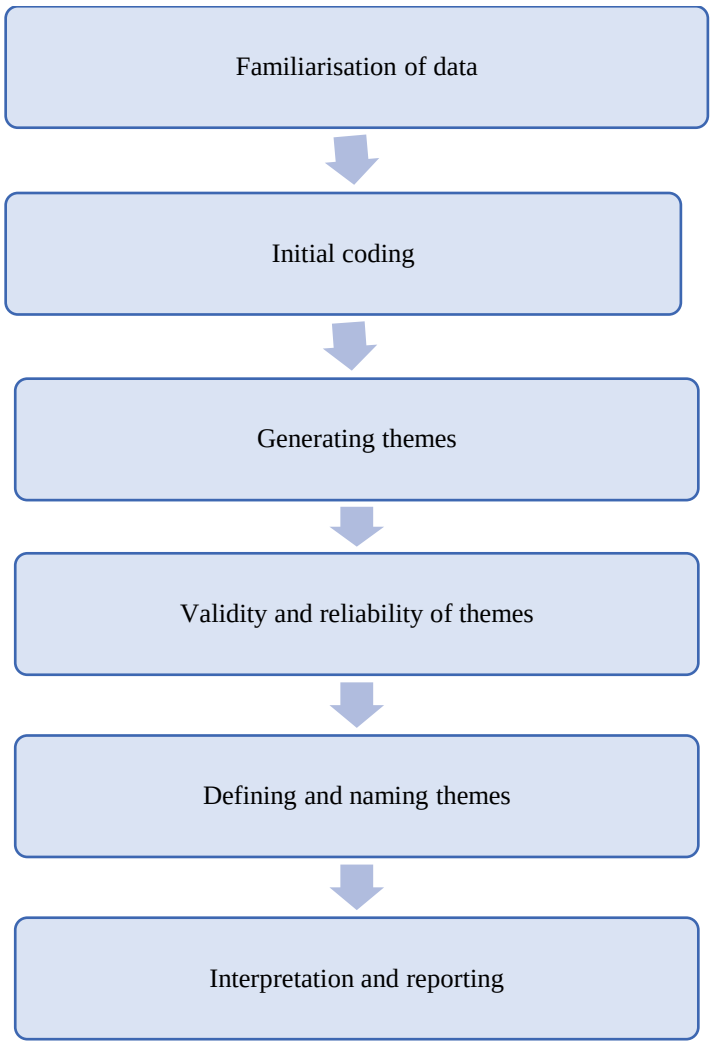


Table 29: Summary of themes, sub-themes, and codes from the interviews

| Themes | Sub-themes | Codes |
|---|---|---|
| **Reminders helping with adherence** | • Text messages played as a reminder, encouragement, and facilitator<br>• The impact of text messages on participants' thoughts and Behaviour change | - |
| **Barriers and Facilitators to Study Recruitment** | - | - |
| **The Challenge of Staying Active** | – | - |
| **Concerns About Delivery Modes** | - | - |
| **Message Contents and Perceived Usefulness** | - | - |
| **Acceptability of the Text Messaging Intervention** | Ease of Use | |
| **-** | - | - |

### 6.5.1 Theme 1: Reminders Helping with Adherence

- **Sub-theme: Text Messages Played as a Reminder, Encouragement and Facilitator**

Overall, participants reported positive experiences receiving the text message-based intervention, and some indicated that the messages were reassuring and gave them the confidence to continue participation in physical activity. Some participants reported that without the text messages, it seems they would have exercised much less but the push and pressure from the text messages helped them to adhere:

> ***It was very motivating and reminded me when I felt lazy, I felt more courage to do any kind of exercise even if it was not easy.*** **(Patient 31)**

> ***It is easy to connect with patients, to educate and remind them about their health. Patients can easily forget about their treatment management plan and SMS reminders can fill that gap.*** **(Nurse 3)**

Some participants stated that being involved in this study made them feel motivated to participate in physical activity, they also reported that they improved their fitness and health. They explained that the text messages made them aware of their commitment and the messages served as a reminder on busy days:

> ***The messages helped me especially when I was busy or not paying attention, I feel you challenged me.*** **(Patient 28)**

> ***Thank you for the motivational messages, I received them, and they encouraged me a lot to walk. I'll be honest, they are special and different***

***from other messages. I like to read anything clear, and I hate when I read something difficult to understand.*** **(Patient 29)**

Some participants valued the text messages and reported that they made them feel "special" and "cared for". They described how the messages motivated them, not only towards increased physical activity, but the messages also motivated them to involve their families in the study. For example, one participant said:

***Honestly, these messages made me feel as if there was someone supporting and encouraging me. I also liked their style, it was easy. I shared them with my older sister so she could help herself to walk more.*** **(Patient 13)**

Another participant also noted that the text messaging intervention was useful and made her feel happy and grateful to receive them. She said the messages gave her a feeling of comfort and confirmation that someone was thinking of her and caring about her illness:

***For me, any word of support is like medicine for me. We human beings need to hear such nice and encouraging words; when you sent me those messages, it means you care about me. I felt grateful because I felt that something good was added or coming into my life, it feels strange how much I get overwhelmed when I hear a nice word.*** **(Patient 23)**

The structure of the health care service in developing countries is lacking and is often poorly aligned to support patients' needs; hence, it is important to look for alternative ways to engage patients with lifestyle education. One nurse said:

***Actually, it is good idea because here most of patients do not want to take any encouragement or initiatives to modify their lifestyles, so your study is a good initiative.*** **(Nurse 1)**

At present, nurses seem to do only routine health checks, so using text messaging explored more ways in which health awareness can be generated and opportunities created to support patients in taking care of their diabetes management. For example, as Nurse (1) explained:

> ***Yes, it is a type of encouragement for us also once any type 2 patient will come or approach us. On our side also we need some initiates to give some instructions to patients, instead of only taking information or vital signs; so, we should be involved more in lifestyle education like physical activity.*** **(Nurse 1)**

Another concern was raised in elderly groups, nurses reported that many older adults are not exercising enough because of the impaired ability to self-care; or sometimes the support is omitted from the routine service provision. Text messaging can serve as encouragement and also as a reminder to increase exercise levels. One nurse said:

> ***Of course, it is a good study, because it is kind of encouragement. The type 2 patients that we see are mostly old, they don't like to make any changes in their lifestyle. They need outside encouragement like this; so, if you follow up with them, I think they can change a lot in their lifestyle.*** **(Nurse 1)**

- **Sub-theme: The Impact of Text Messages on Participants' Thoughts and Behaviour Change**

Overall, text messages were perceived as positive encouragement and helpful to some participants. It improved their awareness regarding the importance of physical activity and diabetes management:

***The messages were helpful, they changed my thinking. They were very short and had good timing when they were sent.*** **(Patient 22)**

Some participants did not notice any improvement in the short run, many factors could have intervened concerning their motivation to change set behaviours. They stated that the text messages improved their awareness of the long-term benefits of behaviour change, in addition to helping them to increase the likelihood of changing their behaviour with implementation intentions:

***Sadly, there is no change in my life; this is upsetting, but I keep trying. I enrolled at the gym and hope to continue with that.*** **(Patient 42)**

***Not a remarkable change, but inshallah this may be seen in the long run.*** **(Patient 29)**

### 6.5.2 Theme 2: Barriers and Facilitators to Study Recruitment

Most participants were comfortable with being approached during their clinic visit; although, a few participants reported barriers which included the uncertainty of their lab results and tiredness. Some participants stated that they were feeling exhausted and worried about their lab results; thereby, suggesting that it would have been better if they could have been approached at other times.

***It was good timing, but I wasn't in a good mood to talk to anyone. I was tired and worried about my lab results.*** **(Patient 31)**

***It would be better if I was approached after the clinic, as I was tired during the clinic.*** **(Patient 55)**

Most participants reported that they were happy to be included in the recruitment process, but some participants had a concern regarding the length of the surveys. They stated that it was too long for time given to complete it, this seemed to force them complete it after the visit to the clinic.

> ***It was good, but the questionnaires were long, and time was not enough because I had to leave for my doctor.*** **(Patient 22)**
>
> ***It was good, but the questions were long, and it made me get headache looking at it.*** **(Patient 23)**
>
> ***It was ok but I had to leave to see my doctor when I finished with my other doctor, so I waited to finish them.*** **(Patient 29)**

Many participants found that the waiting room experience was useful to complete the distributed questionnaires. They seemed to enjoy being occupied during the wait; this might have increased their satisfaction.

> ***The timing was ok, I waited for a long time in the waiting room. So, I made use of the time by filling in your questionnaires.*** **(Patient 60)**
>
> ***The timing was ok for me, because I don't like waiting. I get bored and prefer to get busy doing something, so it was ok, I think.*** **(Patient 40)**
>
> ***There was suitable time, I made use of it while I was waiting for my turn, and I completed the questionnaires.*** **(Patient 07)**

Some participants reported that other facilitators were the novelty of the text messages and their satisfaction of participation in research studies:

***I personally like new and rare things, the title of your study attracted me, and I wanted to participate. I also love humanities volunteering opportunities, since my college days in US, and I am very active on social media in Saudi.*** **(Patient 23)**

***I am retired now, I had worked as a head of research committees, had many roles and positions. I know the importance of research; I feel happy when I see researchers conducting rare studies. I liked your messages; they were easy to learn.*** **(Patient 29)**

Some participants identified that the support of their family and medical team was a motivator to exercise. Two participants put it simply:

***My daughter encouraged me to register in the study.*** **(Patient 28)**

***My blood sugar is not good at the moment, the doctor told me to change my lifestyle in food and exercise. I really wish to get better through my lifestyle, and I am a sporty man and eat healthy food.*** **(Patient 60)**

One participant disliked the sharing of personal information in the presence of other nurses. He preferred if he could have been privately consulted about this research; thus, to avoid any personal data leaking to people that might know him.

***It was fine, but I felt embarrassed when I talked in front of nurses about my private life. I have friends working here, I do not want them to know about my health.***
**(Patient 29)**

### 6.5.3 Theme 3: The Challenge of Staying Active

Some participants reported challenges staying physically active during the study. Challenges that influenced their participation in physical activity included: completing demands on time, caregiving responsibilities, gender issues, and a lack of social support. Some participants reported that they had an intention to change their lifestyle but competing demands were brought up as a barrier which influenced their ability to participate in physical activity.

> ***Honestly, I am still trying a lot to improve my diabetes control, but I am still struggling with that because of my lifestyle and workload.*** **(Patient 13)**

> ***I always get embarrassed by trainees like you, they ask me to be in their studies. I really don't like commitments because some of them ask me to see them again. It is difficult for me, as I have a life.*** **(Patient 42)**

Some participants suggested that the lack of time to exercise, or be more physically active, stemmed from everyday family responsibilities and social or cultural expectations on women. Participants with children at home described how other daily activities left them with little time to exercise.

> ***I love exercise, but my social life is a big barrier all the time. I take care of my kids and husband, and even his family; they all take a lot of my time.*** **(Patient 55)**

Some participants stated that their barrier of physical activity was the lack of family support and the high demand and expectations placed on women for caring responsibilities in

Saudi society. This is one of the main socio-cultural barriers which can dominate their time from planning their physical activity.

> ***Your study title is convincing, and I felt there might be hope for me to change my life and be better; but I do not know why it is so hard. It is not easy when you live with people that do not support you.*** **(Patient 40)**

> ***With all honesty, I did not follow them at all, because my life routine is very complicated. I have special circumstances that make things difficult for me.*** **(Patient 40)**

> ***Your explanation why we need exercise in relation to my sugar control; I want to do this, but it is very hard because of my life challenges.*** **(Patient 55)**

Bad weather conditions seemed to be one of the main barriers which restrain physical activity in Saudi Arabia. One participant was frustrated in their aim to create a balance between the personal and environmental barriers.

> ***Yes, to remind them to do certain activities during the week or in the day, as people easily forget especially in Saudi. We have a lot of life responsibilities, and our weather is so hot and miserable.*** **(Patient 13)**

Some participants stated that the lack of motivation and time were the main reasons that restrained them from participating in physical activity. They felt they needed something to motivate them and help them to adhere to physical activity.

> ***Honestly, I love exercise, but I always forget and feel lazy. I like your study when you told me I have no commitment.*** **(Patient 31)**

### 6.5.4 Theme 4: Concerns About Delivery Modes

Participants faced issues while receiving the intervention, some participants mentioned that they disliked the fact that the text messages came from different SMS providers each time; however, others commented that the messages were not even delivered to their phones:

> ***In recent weeks, the title of messages changed, I mean the service provider, which made me ignore some of them.*** **(Patient 29)**

> ***Not sure how many messages I received, I live outside Riyadh, and sometimes the network is weak, so not sure.*** **(Patient 55)**

> ***Not sure which one, because I received nothing from your mobile number. I receive many messages and I don't open them, especially if they are promotions.*** **(Patient 42)**

Overall, participants appreciated that the text messages came from valid sources, which would not put their privacy at risk. They liked receiving reminders to improve their lifestyle, but it is the psychological impact of feeling that something is not secure, or the lack of trust can demotivate them from participation:

> ***I worry a lot about getting the correct information and education about my diabetes. I receive many links in WhatsApp, but I don't trust their sources. I trusted your messages because you are working here.*** **(Patient 60)**

> ***I like the hospital messages, mainly those reminding me of appointments, and those for my medications through the Wasfati program. They are useful***

***if the sender's name is clear, or I have them in my phone contacts.*** **(Patient 42)**

Some participants preferred the evening time to receive the text messages, as they arrived during their break times between prayers. These prayer times varied from time-to-time:

***No, I received them between the Maghrib and Isha prayer times while I was taking my routine coffee.*** **(Patient 40)**

### 6.5.5 Theme 5: Message Contents and Perceived Usefulness

This theme emerged during the research and was related to changes in the knowledge of physical activity before and after being exposed to the promoted messages. The messages were purposely designed to encourage participants and increase their knowledge of physical activity, including its benefits and effects on blood sugar levels. So, participants were asked whether if they have learnt something new:

***Yes, I learned about the importance of exercise on my diabetes control, inshallah I will be active every day.*** **(Patient 31)**

***Somehow yes, but I like walking, it makes me feel good and healthy.*** **(Patient 07)**

Another participant expressed that he followed the different strategies proposed in the delivered text messages (e.g., Hi, do you know if physical activity can be in many forms, like taking the stairs not the lift, walking further away to mosques or shops, small effort counts).

***I started using stairs more than before, I also started walking, one time I walked more than five thousand steps.*** **(Patient 22)**

The text messages seemed to have strengthened self-efficacy among participants. Some participants stated that the messages helped them understand the importance of physical activity and improved an individual's belief in his or her capacity to perform some of the promoted tasks:

***Being exposed to this study, I have gained knowledge which makes me want to apply it to myself first, because I am overweight and have prediabetes. This study is a way of motivating me to change my lifestyle and stay healthy.*** **(Staff 6)**

***I liked your study topic as I always want to improve my fitness. It is my first time to register in a study.*** **(Patient 22)**

Many participants have emphasised the importance of including physical activity in daily clinic routine assessment to ensure people's physical health needs are assessed and that participants are provided with suggestions for healthier lifestyle behaviours. They suggested that more effective and convenient approaches are needed for diabetes management support that could lead to behavioural change and better health outcomes:

***Of course, because I was thinking only medication can improve the patient diabetic condition. But I know now physical activity is also important. Patients must do some exercise to improve their blood sugar.*** **(Nurse 2)**

***I have learnt we should add physical activity to our routine treatment not only medication or vital signs. Our doctors do not tell us about these things, I do not remember if we told patients about physical activity.*** **(Nurse 5)**

***I think it's very important for type 2 patients to have knowledge that physical activity is important for their daily living because it can increase their metabolism. Also, it can also lower down their blood sugar.*** **(Nurse 3)**

### 6.5.6 Theme 6: Acceptability of the Text Messaging Intervention

- **Sub-Theme: Ease of Use**

Many participants believed the text messages were easy to understand and useful, they reported reading the messages during the study period. Many participants also expressed their willing to continue receiving the text messages to improve their physical activity and diabetes management:

***Yes, I do. They are easy and fast.*** **(Patient 31)**

***I think it is suitable for Saudis, as people here are familiar with SMS messages, they like them as we used them for appointments reminders, and we saw it is effective and easy to open and they told us it is good.*** **(Nurse 1)**

***No, they were clear and easy.*** **(Patient 22)**

***Please if you ever do this again, try to include health workers in the messages. I think we need to learn as well; it is important for all of us.*** **(Nurse 3)**

***I liked the messages you sent to patients, they seemed easy to understand. SMS messages are used by many hospitals to contact patients and inform***

***them about their appointments and prescriptions; we are doing that here now with appointments.*** **(Nurse 8)**

For the usability of text messages, participants stated that the text messages can offer a way for patients to communicate and provide considerable advantages for people in rural areas who may often have to travel to see their health provider:

***Yes, particularly for those living in far cities not close to big cities like Riyadh.*** **(Patient 29)**

***Yes, this is a very important social service.*** **(Patient 23)**

***SMS messages are sometimes better than normal conversations with patients. They are clearer and easier, and it is good source of communication media to be used with patients and research. SMS is a good method to be used for both contacting or being contacted. As long as you have patients' numbers, it is always easy to stay in touch with them and they can read your messages anytime.*** **(Nurse 4)**

Some participants felt that text messages were not reaching all sections of the community. They emphasized that older people might not even have mobile phones or be unable to read or understand the text messages:

***It depends on their age, some people don't know how to read, or they prefer face-to-face meetings.*** **(Patient 22)**

***Yes, for sure using a mobile is important and it is a big part of everybody's lives, but maybe some people cannot read or use the phone.*** **(Patient 60)**

Some participants preferred other platforms, such as Twitter or WhatsApp, for sharing messages and thought these would be more suitable:

> ***There may be some people who can benefit from this, and they will maybe like this method. I personally prefer Twitter and WhatsApp; I just check anytime I want.*** **(Patient 40)**

> ***Yes, if you can send these messages through Twitter, from my experience in social media, it can be better.*** **(Patient 23)**

> ***Probably, you need to tackle more communication options with the patients instead of only the text messaging tool.*** **(Nurse 8)**

> ***I am a physical therapist and very interested in exercise and improving my patients' lives. I also use mobile messages through WhatsApp to follow up with my patients.*** **(Patient 13)**

### 6.7 Discussion

The qualitative approach used in this study allowed us to explore the perceptions and experiences of Saudi people with T2DM. This study shows that our physical activity intervention has been delivered successfully via the text messages, as intended, and it is feasible and acceptable among people with T2DM. The delivered messages were valued by most participants and they found the intervention useful in supporting them to engage in exercises; this finding is consistent with the literature (Moyano et al., 2019). Many participants reported some improvement in one of the behavioural determinants of physical activity. Although changes in these determinants need to be assessed in a randomised controlled trial (RCT).

However, it is possible the texts provided triggers which then influenced participants' self-efficacy and these allowed participants to experience past performance accomplishments; thereby, increasing self-efficacy. Our quantitative results reported higher levels of self-efficacy post-intervention for walking and vigorous physical activity, see chapter (5). Increases in behavioural determinants (self-efficacy) have been demonstrated in other studies to also deliver health messaging by mobile phone text messaging (Arambepola et al., 2016, Dobson et al., 2017). Many participants stated that they valued the supportive content, it made them feel that someone has cared about them, they even shared the messages with family members, believing that those messages could improve the health of their relatives and help them to become physically active. These findings highlight the role of text messages for augmenting engagement between patient and family (Carman et al., 2013, Krist et al., 2017). These positive findings could be associated with the involvement of the Patient and Public Involvement and Engagement (PPIE) group during our intervention development. All texts were consulted on the behaviour change techniques and their mechanisms, in order to increase the likelihood of behaviour change and mitigating factors that might inhibit behaviour change (Muller et al., 2019). The PPIE group also helped us to reshape the texts focusing on aspects that are important and contextually relevant to people in Saudi Arabia. Some participants reported that they had developed intentions to change, this supports the evidence found in the literature that people felt the need to change and improve their lives. These findings were found in studies targeting medication adherence, physical activity, sexual health, and smoking cessation in various populations (Head et al., 2013, Scott-Sheldon et al.,

2016, Bin Abbas et al., 2015, Hall et al., 2015). Texts messages worked as a facilitator for exchanging healthy lifestyle discussions between the people with T2DM and the health care team (nurses). Similarly, this association was found in other studies aimed at patients with diabetes (Moyano et al., 2019). Most of participants appreciated the utility and convenience of text messaging; this is consistent with the findings of a variety of topics supporting the acceptability of text messaging for promoting healthy behaviours among people with T2DM (Redfern et al., 2016, Bin Abbas et al., 2015, Eysenbach et al., 2017). Some nurses reported that some older patients did not seem to engage with health promotion activities, this has been also highlighted in several studies conducted on how 'hard to reach' older people engage in health promotion interventions outside their clinic routine (Liljas et al., 2017). These findings provide encouraging evidence related to the use of health text messaging to improve health promotion with different age groups; this is consistent with previous studies (Hughes et al., 2011, Besse et al., 2016, Lilje et al., 2017). Participants were also asked about the possible benefits of text messages. They responded that text messages are effective, that they were often used as reminders, and offered the possibility of reaching larger groups in different geographic locations. These findings are consistent with the previous studies; thus, demonstrating the acceptability of text messages in diabetes management (Redfern et al., 2016, Miele et al., 2019).Regarding the recruitment process, the majority of participants were comfortable with being approached during their clinic visit; although, a few participants reported barriers which included fears regarding the uncertainty of their lab results and tiredness.

They suggested that they should have been approached at other times because they were tired and worried about their lab results; however, none of these individuals stated a time preference. The present findings are consistent with the literature; furthermore, several strategies have been presented to enhance recruitment during clinic times and avoid having patients decline to participate for reasons related to timing and fatigue of respondents (Chlan et al., 2009, Singh et al., 2016, Ba et al., 2021). A few participants reported that the questionnaires were too long and time-consuming; although, this study used a short version of each questionnaire to reduce the fatigue response which can directly affect response rates and data quality (Koitsalu et al., 2018). One explanation could be that participants were approached at waiting rooms at the last minute; this could have given them insufficient time to complete our pre-questionnaire tools. For most participants, the timing was good and convenient, and the waiting time was a tangible aspect of practice that patients could use constructively. This is consistent with previous studies were many patients expressed a desire to spend their wait time productively (Chu et al., 2019). This identified theme demonstrates an important implication for future studies. Firstly, they suggested that the length of questions should not be too long; one systematic review found that there is a potential association between respondent burden and questionnaire length. They also indicated that response rates became lower for longer questionnaires; thus, higher responses are more likely to occur when comparatively shorter questionnaires are used (Rolstad et al., 2011).

They also suggested that the given time should be enough to complete the required tasks; furthermore, respondents might require a longer time to read the study information and answer them accordingly (Marleen et al., 2017). It is arguable that giving sufficient time is not a clear indication of easing burden, but it reflects the fact that the longer questionnaires, the more time is required to complete them (Koitsalu et al., 2018). Future studies should consider these findings and utilise the different strategies found in the literature to eliminate barriers to recruiting participants. Some participants reported their concerns about confidentiality. This is a very common issue and often arises when recruitment occurs in a public setting. When recruiters ask questions to determine eligibility, participants might not like to share their health status while in the presence of accompanying nurses or family members. This is consistent with results provided in Maria et al. (2014). Several strategies have been suggested that should be in place to facilitate this issue, such as bringing the participant to a more private area and establishing ethical practices that specifically address the issue of confidentiality within the recruiting environment (Maria et al., 2014, Yolanda R. Smith, 2007). Overall, the use of text messages was acceptable to most participants, and they were willing to continue in the intervention, even if there was no noticeable improvement. It must be noted that changing healthy behaviours might not come easily (Samdal et al., 2017). We must understand that the process of behaviour change is complex and changing someone's behaviour can be impeded and influenced by several barriers (Kelly and Barker, 2016). Some participants reported that women have more roles and burden in the society which prevented them for participation in PA, it is very interesting and worth investigating in

future studies. However, this is very sensitive matter in the society, and it was not possible to ask participants what exactly their concerns were. Our mainly focus was on the acceptability of text messaging amongst people with T2DM.

### 6.8 Summary

To our best knowledge this is the first study to explore the experience and attitude of participants (patients with T2DM) and healthcare professionals (nurses) towards the use of text messages in the context of Saudi Arabia. Our findings support prior studies in continuing to explore the use of text messages to promote healthier lifestyle intervention programmes in diabetes adult populations (Saffari et al., 2014a, Valles-Ortiz et al., 2015, Arambepola et al., 2016). A large-scale trial is required to assess the impact of text messaging promoting solely physical activity in people with T2DM.

# Chapter 7. Discussion Chapter

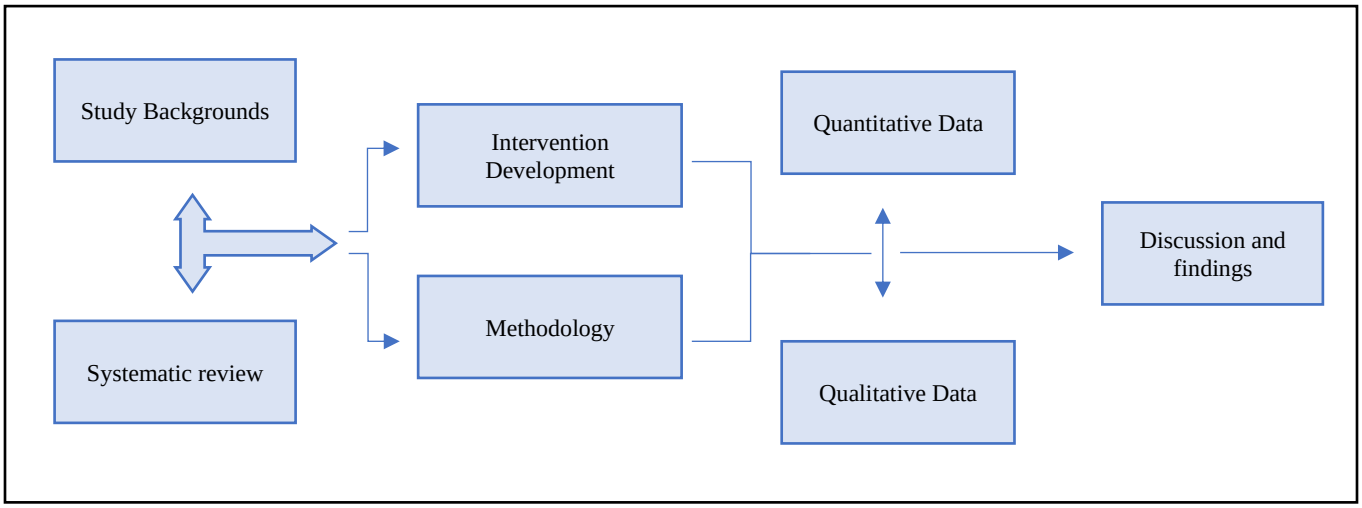
## 7.1 Introduction

The final chapter of the PhD thesis will present a discussion of the overall findings of the project with reference to previous research in the area. In addition, the strengths and weaknesses of the PhD project will be highlighted and discussed in the following chapter, with the chapter concluding with the novel aspects of the trial, and future recommendations for scaling up the research. The study provided insights into the development of mobile text messaging-based interventions for physical activity in people with T2DM using the BCW theory and its model. I will highlight the key findings from the study in relation to the research objectives. Overall, the key finding was the demonstration of the acceptability and feasibility of the mobile text messaging Intervention, study design and methods for evaluation. In addition, with regard to the former, participants and healthcare staff were both enthusiastic about the value and utility of the intervention. In the latter regard, the main objectives of the study, which related to the recruitment, assessment measures and drop-out rates of participants were also achieved, with the findings suggesting feasibility.

### 7.2 Thesis Overview

The current study was developed based on the Medical Research Council (MRC) guidelines for the development and evaluation of complex interventions (HaddadCraig et al., 2013). It followed a systematic approach during the intervention development, resulting in the development of a novel intervention to promote PA amongst people with T2DM. The results from chapter (1) presented an introduction, context and origins, rationale for the thesis, and some justification for the study. In chapter (2), we identified the gap in the current literature, by conducting a systematic review and meta-analysis of the randomised controlled trials (RCTs) aimed at evaluating the impact of mobile text messages to promote PA in people with T2DM. In chapter (3), we presented the intervention development processes based on the Behaviour Change Wheel (BCW) theory. The methodology approach was developed and described in chapter (4), followed by the results of the main study in chapters (5) and (6). The key results from each chapter are outlined in this chapter, followed by a broader discussion and final conclusions.

Figure 13: Thesis Overview



## 7.3 Summary and Discussion of the Thesis Findings

### 7.3.1 Chapter 1: The Use of Mobile Text Messaging as a Behavioural Intervention to Increase PA in Adults with T2DM in Saudi Arabia

In the literature review presented in chapter (1), T2DM was identified as a global pandemic, which is continuing to grow in low- and middle-income countries (Chatterjee et al., 2017). The latest statistics from The International Diabetes Federation (IDF) indicated that more than 415 million people worldwide have diabetes, and the highest prevalence of T2DM is anticipated to occur in the Middle East, particularly Saudi Arabia (Unnikrishnan et al., 2017, Al Dawish et al., 2016). Although PA is a key element in management of diabetes, most people with T2DM are not active and show poor adherence to PA, for details see chapter (1). This review highlights the need for high-quality interventions to promote PA in people with T2DM in Saudi Arabia. Thus far, text messaging-based interventions were found to be effective in improving a range of health conditions, in addition to being shown to stimulate behaviour change and support self-management for people with T2DM (Orr, 2015, Haider et al., 2019a, Leahy et al., 2017, Eysenbach et al., 2017). According to our knowledge, no study has explored the use of mobile text messaging to promote PA amongst people with T2DM in Saudi Arabia. For more details, see chapter 1. The table below summarises the main findings of the literature review.

Figure 14: Summary of Chapter 1

**The key findings:**

- Saudi Arabia has the second highest prevalence of diabetes in the Middle East, and it is ranked seventh in the world.
- Diabetes mellitus (DM) is the fourth leading cause of death in Saudi Arabia.
- Saudi Arabia's health system faces several challenges in T2DM management, including complications that cause majority of the morbidity, hospitalisations and financial burden.
- Physical inactivity in Saudi society is prevalent; furthermore, studies have reported high rates of physical inactivity.
- The use of mobile text messages to solely promote PA in people with T2DM in Saudi Arabia have not been yet explored; thus, this study is needed to direct future main studies.

### 7.3.2 Chapter 2: The Effectiveness of Mobile Phone Messaging-Based Interventions to Promote Physical Activity in Type 2 Diabetes Mellitus: A Systematic Review and Meta-Analysis

As outlined in the Medical Research Council (MRC) guidelines where they suggest that it is important to identify the evidence base prior to clinical studies. The systematic review helped to identify the bigger picture of the current knowledge. It was utilised in building the evidence base by exploring the effectiveness of mobile text messaging promoting solely physical activity in people with T2DM, the text messages characteristics and the outcomes

selected to assess these interventions. The current review summarised and aggregated the findings of such studies to produce more generalisable and definitive conclusions about the effectiveness of text messaging targeting only physical activity. Most studies in the literature does not focus only on physical activity, rather they focus on combined healthy behaviours such diet and physical activity together or more. This supports the rationale of this study, to solely focus on physical activity not combined by other healthy behaviours. So that we be more accurate where did the impact come from. For more details about these studies and why our review adds good knowledge to the current literature. Please refer to chapter (2) section 2.2.

Figure 15: Summary of Chapter 2

**The key findings:**

- There are very limited studies, our review identified only 6 RCTs examining the effectiveness of text messaging to specifically promote PA in people with T2DM.
- To our current knowledge, this is the first systematic review examining the impact of text messages on PA in people with T2DM.
- Text message-based health interventions have the potential to increase and improve PA in people with T2DM.
- Our meta-analysis found a statistically significant effect but could not clinically find any identified health outcomes.
- There was a heterogeneity in the included studies in their study design, methods, and the clinical outcomes.

**Implications of the findings:**

- Our systematic review found few studies assessing the effectiveness of text messaging in promoting solely physical activity in T2DM, so RTCs with larger sample size is needed.
- Future studies should seek to include objective outcome measures (e.g., physical activity, glycaemia control and anthropometric measures).
- Future studies should be consistent with selecting the outcome measures to evaluate the effectiveness of such interventions and be able to and make firm conclusions.
- There is a need for more research to determine frequency of messaging and duration of such interventions.
- There is a need for more research to assess the cost-effectiveness of a text messaging intervention in promoting physical activity among people with T2DM.

### 7.3.3 Chapter 3: The Process of Developing a Theory Driven Text Messaging Intervention for Physical Activity (PA) in People with Type 2 Diabetes Mellitus (T2DM)

The use of theory in research has been advocated by the MRC framework for the development and evaluation of complex interventions (Evans et al., 2013). Substantive evidence suggests that for behaviour change interventions to work effectively, they must be underpinned by a behavioural theory (Guerin et al., 2018). The current thesis adopted the Behaviour Change Wheel (BCW) as a practical guide to design and develop the intervention content. The messages were designed to be prompts and reminders to improve PA among people with T2DM. The final set of messages for this study was validated by a multidisciplinary team, led by the principal researcher (PR) and the research supervisors (RS). Patient and Public Involvement and Engagement (PPIE) were also consulted on each text message created, they were asked to evaluate if the messages content tone was understandable, clear, and as intended for this study. For more details, see chapter (3).

Figure 16: Summary of Chapter 3

**The key findings:**

- The text messages were developed based on the BCW theory and COM-B model process analysis.
- The BCW framework encompass multiple theories and models which were allowed to draw on a wide range of constructs to address what mechanisms were needed for the targeted behaviour to occur.
- The researcher selected the intervention functions from the BCW's model that will most likely initiate the behaviour change.
- The researcher selected the frequently used behaviour change techniques taxonomy (BCTs) within the model.
- A panel of experts in health research and Patient and Public Involvement and Engagement (PPIE) were consulted in all stages of the research process.

### 7.3.4 Chapter 4: The Methodology approaches for Developing and Implementing the Text Messages Intervention

The methodology developed in chapter 4 was used for the intervention delivery, data collection processes and analysis. Both quantitative and qualitative data were collected concurrently and analysed and compared in various stages. The mixed-methods research (MMR) design was chosen as an appropriate method in this study to address the aim and objectives of this thesis. The feasibility objectives were achieved using quantitative data collected at pre- and post-intervention surveys. The acceptability objectives were achieved using the qualitative interviews collected at the end of the intervention. The current study has

combined the strengths of both approaches to reach a comprehensive understanding of the delivered intervention (Shorten and Smith, 2017, Evans et al., 2013).

Figure 17: Summary of Chapter 4

**The key findings:**

- The study used a single group design to achieve the aim and objectives of this study (Ip et al., 2013).
- The study protocol was prepared according to the National Institute of Health Research (NIHR) for feasibility design studies (NIHR, 2018).
- The researcher followed the NIHR guideline for the sample size.
- Quantitative data was analysed using the statistical package for social science SPSS (version SPSS 27).
- Qualitative data was transcribed verbatim by the main researcher and a back-translation was conducted by a professional agent.
- The study protocol was approved prior to the intervention by a research ethics committee at both settings.

Ninety-eight participants invited to participate in a single group (pre-post individual intervention), of that, only 57 participants who consented to take part in the study. Only 40 (70%) participants were available for follow-up at 3 months, for details see section (5.3). The process evaluation and effects of the are discussed in detail throughout the subsequent sections which follow. Descriptive and inferential analysis was conducted to draw conclusions from the feasibility sample size and to determine the likelihood of changes in the related outcomes (see chapter 5).

### 7.3.6 Chapter 6: Qualitative Results

The use of qualitative approach in this study allowed us an in-depth understanding of the surrounding patterns and the perceived experience. The study collected qualitative data through semi-structured interviews with 11 patients and 8 health care staff (nurses). The interviews were audio recorded and were transcribed verbatim. All identifiable information was removed from the transcripts and each participant was provided with a unique study code to anonymise their data. Please refer to section (4.5) for details on ethics and data management and analysis. A thematic analysis framework was applied to interpret the findings of the interviews (Braun and Clarke, 2006). The analysis framework revealed that there are four themes: the effect of the delivered text messages, barriers and facilitators, the impact of messages on knowledge about physical activity and acceptability of text messaging. For more details, see chapter (6).

## 7.4 The Process Evaluation:

### *7.4.1 Quantitative Results*

The main aim of this study was to explore the feasibility and acceptability of a theory-based text messaging intervention to promote PA for T2DM in Saudi Arabia context. This feasibility study, which is the first of its kind in the Saudi Arabian context, has demonstrated that text messaging is feasible and is an acceptable way of promoting PA for T2DM. The overall aim of this study was designed to measure important elements for a future main study, it included the recruitment and response rate, retention rate, sensitivity in related outcome

measures and participant's experience and intervention delivery. The next subsections will discuss the key elements and compare them with findings of prior studies.

- **Sample Size in the Feasibility Trial**

One of the most important objectives of a feasibility study is to estimate the sample size and the likelihood of recruiting participants for the future main trial. The current study followed the strongest guidelines on feasibility interventions. The sample size was determined based on the NIHR guideline for feasibility studies and similar conducted health interventions (HaddadVasileiou et al., 2018, Arain et al., 2010, Haddad, 2014). As demonstrated in chapter (5), the recruited number was sufficient to measure the key elements of this study and also consistent with similar studies where 30 to 50 participants per group have been deemed adequate and acceptable (Hertzog, 2008, Julious and Patterson, 2004, Whitehead et al., 2015, Billingham et al., 2013, Sim and Lewis, 2012).

- **Recruitment and Response Rate**

Ninety-seven patients with T2DM were approached during their routine clinic visit, only 57 (58%) (26 women and 31 men) were included in the study. The current study successfully achieved the enrolment of subjects in a timely and efficient manner, with the study completing 2 weeks recruiting. This was the same as the 2-week protocol specified target, with a recruitment rate reached 5 participants per day which exceeds similar health studies (Owolabi

et al., 2019, Watterson et al., 2018). Recruitment rates in previously published studies in same populations varied from 40-60% (Lari et al., 2018b, Stephen Agboola et al., 2016). The timely identification and recruitment of a pre-specified number of participants in research is vital to the success or failure of clinical trials. A systematic review of RCTs found that most clinical studies do not meet recruiting targets on time, which sometimes can delay or interpret the research processes (Rosenthal et al., 2015). Our potential participants may have been attracted by the prospect of face-to-face recruitment strategy during the clinic; participants were informed of the study either by their medical doctor or nurses at their endocrinology and outpatient clinics. Participants were then forwarded to the main researcher in the education room, where he explained the study details as outlined in the study protocol. The researcher explained the perceived benefits of physical activity on their diabetes management and then ensured that questions regarding their role and participation in the study were well addressed. The traditional recruitment approach of posting flyers did not yield any number of interested participants. It is obvious that the health care providers accelerated the process of recruitment, by referring potential participants and motivating them to be included in the study. The enrolment strategy for identifying eligible participants seemed appropriate; thus, future studies should consider these strategies and enhance good communication between researchers and healthcare team members (Bower et al., 2014).

Recruited participants were asked to complete the pre-assessment questionnaires; of 57 completed forms were (100% response rate) were returned with the pre-questionnaires back to the research team. This is a very high response rate when compared with previous studies (Haider et al., 2019a). The high response rate in this study may have been due to the method of invitation (face-to-face contact); where participants responded promptly and completed baseline assessments. Effective recruitment is a fundamental component of the study success, after identifying the target population, methods to contact them must be appropriate and yields the greatest enrolment rate. In our study, direct referral proved to be a successful recruitment strategy in this as well as other clinical trials (Goldman et al., 2019). Research is needed to determine if other recruitment strategies would generate better results. Future researchers should learn from these strategies by understanding the surrounding patterns and motivators. The interviews have demonstrated why participants responded to the study recruitment and follow up. Participants reported the waiting time during the clinic visit was helpful and motivated them. Also giving them different options to fill up the surveys were helpful and encouraged participation in the study, see chapter (6). We can not conclude which one is more helpful, however, mixing these strategies would enhance their participations and confirm our findings.

- **Retention and Attrition Rate**

Of the 57 participants who consented to take part in the study, n=40 (70%) participants were retained for follow-up at 3 months. The attrition rate in the intervention was n=17 (29%) which demonstrates good finding compared to what is found in similar studies (Eysenbach et al., 2017, Hamideh Lari et al., 2018). Most of the retention strategies were applied during the follow-up, reminder messages were sent with shopping coupon incentives on timely completion of the post-questionnaires. The reminders were sent via the WhatsApp application, participants were given options using an online or traditional paper surveys to complete their post-assessment tools. It is possible that those methods boosted the retention rate in our study. Several systematic reviews supported the above-mentioned strategies, incentives are a great way to increase response rates and thank participants for their time, it motivates them and promote a sense of value and belonging (Brueton et al., 2013, Bower et al., 2014, Adel et al., 2020). Research indicates that electronic survey methods improve response rates, improves data quality and overall cost savings (Cook et al., 2016). Future studies should consider incorporating strategies to better target participant retention and alleviate unintended burden for participants (Brueton et al., 2014). The main aim of this feasibility was to use most scientific evidence for feasibility studies to guide the main study in the future, there is no doubt that every study has its own challenges, but this feasibility

study should answer many questions needed for the future study. The current study has used different approaches to gain participants' engagement throughout the intervention, future studies should use these approaches and build upon stronger evidence.

- **Delivery and Engagement of the Intervention**

The delivery of the intervention was assessed by monitoring the text messages delivered to the mobile phones of participants. The intervention package included 12 SMS text messages, two messages per week were sent off over a period of six-weeks. Thus, a total of 697 messages were sent to the 57 participants during the intervention period. Of these, 668 messages (96%) were delivered to participants' telephones. The remaining 29 messages were recorded as undelivered, this might be because of the phone was switched off or it had no signal for 24 hours. The system did not report their missing reasons. However, this will be discussed in the coming sections regarding the learned lessons, study limitations and future recommendations, see section (8.4). Also, engagement with the intervention was not assessed because of the SMS provider limits and restrictions in Saudi Arabia, see section (8.4). We were not able to record the frequency of responses from participants during the intervention phase; the SMS provider in Saudi Arabia was very limited and regulated by high authorities within the new rules and government. Due to the above-mentioned limitations, the text messages were sent only one-way. A systematic review revealed that one-way messages can be effective in enhancing behaviour change if they are sent infrequently (Sahin et al., 2019b). Despite the expanding use of text messaging, there is still a lack of knowledge on the optimal way to create and deliver the text messages which can ultimately stimulate

the desired behaviour change (Sahin et al., 2019a). This limitation was overcome by using the WhatsApp application, participants were asked if they had any questions, at the beginning, in the middle and at the end of the study. The messages were sent to confirm if anyone had not received the SMS messages, or if anything was gone wrong or unclear, none of them reported any concerns during the intervention period. Evidence has shown that WhatsApp messages are increasingly used in hospital environment by healthcare providers and they are effective in engaging with patients (Segal et al., 2016, Alkhaldi et al., 2015). Future studies should consider exploring the potential effect of two-way text messaging and the available strategies used in the literature to engage participants.

- **Adherence to the Intervention**

Adherence to the intervention was measured for participants who completed the study-follow up and sensitive change across the selected outcome measures, see chapter (5). Although, adherence was not included in our feasibility objectives, but were assessed through the completed pre- and post-self-reported outcome measures. A total of 57 participants took part in the study and 40 participants were retained for follow-up at 3 months. Their reported data indicated a significant statistical improvement across outcomes such as physical activity levels, self-efficacy, and barriers to PA, this will be discussed in section (7.5). The definition of adherence becomes very challenging when applied to physical activity, as there is less reliance on self-report data. There is a clearly gap in the literature about the definition of adherence, a systematic review showed that majority of studies focused on health outcomes: completion (i.e., retention), attendance, duration and intensity adherence (Hawley-Hague et al., 2016).

Other studies defined adherence as completion or conversely lack of adherence as drop-out (Hawley-Hague et al., 2013). Another recent systematic review described adherence as actual full completion of the intervention (Beintner et al., 2019). So, from findings reported in chapter (6), text messages have seemed to have influenced participants to adhere the promoted content and achieved a significant statistical improvement across our outcome measures. The use of BCW theory could have motivated participants to adhere to physical activity, for example some text messages were designed to improve self-efficacy or encourage them to complete their given tasks. Some participants reported that the messages acted as a reminder every time they forgot to perform their physical activity. The current study confirms what is found in the literature that text messages can be helpful to adhere to physical activity participation. However, the current findings encourage future studies use rigorous methods for assessing adherence and follow the most relevant and appropriate methods to provide consistency in the literature. If possible, adherence should be addressed from two perspectives: progress through the intervention (e.g., if participants have read the text messages) and the level of active engagement with the intervention content (e.g., if participants engaged to any required task during the intervention). Unfortunately, the limitation of the selected SMS provider in the current study did not enable the two-way direction messages, therefore, we could not have sent direct adherence measurements to assess if participants were adherent to the intervention. It is, however, a challenge to measure adherence, which should therefore be a priority for future research to investigate. For the limitation of this study see section (8.4).

### 7.4.2 The feasibility of Outcome Measures

The aim of this feasibility study was not powered to detect clinically significant changes in physical activity or the selected outcome measures but to respectively generate interval estimates of the change and determine whether the testing elements could be used in a larger evaluation are feasible. The assessment of outcome measures was conducted at baseline and at three months follow-up. Demographic data and self-reported measures were obtained using validated questionnaires (Cleland et al., 2018, Sawchuk et al., 2011, Darawad et al., 2018). The clinical data were obtained from the available clinical records at recruiting time, however clinical data were not available at the follow up visit, for limitation of this study, see chapter (8).

- **Self-Reported Change in Physical Activity**

All participants were asked to complete the Arabic version of IPAQ tool at baseline and follow-up visiting. 40 participants in the intervention completed their baseline and follow-up questionnaires. The IPAQ scores are measured in metabolic equivalent of task units (METs), so the higher the MET score, the higher is the intensity of exercise, see section (5.6.1). Our descriptive analysis using means and standard deviations showed that the intervention group increased their total physical activity between the average pre- and post-measurements, the (t) value was a statistically significant at the 0.05 level or less in variables: (MET- Vigorous physical activity, MET- Moderate physical activity), as well as in the total of MET value, see section (5.6.1) for details. Our findings are consistent with prior studies identified by the systematic review and meta-analysis in Chapter (2). All included studies assessed the effect of using text messages on physical activity among T2DM patients. Three studies showed a

statistically significant effect of text messages on physical activity (Arovah et al., 2018, Lari et al., 2018c, Ramirez and Wu, 2017). This study provides preliminary evidence that a text message-based intervention can be a promising approach for improving physical activity among people with T2DM. Although the current study used subjective measurements which could have resulted in biased findings, the. Literature suggest that objective measurements could have resulted in more accurate findings (Silfee et al., 2018). Also, the small sample size prevents us for making any conclusions about the efficacy of text messages solely on physical activity, but results has provided encouraging evidence for future text messages-effectiveness design.

- **Self-Reported Change in Self-Efficacy**

All participants completed the exercise self-efficacy questionnaire which assessed the positive and negative feelings towards physical activity (Darawad et al., 2018). The self-efficacy scores have shown that the t-value was statistically significant at the 0.05 level, which is suggesting there was sensitivity change in self-efficacy after receiving the text messages as reported in Chapter (5). Despite the positive findings, we could not draw definite conclusions about which text messages had greatest effect on self-efficacy scores. Also, the current study was not powered to detect an actual difference or which BCTs components have more impacted self-efficacy but rather to determine the sensitive change favouring the text messages. From the qualitative findings described in chapter (6), we could indicate that participants felt motivated to increase their physical activity levels because of the alternative strategies provided in the text messages, we assume it might have improved self**-**efficacy**.**

Another possible explanation that our text messages were designed and mapped onto the BCW and COM-B model, for example, a set of messages focused on the capability component, to encourage participants that they can perform physical activity at home like cleaning or walking around the house, to not underestimate small tasks performed at home, to not give up if failed and instantly start again. The COM-B model is an appropriate starting point for health Behaviour change interventions, as it provides insight into the determinants of the potential Behaviour and what changes required to encourage changes in the new Behaviour. We have mainly used this model to understand the needs that need to be altered therefore encourage Behaviour change. Finally, we were not able to conclude what components of the BCW framework have impacted or influenced the change scores in self- efficacy, this is a potential gap should be carefully evaluated in future studies, see chapter (8) for recommendations.

- **Self-Reported Barriers to Physical Activity**

There was a statistically significant difference between the average pre- and post-measurements in the following variables (social influence, fear of injury, lack of skill) but not statistically significant in the variables (lack of time, lack of energy, lack of willpower, lack of resources); see chapter 5 for details. This study showed that our text messages intervention has improved some barriers to physical activity among T2DM patients, subsequently increasing their level of physical activity. Several studies have indicated that changing health beliefs about barriers to physical activity could significantly increase physical activity participation among people with T2DM (Rouholamini et al., 2020, McGuire et al., 2014).

The systematic review in chapter (2) reported that there are only two previous studies which suggest that text message-based education can reduce or overcome people's perception of barriers to physical activity in people with T2DM. The significant change in our study could have been from different reasons, some of the text messages focused on the psychological capability such as knowledge, like what types of physical activity they could engage in and the possible health related benefits to diabetes management. The qualitative findings in chapter (6) reported that unhealthy routine, changeable weather, workload, and family responsibilities have an impact on their lives when it comes to performing physical activity. Our findings are consistent with prior studies, suggesting that lack of time, coexisting diseases and adverse weather conditions are the main factors to physical activity (Alghafri et al., 2017).These barriers need consideration and should be addressed for any future intervention to be effective, see chapter (8) for future recommendations.

### 7.4.3 Clinical Data

With consent from participants, the researcher was given limited access to the patient's clinic notes for HbA1c and BMI collected most closely with the data collection period. The clinical data (HbA1c, BMI) were successfully collected at the baseline; however, the date clinical outcomes were not available at follow up points due to the scheduling of clinic appointments. In Saudi Arabia, the HbA1c is taken during routine clinic appointments every six to twelve months and the results are retained on clinic notes. This should be carefully thought about in the main study because some hospitals might ask the researcher to sponsor their lab tests and their appointments.

- **HbA1c and BMI**

We could not compare results because of the unavailability data post to the intervention; we acknowledge this as a limitation and future studies should pay attention to routine clinic appointments and make sure that HbA1c and BMI is retrieved post the intervention. Although, we would not expect any change in HbA1c and BMI as the intervention was delivered over short period (Six weeks). Our meta-analysis in chapter 2 showed no statistically significant difference (P=.14) between intervention and control groups, with no difference observed between text messages plus pedometers and only pedometers on HbA1C; MD -0.16 (95% CI -0.36 to 0.05). Also, two studies assessed BMI; the first study showed no statistically significant difference between intervention and control groups, with no effect of text messages plus pedometers on BMI (P=.77). The second study found no statistically significant difference in BMI between the three groups.

## 7.5 Experiences of Participants in the Study

### 7.5.1 Qualitative Results

The qualitative approach used in this study allowed us to explore the perceptions of people with T2DM that received the promoted text messages content. Our findings showed that a theory-based text messaging intervention contributed positively on physical activity promotion and was accepted by people with T2DM in Saudi Arabia, for details of participant's experience see chapter (6). The qualitative analysis revealed the following primary themes regarding participants' attitudes and experiences surrounding the text messages: 1) reminders helping with adherence; 2) barriers and facilitators to study recruitment; 3) the challenge of staying active; 4) concerns about delivery modes; 5) message contents and

perceived usefulness;6) acceptability of the text messaging intervention. The themes and subthemes are identified and described in detail in chapter (6) section (6.6.1). All participants indicated positive experiences with the use of text messages when asked about it. They felt comfortable with the text messages as a communication tool and were encouraged to initiate the promoted behaviour. These themes are consistent with findings from prior studies, which show that implementing text messages can increase the likelihood of behaviour change in diabetes related lifestyle behaviours (Owolabi et al., 2019, Moyano et al., 2019, Morton et al., 2015, Leon et al., 2015). Despite participants indicated positive experience of the text messages, a few expressed helpful concerns related to privacy: some participants showed their concerns about their health information, and they were concerned about friends knowing their health condition, this is very important issue especially in Saudi culture, people fear what others might say about them and this could apparently impact their lives. The Saudi culture is similar to every other culture but still unique in many ways (Alshammari et al., 2019). The perception that the Saudi culture is inherently problematic and has been a barrier to PA. This finding was more common amongst the female participants than the male participants. Female participants reported that the expectations placed on female is too frustrating which can be an impeding factor to adopting self-management behaviours. See chapter (6) for more details. The current study requires simple alteration to optimise its efficiency and potential efficacy. Future recommendations for the implementation of the text messages are presented in chapter (8)

## 7.6 Conclusion

The current thesis is the first to implement the BCW to the design of mobile text messages within the context of physical activity in people with T2DM in Saudi Arabia. The literature suggests that many interventions are developed without sufficient knowledge to factors that might minimise the likelihood that they will be effective and engaging. The current study carried out a systematic process drawing on the BCW components which has led to motivators drove the behaviour change in the study. In summary, the quantitative and qualitative findings of this feasibility study suggest the feasibility and usefulness of using text messages for patients with T2DM to improve their physical activity levels. This feasibility study used a novel approach and informed the development of a protocol for a large RCT. In future studies, if text messaging is proven effective, this would have a potential impact to reach widely population at a low cost.

# Chapter 8: Conclusion and Recommendations

## 8.1 Overview

This chapter provides a summary of the findings of this thesis and offers recommendations for the future definitive trial in line with these findings. In this chapter, we conclude by briefly foregrounding the strengths and limitations of this study and the study's implications for future research and clinical practice.

## 8.2 Summary of Findings

This study was designed to examine the feasibility and acceptability of text messages to promote physical activity (PA) in people with type 2 diabetes (T2DM). The intervention was successfully implemented, completion and retention rates were adequate and there were no major issues affecting the study delivery. The strength of the current study therefore lay in the amount of the collected data on feasibility which will contribute to the design of a larger randomised controlled trial (RCT). This included data on the intervention development, recruitment processing, health outcomes, the intervention delivery, data collection processes and participants' experience (refer to chapters 5 and 6 for more details). This study was also strengthened by the systematic review and a theoretical underpinning (please refer to chapters 2 and 3). The findings from this this study have been refined to guide future researchers aimed at examining the effectiveness of text messages intervention in the Saudi Arabian context. Having presented the key findings of this thesis, the following sections will attempt to relate these findings with the strength and theoretical shortcomings and suggest implications for future studies.

## 8.3 Strengths and limitations of the study

### 8.3.1 Strengths of the study

The burden of T2DM in Saudi Arabia is likely to progress to disastrous levels, unless a comprehensive diabetes management program is implemented rigorously promoting active lifestyles such physical activity (Alshayban and Joseph, 2020). As outlined in previous chapters, the present study has explored a novel delivery management strategy, namely text messages, for promoting solely physical activity in people with T2DM. At this point in time, there are no robust scientific interventions using mobile phone text messages to manage lifestyle behaviours in Saudi Arabia. Our study followed the most reliable evidence that fitted our design protocol to minimise bias and maximize reliable findings that can be used to inform future main studies. For more details, see chapter (4).

- **Evidence-based design**

This study has followed The UK Medical Research Council (MRC) framework for complex health interventions to guide the choice of the appropriate research methods; in addition to the planning, conducting and reporting the study findings (Moore et al., 2015). As identified in previous chapters, this is the first study to explore the use of text messages to promote solely physical activity in the Saudi Arabian context. Thus, the MRC framework recommends a feasibility study to be done before the main study to test important parameters before designing the main study (Moore et al., 2015).The strengths of conducting feasibility studies include an assessment of primary outcomes that are needed to design future RCT trials. Examples of such parameters included:

- Willingness of participants with T2DM to be randomised.
- Willingness of healthcare providers to recruit participants.
- Number of eligible participants.
- Follow-up rates, response rates to questionnaires, adherence/compliance rates.
- Time needed for data collection and analysis.
- Sensitivity in T2DM related health outcomes.

The importance of feasibility testing is outlined in the MRC framework which describes various stages of the intervention development (see chapter 4). The framework also recommends using both quantitative and qualitative evidence within a feasibility study, described as a mixed methods design. The integration of quantitative and qualitative data has strengthened the rigour and enrichment of our study findings. Evidence suggests that a mixed methods design can strengthen the depth and breadth of research findings, help potential studies with understanding of whether there has been theory failure and/or implementation failure before the future full size trial design (Noyes et al., 2019). This approach was deemed most appropriate design to fulfil the aim and objectives of this study. A further strength of the study that we followed the National Institute for Health and Care Excellence (NICE) guidelines to justify our sample size (see chapter 4). Another strength that our text messages were theory driven and culturally tailored to provide educational and motivational information on physical activity. Involving theory in our study has ensured the intentions and drivers in the development of the intervention are replicable and clear.

This has been shown to be important in text message-based health behaviour change interventions (Webb et al., 2010, Fernandez et al., 2019). In addition to that, a panel of Patient and Public Involvement and Engagement (PPIE) representatives reviewed the developed text messages, the study assessment tools and changes were made in line with their suggestions prior to the feasibility trial. The involvement of the PPI group in this study helped to improve the intervention development and made sure that the text messages are relevant to people with T2DM. Evidence also suggests that PPI can Improve patient experience and influence the trial recruitment and retention (Dudley et al., 2015, Muller et al., 2019). Finally, ethical approval was obtained from the research committee at the university of Nottingham, as well as King Fahd Medical City (KFMC) in Saudi Arabia.

**8.4 Limitations of the study**

This study has several limitations. First, this study included a small sample size, only forty people (n=40) were included in the final analysis, this may thus limit the generalisability of the findings. Small samples can affect the internal and external validity of a study. Small sample sizes can also result in statistically significant differences that have no practical value or may have misguided clinicians and eventual failure in treatment decisions (Faber and Fonseca, 2014, Tipton et al., 2017). In addition, this study used a single group, pre-post-test, non-controlled and non-randomised design because of the time constraint. As a result of the lack of randomisation, we cannot conclusively determine if the intervention caused any observed differences in outcome between groups. For these reasons, RCTs have been considered the 'gold standard' for clinical interventions.

Their strengths of being able to establish a causal inference as to the effects of a treatment in an unbiased manner (Deaton and Cartwright, 2018). Owing to time restrictions, we could not collect clinical follow-up data. We were, therefore, unable to determine the effect of text messages on HbA1c and BMI in people with T2DM, although this was beyond the scope of our feasibility study. A further limitation is that the majority of outcomes rely on self-reported data from patients, as previously discussed, collecting information through a self-report has disadvantages; participants could have been biased when they reported on their own experiences, especially in Saudi culture, they most likely reported experiences that are socially acceptable or preferred (Demetriou, 2015). Another possible methodological limitation was that our qualitative interviews were carried out in the Arabic language and the analysis was held in the English language; this could adversely affect the reliability of the translation processes and negatively impact the integrity of results (Al-Amer et al., 2016). Due to technological limitations, we were unable to report the reasons why some of the sent text messages were unsuccessfully delivered. In these instances, we made our assumptions that it is possible that participants' phones were switched off or the network operator was experiencing technical issues. The selected service provider (Mobily company) also did not provide any assessment tools to record our participants' engagement during the intervention. In Saudi Arabia, there are still some restrictions over the public telecommunications networks, foreign companies are not allowed to communicate through Saudi networks unless it is a registered company.

These restrictions have limited us from choosing SMS advanced operators in the market. Despite the limitations, the study findings remain promising, and this study is the first lifestyle intervention study thus far on T2DM within the Middle East region. The study adds to the current literature, further studies are warned to sustain desired long-term changes within the region. In this thesis, our data collection took place in Riyadh, the capital city of Saudi Arabia. Therefore, caution is needed when generalising our findings to other clinical settings where the contextual factors are different, both within and outside Saudi Arabia. However, the findings of this thesis still can be compared with findings from future studies in other settings to assess transferability of the results. Since this thesis is at the stage of feasibility/piloting of the Medical Research Council guidance of complex interventions (Evans et al., 2013), no firm conclusions and recommendations for practice and policy can be made as standards state that evidence for each mHealth-based intervention has to consist of at least one effectiveness study.

### 8.5 Implications for Improving Future Research

This study has presented evidence demonstrating the promise of health text messaging interventions to improve health behaviours and outcomes, particularly related to physical activity and T2DM management. The findings from the current study suggest that the six-week text message-based intervention had promising effects on the participants' self-efficacy for walking and vigorous physical activity and other health related outcomes (see chapter 5). Also, participants' feedback stated that the text messages were perceived as useful and beneficial, helped them to self-care management regarding physical activity

adherence, this is suggesting the feasibility and usefulness of the intervention (see chapter 7). While this feasibility study provides an excellent foundation for future studies within the region, there is much remains to be done, and the effort will need to be focused, coherent and sustained. To build a strong evidence base for the effectiveness and acceptance of text messaging intervention requires additional research, with particular attention to enhancing the quality of the evidence. Future studies should focus on three areas for enhancement: (1) general study design, (2) study planning, and (3) study analytics. In addition, three strategies for ongoing monitoring of the text messaging implementation and effectiveness are suggested.

### 8.5.1 General Study Design

- **Strengthen Methodological Rigour**

Future studies should include RCTs or quasi-experimental designs with comparison groups, this will produce the strongest evidence (Leatherdale, 2019, Hariton and Locascio, 2018). The RCT is the most scientifically rigorous method of hypothesis testing available and is regarded as the gold standard trial for evaluating the effectiveness of interventions (Deaton and Cartwright, 2018).

- **Increase Sample Sizes**

For the purposes of the present study, our sample size was too small. Therefore, it is recommended that future researchers include enough participants to adequately address the research questions. A larger sample size will give greater power of detecting the effect size in the outcome variable. Evidence suggests that a traditional RCT would require a minimum

sample size of 64 per group, so the larger sample is the most likely would give a result that is sufficiently powered to detect significant effects (Gupta et al., 2016).

- **Lengthen Duration of Follow-up**

Future studies should investigate the long-term intervention effects on psychological and clinical outcomes, according to the literature, most studies included short-term outcomes (such as behaviour change during the intervention) and did not address longer-term outcomes (over 6 to 12 months post-intervention)(Llewellyn-Bennett et al., 2016). According to the literature and the findings of this study, the following recommendations for future research are offered:

- Intervention trials should include evaluation of maintenance of behavioural and clinical outcomes following the end of intervention (optimally 12 months or longer).

- Intervention trials should include evaluation strategies that target maintenance of behaviour change and explore differences in determinants of behaviour change initiation and maintenance.

- Intervention trials should consider the use of follow-up prompts to maintain long-term contact with participants while reducing burden and increasing cost-effectiveness.

- Intervention trials should consider methods for handling missing data, with attention to the potential impact of imputing missing data on maintenance outcomes.

### 8.5.2 Study Planning

- **Incorporate Theory of Change into Study Designs**

The MRC guidance highlights the benefit of theory-driven approaches for planning, evaluating, and designing interventions (Evans et al., 2013). Incorporating theory into the intervention design development can help researchers understand whether, how and why an intervention has a particular effect, and which parts of a complex intervention have the greatest impact on outcomes (refer to chapter 3). The current study has successfully applied the Behaviour Change Wheel (BCW) and its COM-B model, which helped us to understand the drivers of the behaviour physical activity, based on that we developed a content that most likely would influence an individual's motivation for executing their new behaviour and therefore encourage behaviour change; for more details, see chapter (3).

- **Use Standardised Outcome Measures**

The use of common outcome measures across health research studies would facilitate comparisons of findings related to the intervention effectiveness. Future studies are encouraged to standardise outcome measures of health behaviours and clinical outcomes and use high quality methods for measuring those outcomes. This would strengthen the available evidence and support future systematic reviews and meta-analyses (Silfee et al., 2018). Further studies are warranted to examine objective and subjective measures and not to rely on either one as a sole dependent variable (Urda et al., 2017); for more details, see chapter (1).

### 8.5.3 Study Analytics

Future studies should consider conducting more analytical features—such as the content, number, duration, frequency, tailoring, and interactivity of text messages—on psychological and clinical outcomes (Sahin et al., 2019a). Evidence suggest that all randomised participants should be counted in the statistical analysis. Some participants may not receive the intervention or may drop out or die before the end of the follow-up period, but for the purposes of analysis, they all should still be considered as having been assigned to their intervention arm. This analysis method is called an intention-to-treat (ITT) analysis. The ITT method can preserve the benefits and prognostic balance afforded by randomisation which, therefore, can draw unbiased conclusions regarding the effectiveness of an intervention (McCoy, 2017). Further evidence should be developed on the effectiveness of text messaging interventions in promoting physical activity in people with T2DM with other web-based approaches. This would facilitate adoption of more-effective approaches and provide discontinuation of less-effective approaches in clinical practices. In addition to that, little is known about the effect of text messaging on health care costs. Measurement of text messaging costs can help generate the data necessary to target and attract decision makers in mobile health technologies industry and prioritise the tough choices about how to prioritise competing demands for medical care treatments in general and diabetes management (Iribarren et al., 2017, Schweitzer and Synowiec, 2012).

### 8.5.4 Ongoing Strategies for Monitoring and Updating Clinical Practice Research:

- **Conduct Periodic Systematic Reviews of Evidence on the Use of Text Messages**

With the acceleration of scientific research, more emphasis should be placed on conducting systematic review and meta-analysis reviews. These reviews attempt to summarise all past research up to date for a certain outcome or disease. This can be particularly useful for informing decisions about which interventions are most effective and can be used as justification evidence for further research (Gopalakrishnan and Ganeshkumar, 2013, Gordon et al., 2019). To conduct and report systematic reviews and meta-analyses, it suggests following the PRISMA framework, it is best known and probably the most used framework nowadays in research practices, it provides most useful method for identifying and characterising evidence gaps from the literature; for more details see chapter (2).

## 8.6 Conclusion

This feasibility study has informed the suitability of the protocol design for a future full-size RCT. The primary aim of this study was to evaluate the feasibility and acceptability of text messaging to improve physical activity for T2DM in the Saudi Arabian context. Our findings have demonstrated that the research processes for our feasibility design have been feasible and acceptable. The secondary aim of this study was to determine the likelihood of changes in T2DM related outcome measures. Our results demonstrated a small but statistically significant increase in exercise self-efficacy, physical activity levels and barriers to physical activity, see chapters (5) and (6).

Although these findings need to be confirmed by randomised experimental trials in the future. Finally, mobile health tools such as text messaging intervention are more effective and show promising results if guided by evidence-based content and theoretical constructs (Cho et al., 2018). All evidence provided in this thesis should be tested in a larger RCT to optimise their potential efficacy in real practices. For future researchers, we have explored the theme trends on the use of mobile text messages in promoting physical activity amongst people with type 2 diabetes mellitus: bibliometric analysis, see the appendix. It is a popular and rigorous method for exploring and analysing large volumes of scientific data. It enabled us to unpack the evolutionary nuances and light on the emerging areas in that field.

# Appendix

## Theme Trends on the Use of Mobile Text Messages in Promoting Physical Activity amongst People with Type 2 Diabetes Mellitus: Bibliometric Analysis

### 9.1 Introduction

Type 2 diabetes mellitus (T2DM) is a chronic metabolic disorder, which is characterised by impaired insulin secretion, resistance to peripheral actions of insulin, or both (Galicia-Garcia et al., 2020). The rising burden of T2DM is a global concern to human health in the 21st century. The latest figures from the International Diabetes Federation (IDF) indicate that approximately 415 million people between the ages of 20 to 79 years had diabetes mellitus in 2015, this number is expected to rise to 642 million by 2040 (IDF, 2017). T2DM is a significant cause of premature mortality and morbidity related to cardiovascular disease (CVD), blindness, kidney, and nerve diseases (Chatterjee et al., 2017). Several studies demonstrate that regular physical activity (PA ) can prevent or delay the short-term and long-term incidence of T2DM related complications (Sahin et al., 2019b). Despite this, majority of people with T2DM do not participate in the recommended levels of PA to achieve T2DM related health benefits (Guthold et al., 2018). Mobile text messaging has been put forward as a cost-effective tool, convenient approach and can provide support to these patients who often fail to follow traditional self-management practices (Sahin et al., 2019a).

An increasing number of health care interventions are using mobile text messages to address behavioural management of T2DM specifically physical activity (Sahin et al., 2019b). Several studies have explored this topic using different review designs, mainly systematic reviews, and meta-analysis with a limited search strategy, such as specific age groups, specific diseases, and specific target groups. These study designs intend to understand and interpret a complex phenomenon of interest, in order to find the meaning of actions in a given context (Linnenluecke et al., 2020). Although these reviews summarise important aspects on the effectiveness and efficiency of mobile text messaging, yet no attempt has been made to map out the entire field in a systematic manner. Bibliometric analysis is used to fill this research gab by mapping the essential information, such as the trends and contributions of countries/regions, journals, scholars, and keywords. Bibliometric studies can reveal the stage of maturity and growth of a research area to gain a bird's eye view, therefore, providing researchers with valuable insights on future research directions in this rapidly developing field (Linnenluecke et al., 2020). Therefore, this study aims to explore trends on mobile text messages in promoting physical activity amongst people with type 2 diabetes mellitus using a bibliometric analysis.

## 9.2 Material and Methods

### 9.2.1 Search Strategy

We opted for using the Web of Science (WOS), because it is an extensive international database of academic information, including more than 13000 prestigious and high-impact research journals from around the world (Peng et al., 2020). The WOS database provides many bibliometric indicators and includes literature from most disciplines. The choice of WOS was made based on the idea that it primarily contains full articles and higher indexed articles in comparison with other databases (Li et al., 2018). We developed a search strategy in an iterative manner starting from search terms used in our systematic reviews, see chapter (2). The search terms were then refined by consulting 2 experts in mHealth-based interventions for patients with diabetes. The terms were chosen based on the target population (e.g., type 2 diabetes, diabetes type 2, and type II diabetes), target intervention, (e.g., text messaging, text messages, and short messages), target outcome (e.g., physical activity, physical exercise). We searched for articles from 1982 to 2021-08-08 using the above search terms. The study included all papers with an abstract, title and keywords. We excluded news, congresses, and letters to the editor. All article retrieved from the database were transferred to an electronic spreadsheet.

### 9.2.2 Data Analysis and Visualisation Maps

Retrieved data were analysed for document type, Keywords, authorship, country productivity, annual growth, and citation analysis. We used the WOS viewer software to visualise the bibliometric networks. The visualisation techniques were utilised to produce a density map of institutions, countries/regions, co-citations of references, and co-occurrence of keywords. Each node in a map is represented by a circle with a label. Larger circles indicate higher-frequency items. The colour of each circle is determined by the clusters it belongs to. The thickness and length of links between nodes represent the association strength between corresponding nodes.

### 9.2.3 Results Ethics

Data on bibliometric information were retrieved and downloaded from WOS database. This information is accessible to the public. Such data extraction did not involve interaction with human subjects or animals. Thus, there is no ethical issues in research, approval from the Research Ethics Committee is not required, including the use of these data.

## 9.3 Results

A total of 56 articles published by 351 different authors in 37 different journals are analysed in this study. Data set retrieved from the WoS Core Database is analysed with the help of VOS viewer (Version. 1.6.16; Leiden University, Leiden, The Netherlands) and the results were used to envision the relationship mapping procedures (Eck and Waltman, 2010, Van Eck, 2014). We also used an inbuilt citation analysis tool called Clarivate provided by the WoS platform to prepare a citation report of our dataset.

### 9.3.1 Publication Outputs

The study used the Web of Science database to identify the relevant literature by using a domain-specific search strategy. A total of 56 relevant articles were retrieved from the database that primarily focused on promoting physical activity among T2DM patients via text messaging. The search strategy was applied to all the articles that were published since 1965. However, the first article that met our search criteria was published in 2009. Hence the effective timeline for this study is from 2009 to August 8, 2021. The search strategy in this study is confined to the "TITLE", "KEYWORDS", and "ABSTRACT" sections of the articles. Our analysis showed that researchers had published higher number of articles, i.e., 11 in 2019, related to the correlation between text messaging and physical activity among T2DM patients. Table 30 shows the number of articles published in each year since 2009.

Table 30: Number of documents published per year

| Publication Years | Records | % Of 56 |
|---|---|---|
| 2019 | 11 | 19.643 |
| 2020 | 8 | 14.286 |
| 2018 | 6 | 10.714 |
| 2013 | 6 | 10.714 |
| 2021 | 4 | 7.143 |
| 2016 | 4 | 7.143 |
| 2015 | 4 | 7.143 |
| 2014 | 4 | 7.143 |
| 2017 | 3 | 5.357 |
| 2012 | 2 | 3.571 |
| 2011 | 2 | 3.571 |
| 2010 | 1 | 1.786 |
| 2009 | 1 | 1.786 |

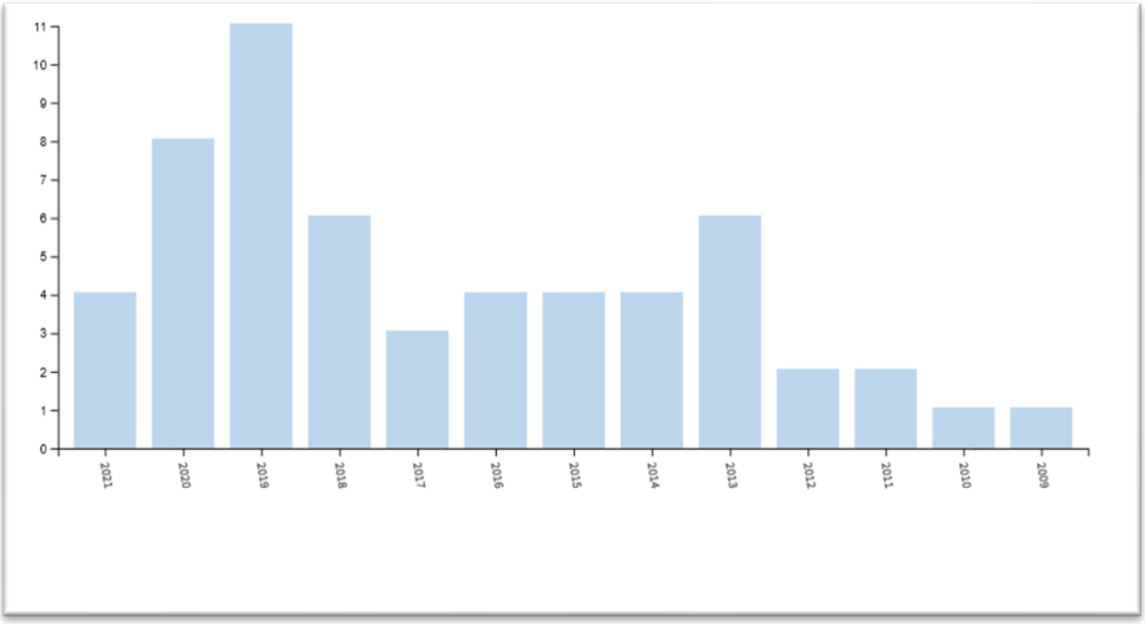



Figure 18: Number of documents published per year

### 9.3.2 Distribution of Source Journals

A total of thirty-seven journals have published articles about the use of text messaging for promoting physical activity among T2DM patients. Each journal has published at least one article on the topic. The greatest number of articles were published in Journal of Medical Internet Research (n=7) followed by JMIR mHealth and uhealth (n=5) and "BMC Public Health" (n=4). The top three leading journals with the highest number of citations are "Epidemiologic reviews" (687 citations), "Telemedicine journal and e-health" (563 citations) and "Translational behavioral medicine" (527 citations). The list of the top ten performing journals based on the citations is shown in table 31 below.

Table 31: Top 10 cited journals

| Rank | Source | Documents | Citations |
|---|---|---|---|
| 1. | Epidemiologic reviews | 1 | 687 |
| 2. | Telemedicine journal and e-health | 1 | 563 |
| 3. | Translational behavioural medicine | 1 | 527 |
| 4. | Cochrane database of systematic reviews | 2 | 333 |
| 5. | Circulation | 1 | 246 |
| 6. | Journal of medical internet research | 7 | 225 |
| 7. | Journal of diabetes and its complications | 1 | 115 |
| 8. | Diabetic medicine | 1 | 79 |
| 9. | Journal of clinical nursing | 1 | 68 |
| 10. | Jmir mhealth and uhealth | 5 | 55 |

### 9.3.3 Distribution and Co-Authorship of Countries

The identified 56 articles were published in 29 different countries. The results are based on the qualifying criteria of the minimum number of articles published, i.e., 1. The United States with 20 articles, the United Kingdom with 14 articles, and Australia with 6

articles are the leading countries in terms of published articles. Further, United States has higher collaboration with Germany. In contrast, the United Kingdom works more closely with India, as shown in the heat map (see figure 19).

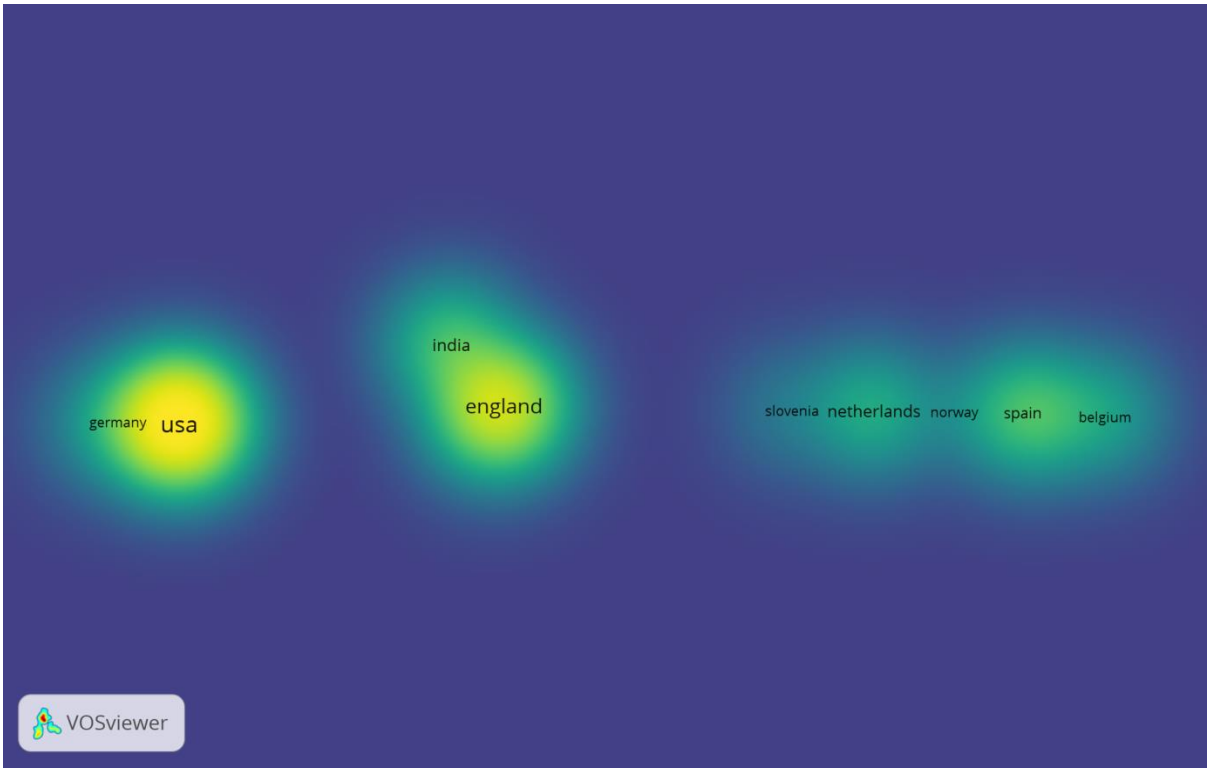



Figure 19: Co-authorship density analysis of countries

The co-authorship analysis among the countries shows the intensity and the level of collaboration in a particular area. The size of the node shows the productivity of that country. The bigger the node size, the more significant the number of articles is originating from the country. The girth and length of links connecting different nodes represent the level of collaboration among countries. The co-authorship network analysis of the corpus based on the countries identified 6 clusters and is shown in figure 20. Furthermore, Table 32 highlights

the top 5 most productive countries in terms of the number of the articles originating from a particular country.


Figure 20: Distribution and co-authorship of countries

Table 32: Top 5 performing countries

| Rank | Country | Documents | Citations |
|---|---|---|---|
| 1. | USA | 20 | 2319 |
| 2. | England | 14 | 503 |
| 3. | Australia | 6 | 9 |
| 4. | Netherlands | 4 | 177 |
| 5. | India | 4 | 13 |

### 9.3.4 Distribution and Co-Authorship of Organisations

Based on the co-authorship analysis of the organisations on our dataset from the Web of Science core database, a total of 155 different organisations have published articles related to the use of text messages in promoting physical activity among T2DM patients, and 20 of them have contributed more than 2 articles. The University of Sydney leads the list with 5 articles and has garnered 9 citations, followed by the University of Cambridge and the University of California San Francisco, each with 4 articles and has 17 and 46 citations, respectively. The five topmost performing organisations are shown in table 33 below.

Table 33: Top 5 performing organisations

| Rank | Organization | Documents | Citations |
|---|---|---|---|
| 1. | University of Sydney | 5 | 9 |
| 2. | University of Cambridge | 4 | 17 |
| 3. | University of California San Francisco | 4 | 46 |
| 4. | Dr. A. Ramachandran's Diabetes Hospitals | 3 | 8 |
| 5. | India Diabetes Research Foundation (IDRF) | 3 | 8 |

The network visualisation map of the organisations is shown in figure 21 below. The nodes in the map shows the organisations, and the links between them represent the number of articles co-authored. With the minimum number of articles co-authored between the organisations as 2, the analysis shows two distinct clusters. The University of Cambridge is the focal point of collaboration between the two clusters. This justifies the highest link strength of ten for the University of Cambridge in the network. Further, India Diabetes Research Foundation works closely with Dr. A. Ramachandran's Diabetes Hospitals and have published a total of 6 articles in collaboration with 16 citations in accumulation.


Figure 21: Co-authorship network analysis of organisations

### 9.3.5 Distribution and Co-Authorship of Authors

The co-authorship analysis on the Web of Science core database identified a total of 351 unique authors who have contributed to the literature by publishing articles that highlight the utility of text messages in promoting physical activity among T2DM patients. There are 58 authors with a minimum of 2 publications. The maximum number of publications co-authored by any author is 3. Scott A. Turske leads the list with the highest citation count of 59 followed by Sheikh Mohammed Shariful Islam with 27 citations. The network virtualisation map shown in figure 22 highlights the arrangement of authors into two clusters. Table 34 shows the 10 most productive authors in this area.

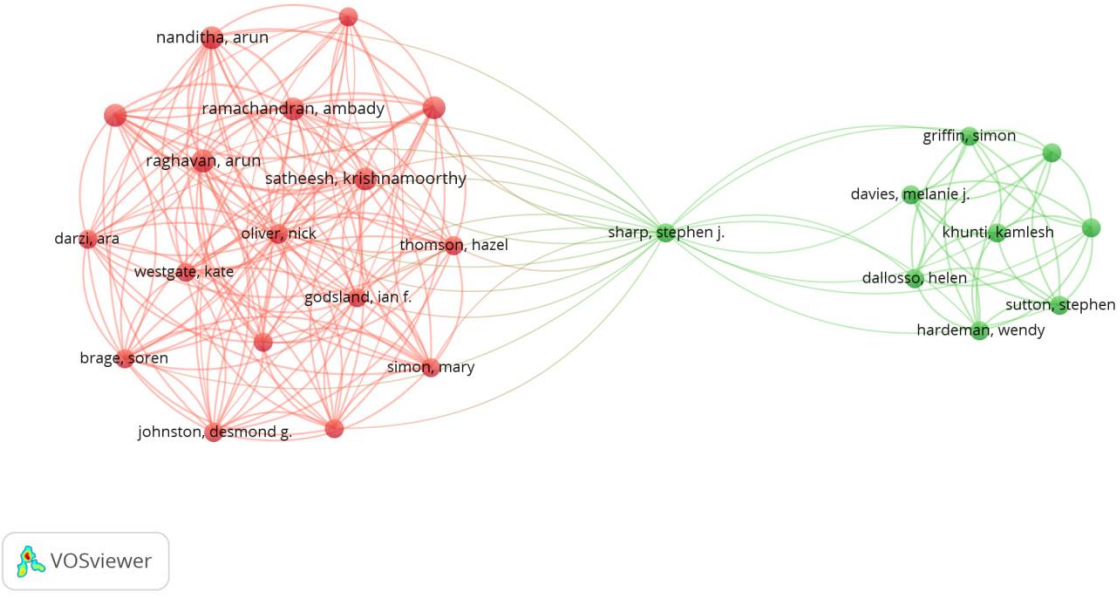



Figure 22: Co-authorship network analysis of authors

Table 34: Top 10 performing authors

| Rank | Author | Documents | Citations |
|---|---|---|---|
| 1. | Turske, scott a. | 3 | 59 |
| 2. | Islam, sheikh mohammed shariful | 3 | 27 |
| 3. | Dickinson, l. Miriam | 3 | 15 |
| 4. | Dickinson, w. Perry | 3 | 15 |
| 5. | Fernald, douglas h. | 3 | 15 |
| 6. | Fisher, lawrence | 3 | 15 |
| 7. | Hessler, danielle m. | 3 | 15 |
| 8. | Nanditha, arun | 3 | 8 |
| 9. | Raghavan, arun | 3 | 8 |
| 10. | Ramachandran, ambady | 3 | 8 |

### 9.3.6 Co-Occurrence Analysis of Top Keywords

Keywords prepared by the authors and approved by the domain experts were used to extract relevant articles from the WoS core database. A total of 369 unique keywords were present in the dataset, from which 68 keywords occurred more than 3 times. The most prominent keywords were "physical-activity" (total link strength of 177), "self-management" (total link strength of 117), and "type 2 diabetes" (total link strength of 86). They occurred 26, 16 and 13 times, respectively. The other keywords that have recently managed to get attention from the research community are "care", "hba1c", "prevention", "life-style interventions", and "sedentary behaviour" among others. The network analysis map of keywords is shown in figure 23 below. Each node represents a keyword, and the size of the node signifies its frequency. The links connecting 2 nodes represents how frequently two keywords have occurred together.

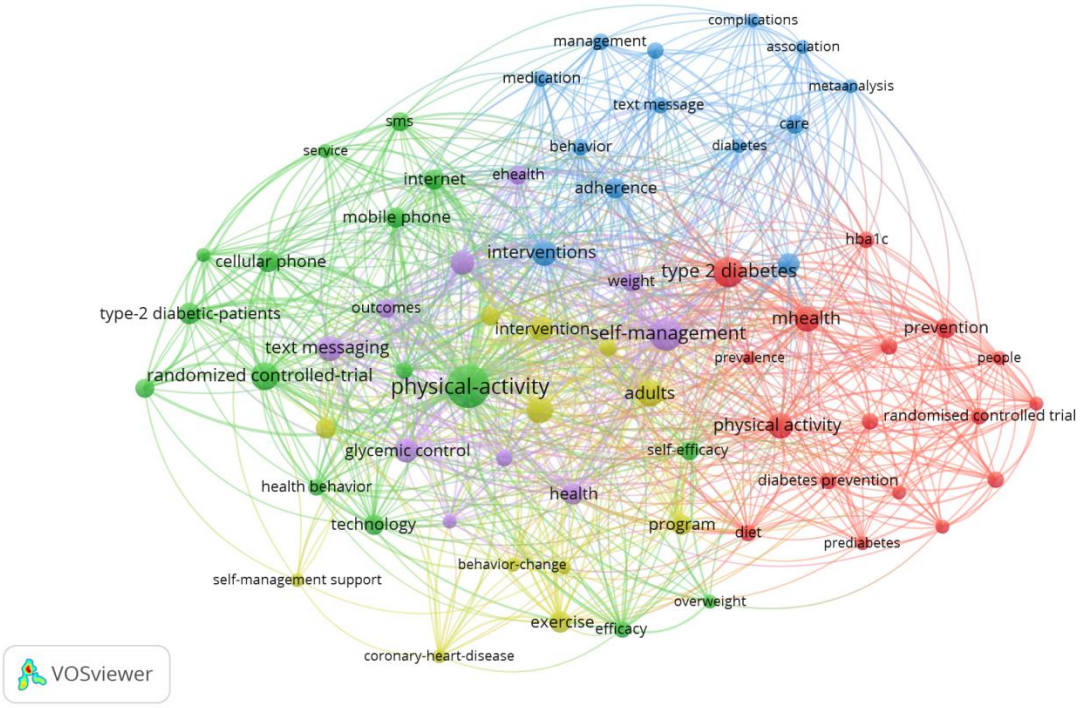



Figure 23: Co-occurrence network analysis of keywords

### 9.4 Discussion

This review gathered and analysed bibliometric data from the studies related to the application of text messaging in promoting physical activity among T2DM patients. The study identified various insights like research trends, level of collaboration among countries and organisations, top performing authors, and significant keywords related to the topic. The number of academic papers in the area has been changing with time, which is considered a good measure of how far this field has progressed (Peng et al., 2020). Studies related to the use of text messages for the betterment of T2DM patients has been growing steadily. The top 2 countries that have made a significant contribution in this field based on the number of articles published are the USA and England and are colour coded as blue and green, respectively.

In addition, these countries are also leading in terms of the number of citations garnered. These findings are in line with the previous research that recommends that geographical proximity or a shared language might influence collaboration across countries (Peng et al., 2020). This justifies the large gap between the countries that deviate significantly in terms of geographic and cultural constructs. Further, this also marks the clear division between the developing and developed countries in terms of collaboration. Hence, there is a need to bridge this gap and develop a robust ecosystem that facilitates collaboration between developing and developed countries. Even though the collaboration between the USA and India is less significant, India has equally contributed in terms of the number of the institution in the top 5 performing organisations. These findings further strengthen the need for collaboration among developing and developed countries. It could play a significant role in carrying some novel research. Further, these findings have shown that it is not mandatory that most productive institutions necessarily originate from the top performing countries. The co-authorship network analysis of organisations as shown in figure (21) is horizontal, which demonstrates that the associated professions are mainly from a medical background, and the scope of the issues is limited. Because this communication tool influences not just physical activity among T2DM patients but also non-medical elements of the patients, these findings point to the necessity for active multi-disciplinary study in a variety of disciplines. There are 351 unique researchers who have worked and published in this area, and among them, only 58 have published more than 1 article.

These findings show that numerous researchers are interested in this field. However, collaboration and succeeding study amongst the authors is restricted. Scholarly collaboration facilitates the flow of knowledge and enhances researcher capability by progressively lessening the overall research expenses (Cisneros et al., 2018). Support for collaboration between authors, organisations, and countries can further increase the productivity of the authors, thereby increasing the number of articles published and subscribe to more significant research in the appropriate topics (Peng et al., 2020). Hence it is crucial to improve the collaboration among the organisations, authors, and countries across the globe for the heterogeneity of T2DM studies. Keywords play an essential role in linking articles with the appropriate category. It also facilitates proper indexing of articles, making it practical and convenient to search massive academic literature for a particular topic of interest. Co-occurrence analysis of keywords has helped various studies to uncover hidden structures and patterns in health research (Gan et al., 2019, Kim and Park, 2021). We analysed the relationship among keywords that have occurred at least three times in the corpus and identified five prominent clusters. Each cluster has been reported in the appendix. Each of these five clusters are analysed from the perspective of text messaging adoption among T2DM patients and are described as follows.

Cluster 1 (17 keywords with red)

Cluster 2 (16 keywords with green)

Cluster 3 (13 keywords with blue)

Cluster 4 (12 keywords with yellow)

Cluster 5 (10 keywords with purple)

To the best of our knowledge, this is the first bibliometric analysis conducted to analyse text messages in promoting physical activity among T2DM patients. Although this study unveils various exciting insights, it also has some limitations. To start with, there is no differentiation made among the articles based on the quality of the sources. Each source is assumed to have uniform standards for quality, which may not be accurate in practice. Another limitation is that the analysis is solely performed on a single data source, i.e., Web of Science Core Database. Hence, there is a possibility that the results of this study may not be generalised for other data sources like Scopus, PubMed, and Google Scholar. This will need more study to integrate and evaluate data from multiple data sources. In terms of future research possibilities, we present future research directions through comprehensive literature reviews using bibliometric analysis. To start with, this study focuses on the use of text messaging in promoting physical activity among T2DM patients, which falls under the ambit of mHealth adoption among T2DM patients. However, the range of this topic is diverse. It could be impacted by multiple dimensions, including socio-economic and cultural constituents of the patient. Thus, in this regard, future research should also focus on investigating the topic from these dimensions. Next, given the field's infancy and rapid growth of text messages-based interventions, there will undoubtedly be many more significant publications to come. Thus, future research should continue to carry out such bibliometric studies on the use of mHealth-based interventions, including text messaging for promoting physical activity among T2DM patients within the intervals of a couple of years. This will contribute to the ongoing advancement in this research field.

## 9.5 Conclusion

The study used a bibliometric analysis on the data retrieved from the WoS core database. The main aim of this bibliometric analysis to have a full picture of this topic, understand its trends and potentials. We used Clarivate to generate a citation report of the corpus and VOS viewer to show the current developments in the concerned research area. We performed different types of analyses to generate insights about the topic. Some of these are co-authorship analyses based on countries, authors, and organizations. We also performed co-occurrence analysis based on keywords and citation analysis of sources to get deeper insights into the research area's overall progress. We confirm that the application of this communication tool (text messaging) for the benefit of T2DM patients is a promising area to explore by thoroughly assessing and summarising research trends. The findings are expected to support the direction for future study and further develop the field of research.

## Appendix

Date _____ Participant's ID _____

**University of Nottingham**

**Physical Activity Self-Efficacy**

This survey is intended to find out more about how perceived ability to exercise in the event that common barriers exist that may impede participation in exercise on a regular basis.

Please indicate the degree to which you are confident that you could exercise in the event that any of the following circumstances were to occur by circling the appropriate %. Select the response that most closely matches your own, remembering that there are no right or wrong answers. Read each item carefully. Circle one of the numbers that best describes YOU.

**0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%**

**Not at All Confident** **Moderately Confident** **Highly Confident**

**I Believe That I Could Exercise 3 Times Per Week for The Next 3 Months If:**

**1.** The weather was very bad (hot, humid, rainy, cold).

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

**2.** I was bored by the program or activity.

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

**3.** I was on vacation.

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

**I Believe That I Could Exercise 3 Times Per Week for The Next 3 Months If:**

**4.** I was not interested in the activity.

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

**5.** I felt pain or discomfort when exercising.

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

**6.** I had to exercise alone.

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

**7.** It was not fun or enjoyable.

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

**8.** It became difficult to get to the exercise location.

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

**9.** I didn't like the particular activity program that I was involved in.

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

**I Believe That I Could Exercise 3 Times Per Week for The Next 3 Months If:**

10. My schedule conflicted with my exercise session.

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

11. I felt self-conscious about my appearance when I exercised.

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

12. An instructor does not offer me any encouragement.

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

13. I was under personal stress of some kind.

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

**CONSENT FORM**

**Title of Study: The Use of Mobile Phone Messaging as a Behavioural Intervention to Increase Physical Activity in Adults with T2DM in Saudi Arabia: Feasibility study**

**Participants**

**ID:**

**Name of Researcher**: Mohammed Al sahli, Dr Holly Blake, Dr Stathis Konstantinidis

**Please initial box**

1. I confirm that I have read and understand the information sheet version number ……dated..... for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐

3. I understand that relevant sections of my data collected in the study may be looked at by authorised individuals from the University of Nottingham, the research group and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential. ☐

4. I understand that the interview will be recorded and that anonymous direct quotes from the interview may be used in the study reports. ☐

5. I understand that all data will be anonymous and confidential with the exception of information being revealed during the interview which is of concern and may need reporting i.e. potential risks to another person or to myself ☐

6. I understand that information about me recorded during the study will be kept in a secure database. If the data is transferred, they will be made anonymous. Data will be kept for 10 years after the study has ended and then securely destroyed. ☐

7. I agree to take part in the above study ☐

| Name of The HCP | Date | Signature |
|---|---|---|
| Name of Person taking consent | Date | Signature |

**Demographic Information Form**

***Instructions:*** Please provide a response for each of the following questions:

**ID number** ……

**Date of birth**…….

**Patient's Sex** Female ○ Male **O**

**Diagnosis**

……
……
……
……
……

**Medical History**

……
……
……
……
……

**Marital Status** Single ○ Married **O** Separated **O** Divorced **O** Widowed **O**

**Ethnic Category** Saudi ○ Asian ○ Caucasian ○ Latino ○

**Body Mass Index** ……

**Glycated hemoglobin (**HbA1c) ……

# Interview Guide

**Mobile Phone Messaging Intervention: Qualitative Script:**

**Acceptability Part**

Participants Interview

*** RECEIVE CONSENT BEFORE STARTING THE INTERVIEW ***

- Have you read the information sheet?
- Have you had the chance to ask any questions?
- Are you happy to go ahead with the interview?

7. Overall, what do you think about the mobile phone messaging intervention?

8. What do you think about the recruitment process?

9. What attracted you to taking part in this particular research study?

10. Did you encounter any problems with sending or receiving the text messages?

11. Did you make any changes in your life as a result of getting the text messages?

12. What would you change about the messages programme to make it better?

13. What should we do differently if we were starting over with this program?

14. Would you recommend this intervention for others?

15. Do you have any questions?

# Interview Guide

**Mobile Phone Messaging Intervention: Qualitative Script:**

**Acceptability Part**

HCP Interview

*** RECEIVE CONSENT BEFORE STARTING THE INTERVIEW ***

Font

e you read the information sheet?
you happy to go ahead with the interview?

1. Overall, what do you think about the recruitment?

2. What should we do differently if we were starting over with this program?

3. Have you learnt anything from being involved in this project?

4. Would you recommend this intervention?

5. Anything else you would like to say about the messaging programme?

6. Do you have any questions?

Toady's Date _____ Participant's ID _____

**University of Nottingham**
**International Physical Activity Questionnaire (IPAQ)**

The questions will ask you about the time you spent being physically active. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

**The following questions are about physical activity. Please read carefully and answer to the best of your knowledge.**

1. When you are at work, which of the following describes what you do:

Mostly sitting or standing

Mostly walking

Mostly heavy labor or physically demanding work

Don't know/not sure

**The next 3 questions are about vigorous physical activity. Vigorous physical activity causes your heart to beat faster and makes you breathe hard.**

2. Now thinking about vigorous physical activities, you did in the last 7 days, did you do vigorous activities for at least 10 minutes at a time, such as running, aerobics, sports, heavy yard work, or anything else?

Yes

No

Toady's Date _____ Participant's ID _____

**University of Nottingham**
**International Physical Activity Questionnaire (IPAQ)**

The questions will ask you about the time you spent being physically active. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

**The following questions are about physical activity. Please read carefully and answer to the best of your knowledge.**

1. When you are at work, which of the following describes what you do:

Mostly sitting or standing

Mostly walking

Mostly heavy labor or physically demanding work

Don't know/not sure

**The next 3 questions are about vigorous physical activity. Vigorous physical activity causes your heart to beat faster and makes you breathe hard.**

2. Now thinking about vigorous physical activities, you did in the last 7 days, did you do vigorous activities for at least 10 minutes at a time, such as running, aerobics, sports, heavy yard work, or anything else?

Yes

No

3. How many days per week do you do these vigorous activities for at least 10 minutes at a time?

   Days per week: 1 2 3 4 5 6 7

4. On the days when you do vigorous activity for at least 10 minutes, how long do you do those activities?

About 10 minutes

About 20 minutes

About 30 minutes

About 40 minutes

About 50 minutes 1 hour or more

**The next 3 questions are about moderate physical activity. Moderate physical activity causes small increases in breathing or heart rate.**

5. Now thinking about moderate physical activities, you did in the last 7 days, did you do moderate activities for at least 10 minutes at a time, such as brisk walking, bicycling at regular pace, vacuuming, gardening, or anything else?

Yes

No

6. How many days per week do you do these moderate activities for at least 10 minutes at a time?

   Days per week: 1 2 3 4 5 6 7

7. On the days when you do moderate activity for at least 10 minutes, how long do you do those activities?

About 10 minutes

About 20 minutes

About 30 minutes

About 40 minutes

About 50 minutes 1 hour or more

**The next 3 questions are about time spent walking.**

8. Now thinking about the amount of time you spent walking in the last 7 days, that lasted for at least 10 minutes at a time. This includes at work and at home, walking to travel from place to place, and any other walking that you might do solely for recreation, sport, exercise, or leisure.

Yes

No

9. How many days per week do you do spend walking for at least 10 minutes at a time?

Days per week: 1 2 3 4 5 6 7

10. On the days when you do walk for at least 10 minutes, how long do you do those activities?

About 10 minutes

About 20 minutes

About 30 minutes

About 40 minutes

About 50 minutes 1 hour or more

**The next 2 questions are about you sitting.**

1. Now thinking about the amount of time you spent sitting in the last 7 days. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

2. How many hours per day do you spend sitting?

About 10 minutes

About 20 minutes

About 30 minutes

About 40 minutes

About 50 minutes 1 hour or more

***University of Nottingham, Faculty of Medicine & Health***

***Sciences, School of Health Sciences***
**Participant Information Sheet**

Title of Study: **The Use of Mobile Phone Messaging as a Behavioural Intervention to Increase Physical Activity in Adults with T2DM in Saudi Arabia: A Feasibility Study**

**Name of Chief Investigator:** Dr Holly Blake, Faculty of Medicine & Health Sciences, University of Nottingham

**Name of Researcher(s):**

**Mr Mohammed Alsahli, Doctoral researcher**

**Dr Stathis Konstantinidis, Faculty of Medicine & Health Sciences, University of Nottingham**

Study Information

I would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it will involve for you. Please take the time to read the following information carefully and ask questions about anything you do not understand. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Take your time to decide whether you wish to take part or not.

**What is the purpose of the study?**

This research study aims to explore if using mobile phone messaging in promoting physical activity on T2DM is feasible and acceptable in Saudi Arabia Context. We are hoping this study will help people with T2DM to be more physically active and find out what's best methods to encourage them.

**Why have I been invited to take part in the study?**

You have been invited to take part in this study because you have been diagnosed with type 2 diabetes and you have met our study requirements. We are inviting between 40 and 50 participants lie you to take part in the study.

**Do I have to take part?**

It is up to you to decide whether or not you would like to take part. Please take your time to decide whether or not you wish to take part and discuss this with your family and friends. If you do decide that you would like to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you do take part, you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights. you decide not to take part, there will be no impacts on your clinical care, which will continue as usual. You can withdraw your participation at any time.

**What will my involvement require?**

If you agree to take part, we will then ask you to sign a consent form. If you do decide to take part, you will be given this information sheet to keep and a copy of your signed consent form. We will ask you to provide your mobile number.

The research will last 3 months but your involvement would only be 6 weeks, during this time, before and after the study you will be asked to complete 3 questionnaires which we estimate will take you about 15 minutes for each. By the end of the six weeks you will be asked again to complete an interview either face to face or by telephone.

**What will I have to do?**

If you agree to be part of this study, you will be invited to provide your mobile phone number, and we will send you a series of text messages over a 6-week period, promoting physical activity and its benefits, goals and motivational content. We will ask you to complete some questionnaires before and after the messages are sent. By the end of 6 weeks you will be invited for an interview that will last between 30–60 mins, this can be face to face or via phone call. Our interview will be audio-recorded. We will ask you in during this interview about your views of the text messages, if you liked or disliked any aspect of the messages, and we will ask for your views on how to improve research in the future.

**What are the possible disadvantages and risks of taking part?**

We do not anticipate you will experience any distress or discomfort as a result of taking part in this study. However, if you experience any health issues as a result of exercise then please contact your usual clinical team. If you have any concerns about the conduct of the study, then please contact the researcher in the first instance.

**What are the possible benefits of taking part?**

Whilst there are no immediate benefits for those people participating in the study, it is hoped that this work will have a beneficial impact on how physical activity may help people with type 2 diabetes. A summary of results will be shared with you once study is finalised.

**What happens if the research study stops earlier than expected?**

Should the research stop earlier than planned and you are affected in any way we will tell you and explain why. All data collected will then be analysed and the findings reported to the funders. We will seek to disseminate the findings through conference presentations and academic journals.

**Will my taking part in the study be kept confidential?**

Yes. Your details will be Kept strictly confidential and we will follow ethical and legal practice in relation to all study procedures. Unauthorised individuals will not have access to them. Your collected data will be anonymised and follow all appropriate legal, ethical and other approvals in place. For practical reasons your consent will not be sought again unless you indicate you wish us to do this. Your data will not be used for commercial purposes or any unexplained purposes.

**What will happen to the results of the research project?**

Results of the research will be published. You will not be identified in any report or publication.

**Who is organising and funding the research?**

This research is organised by the University of Nottingham and funded by Ministry of Higher Education, Saudi Arabia.

**Who has reviewed the study?**

All research in the University of Nottingham is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This project will be reviewed and given favourable opinion by the Faculty of Medicine & Health Sciences (FMHS) Research Ethics Committee in the UK, and by the ministry of health in Saudi Arabia.

**What if there is a problem?**

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers' contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting:

- Dr Holly Blake (Chief Investigator), Main Supervisor, School of Health Science, University of Nottingham, B floor, Queens Medical Centre, Nottingham NG7 2UH, UK. email: holly.blake@nottingham.ac.uk
- Mohammed Alsahli, (Doctoral Researcher), Health Science, University of Nottingham, UK. email: ntxma27@nottingham.ac.uk

If you have a concern about any aspect of this study, you should contact us via email or mobile phone +966500676741

**Thank you for your time**

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