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EFFICACY, ACCEPTABILITY AND FEASIBILITY OF mHEALTH TECHNOLOGY IN PROMOTING ADHERENCE TO ANTI-DIABETIC THERAPY AND GLYCAEMIC CONTROL AMONG DIABETIC PATIENTS IN EASTERN CAPE, SOUTH AFRICA

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UNIVERSITY OF FORT HARE.**

September, 2019

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BY

EYITAYO OMOLARA OWOLABI

A thesis submitted in fulfilment of the requirements for the degree of

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DEPARTMENT OF NURSING SCIENCE
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Supervisor: Prof DT Goon

September, 2019

DECLARATION

I, the undersigned, declare that this thesis entitled “Efficacy, acceptability and feasibility of mhealth technology in promoting adherence to anti-diabetic therapy and glycaemic control among diabetic patients in Eastern Cape, South Africa” submitted to the University of Fort Hare for the degree of Doctor of Philosophy in Nursing in the Faculty of Health Sciences, and the work contained herein is my original work with exemption to the citations and that this work has not been submitted to any other University in partial or entirely for the award of any degree.

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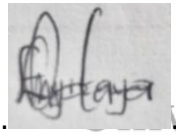
Signature:  .....

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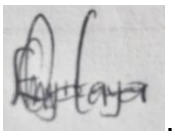
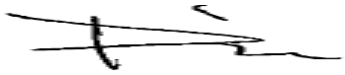
Signature……  …… Date……03-09-2019…….

CERTIFICATION

This thesis entitled “Efficacy, acceptability and feasibility of mhealth technology in promoting adherence to anti-diabetic therapy and glycaemic control among diabetic patients in Eastern Cape, South Africa” meets the regulation governing the award of the degree of Doctor of Philosophy in Nursing of the University of Fort Hare and is approved for its contribution to scientific knowledge and literary presentation.



03-09-2019

Prof. DT Goon

Date

Supervisor

DEDICATION

This thesis is dedicated to the Almighty God, the most gracious, most merciful, Alpha and Omega, my All in All, Jehovah Jireh, Jehovah Nissi, the source of my wisdom, knowledge, and strength. His grace has brought me this far and I will forever be grateful to Him. From the bottom of my heart, Lord, I say, THANK YOU.

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LIST OF ACRONYMS

ADA:	American Diabetes Association
AHA:	American Heart Association
AIDS:	Acquired Immune Deficiency Syndrome
BCMM:	Buffalo City Metropolitan Municipality
BMI:	Body Mass Index
BP:	Blood pressure
CI:	Confidence Interval
CONSORT:	Consolidated Standard for Reporting Trials
CRISP:	Center for Research in Implementation Science and Prevention
DAWN:	Diabetes Attitudes, Needs, and Wishes
DES-SF:	Diabetes Empowerment Scale-Short Form
DM:	Diabetes Mellitus
DPP-4:	Dipeptidyl Peptidase-4
DSM:	Diabetes Self-Management
E-Health	Electronic Health
ED-5D:	Europe Quality of Life 5 Dimension Scale
ED-5D-5L:	Europe Quality of Life 5 Dimension, 5 Levels Scale
FPG:	Fasting Plasma Glucose
GBD:	Global Burden of Disease
GLP:	Glucagon-Like Peptide
GoE:	Global Observatory for eHealth
GPRS:	General Packet Radio Service
GPS:	Global Positioning System
HbA1c:	Glycated haemoglobin
HIV:	Human Immunodeficiency Virus
HST:	Health Systems Trust
ICT:	Information Communication Technology
IDF:	International Diabetes Federation
IL:	Illinois
ITU:	International Telecommunication Union
KG:	Kilogram
KGM^{-2}:	Kilogram per meter-square

mHealth:	Mobile Health
MMAS:	Morisky Medication Adherence Scale
NCDs:	Non-communicable Diseases
QOL:	Quality of Life
RPG:	Random Plasma Glucose
SAARF:	South African Audience Research Foundation
SADoH:	South African Department of Health
SD:	Standard Deviation
SDKT:	Simplified Diabetes Knowledge Test
SEMDSA:	Society for Endocrinology, Metabolism and Diabetes of South Africa
SEXINFO:	Sexuality Information Services
SLGT:	Sodium Glucose CoTransporter
SmokefreeTXT:	Smoke Free Text
SMS:	Short Message Services
SA:	South Africa
SPSS:	Statistical Package for Social Sciences
SSA:	Sub-Saharan Africa
USA:	United States of America
VAS:	Visual Assessment Scale
WHO:	World Health Organisation

ABSTRACT

Background: Diabetes mellitus is a disease of a significant public health concern and a leading cause of death and disability worldwide. In Africa, South Africa ranks second among countries with the highest burden of diabetes, and with a poor level of glycaemic control. mHealth technology is an innovative and cost-effective measure of promoting health and the use of text messaging for fostering health is evolving. In South Africa, there is hardly any study involving the use of mobile health technology, including text messaging for promoting health among diabetic patients.

Purpose: The aim of this study was to determine the efficacy, feasibility and acceptability of mHealth in promoting adherence and glycaemic control among diabetic patients in resource-poor settings of the Eastern Cape Province of South Africa. Also, the study assessed the impact of text messaging on knowledge, self-management behaviour, self-efficacy and health-related quality of life.

Methodology: The study adopted a multi-centre, two-arm, parallel, randomised controlled trial design. Participants were randomly assigned to the intervention (n=108) and control arm (n=108). Participants' socio-demographic information was obtained using the widely validated WHO STEPwise questionnaire, and a self-developed questionnaire, including previously validated measurement scales were used to obtain information on adherence, self-management behaviour, self-efficacy and health-related quality of life. Participants in the intervention arm received daily text messages related to diabetes management and care for six months. Data were collected at baseline and six months post-intervention. Blood glucose, blood pressure and anthropometric measurements followed standard procedure. Mixed-model analysis was used to assess the impact of the SMS on random blood glucose while

linear and bivariate logistic regression were used to assess for effect on other clinical outcomes.

Results: The mean age of the participants was 60.64 (SD± 11.58) years. The majority of the study participants had secondary level of education (95.3%) and earned 1500 to 14200 Rand per month (67.7%). For both the intervention and the control group, majority never used tobacco (98.10% vs 94.40%) or alcohol (88.00% vs 87.00%). Both arms of the study showed improvement in the primary outcome (blood glucose level), with no significant difference, the mean adjusted difference in blood glucose from baseline to six months post-intervention was 0.26 (-0.81 to 1.32), p=0.634. Also, the intervention did not have a significant effect on the secondary outcomes (knowledge, medication adherence, dietary adherence, adherence to physical activity, health-related quality of life, self-management behaviour and diabetes distress). Similarly, the intervention did not have any significant effect on secondary clinical outcomes such as weight (p=0.654), body mass index (p=0.439), systolic (p=0.610) and diastolic blood pressure (p=0.535). An overwhelming majority of the participants (90.74%) were pleased with the intervention and felt it was helpful. Of those who took part in the intervention, 91% completed the follow-up study after six months.

Conclusion: The use of SMS is a highly acceptable and feasible adjunct to standard clinical care in the promotion of health among diabetic patients in this study setting. Although there was a little improvement, the efficacy of a unidirectional text messaging in promoting health outcomes in this study setting is still doubtful.

Keywords: mHealth; Text-messaging; Diabetes control; Adherence; Diabetes knowledge; Self-management behaviour; Diabetes distress; Diabetes self-efficacy; Eastern Cape; South Africa.

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CHAPTER ONE

INTRODUCTION

1.1 BACKGROUND TO THE STUDY

Diabetes mellitus (DM) is an important clinical and public health concern and forms part of the four priority non-communicable diseases (others being cardiovascular diseases, cancer, and chronic respiratory diseases) targeted by world leaders for special attention (World Health Organisation [WHO], 2016a:5). The burden associated with diabetes is enormous, and the 2016 World Health Day was dedicated solely to diabetes, with the slogan: “Beat Diabetes” (WHO, 2016b).

Diabetes mellitus is a disease of significant socio-economic concern and forms a part of the leading causes of death and disability worldwide (International Diabetes Federation [IDF], 2013:32; Seuring, Archangelidi & Suhrcke, 2015:1). Globally, the burden of diabetes is disturbingly high and continues to rise exponentially across several countries (IDF, 2014:2; IDF 2013:36; Whiting et al., 2011:1). The World Health Organisation estimated a 4% increase in the global prevalence of diabetes, with 422 million individuals living with diabetes between 1980 and 2014 (WHO, 2014a). This number is about four times the number recorded in the past three decades; still, 46.3% were yet to be diagnosed. In 2016, approximately 1.6 million deaths among adults were ascribed directly to diabetes mellitus, with an additional 2.2 million deaths attributed to high blood glucose (WHO, 2018). Disturbingly, these deaths occur more frequently among the working age group, that is, those below 60 years, and this poses significant economic implications for any nation (WHO, 2018).

Diabetes mellitus is no longer a disease of predominantly rich nations. It is becoming increasingly prevalent among the poor in developing countries, and even more among the "poorest of the poor" (Anjana et al., 2011:3; Dasappa, Fathima, Prabhakar & Sarin, 2015:1; Hwang, Han, Zabetian, Ali & Narayan, 2012:1). The prevalence of diabetes mellitus is now rising at a faster rate in developing countries than in developed countries (WHO, 2018). About three-quarters of people living with diabetes are in developing countries (IDF, 2014:2; Shen et al., 2016:1). A recent estimate by the International Diabetes Federation showed that 15 million adults in Africa were living with diabetes in 2017, regional prevalence of 3.3% (IDF, 2017). The burden of diabetes in under-resourced areas is complicated by a lack of effective and adequately-equipped healthcare systems as well as a deficiency in the implementation of prevention strategies (WHO, 2016b).

The observed increase in diabetes rates is mostly attributed to economic development and lifestyle changes, and the upsurge in obesity epidemic (Kengne, Echouffo-Tcheugui, Sobngwi & Mbanya, 2013:2; Peer, Kengne, Motala & Mbanya, 2014:1). South Africa is not exempted from the growing menace of diabetes and its related mortality (Guariguata et al., 2014:3). Diabetes is currently the second leading cause of morbidity and mortality in South Africa (Pillay-van Wyk, Dorrington & Bradshaw, 2017). More than four million South Africans are affected by diabetes; about 7% of the population, with as much as 41% cases yet to be diagnosed (Health 24, 2016; IDF, 2015). Likewise, the Eastern Cape Province of South Africa is not excluded from the growing burden of diabetes. Owolabi et al. (2016) reported a high prevalence (24%) of diabetes among adults in one of the largest municipalities in the Eastern Cape Province.

Diabetes mellitus is a disease characterised by an abnormally high blood glucose level (hyperglycaemia) (American Diabetes Association [ADA], 2011:1). Uncontrolled hyperglycaemia is often associated with a high risk of developing microvascular or macrovascular health complications (Cade, 2008; Kirkman et al., 2012:3). Microvascular complications of diabetes include nephropathy, neuropathy and retinopathy, leading to kidney disease, amputation and blindness, respectively (Asif, 2014:1; Deshpande, Harris-Hayes & Schootman, 2008:3). Macrovascular complications, on the other hand, include coronary artery disease, peripheral arterial disease, and stroke (Chawla, Chawla & Jaggi, 2016:3; Fowler, 2011:1). These complications further impose a more significant burden on the individual, reduce their health-related quality of life, increase the risk of premature mortality, and impact tremendously on the already overstretched healthcare system (Nolan, Damm & Prentki, 2011:1).

Although diabetes cannot be cured, it can, however, be managed with various treatments now allowing most individuals with diabetes to live relatively stable and normal lives (Asif, 2014:1; Diabetes UK, 2017). Intensive therapy for patients with diabetes mellitus assist with blood glucose control and reduction in the risk for complications, particularly microvascular complications (ADVANCE Collaborative Group et al., 2008; Duckworth et al., 2009). Blood glucose control indicated by a reduction in the HbA1c level is accompanied by a delay in the onset of complications development, and also slows down the progression of clinically important complications such as retinopathy, including vision-threatening lesions, nephropathy and neuropathy by a range of 35% to 70% (American Diabetes Association, 2019:9; The Diabetes Control and Complications Trial Research Group, 1993). As low as a 1% reduction in HbA1c has been shown to be associated with a 21% reduction in the

risk of end-point death related to diabetes mellitus, 14% reduction in the risk of developing myocardial infarction and a 37% reduction in microvascular complications (ACCORD Study Group, 2010; Ismail-Beigi et al., 2010:1; Stratton et al., 2000).

Notwithstanding the innovative scientific discoveries and treatment modalities, treatment outcomes of individuals with diabetes seem to be generally sub-optimal. Diabetes control in developed countries is below average (Khan et al., 2015; Teoh et al., 2010). Similarly, diabetes control in Sub-Saharan Africa (SSA) is mostly sub-optimal (Camara et al., 2015:3). Various studies across several countries in SSA have documented different diabetes control levels. The prevalence of uncontrolled diabetes range from 62% in Nigeria (Ngwogu, Mba & Ngwogu, 2012:1), 68% in Congo (Longo-Mbenza et al., 2008:5), 79.2% in Uganda (Kibirige, Atuhe, Sebunya & Mwebaze, 2014:4) to 82% in Botswana (Mengesha, 2007:1). Besides, sub-optimal control of diabetes mellitus has also been reported across the various provinces of South Africa (Folb et al., 2015:4; Webb, Rheeder & Van-Zyl, 2015:6). The prevalence of sub-optimal control of diabetes ranges from 69.3% in Northwest (Kadima & Tumbo, 2013), 81% in Cape Town (Daramola, 2012), 83% in Kwazulu-Natal (Igbojiaku, Ogbonnaya, Harbor & Ross, 2013) to 84% in Eastern Cape Province (Adeniyi, Yogeswaran, Longo-Mbenza & Goon, 2016:4). These statistics suggest a higher prevalence of uncontrolled diabetes in South Africa, compared to other countries in sub-Saharan Africa, with Eastern Cape having the highest prevalence in South Africa.

Various reasons have been purported to be responsible for poor glycaemic control. Such factors include the duration of disease (Khattab, Khader, Al-Khawaldeh & Ajlouni, 2010:1; Nemeh, Yousef & Aysha, 2011:3) and comorbidity (Woldu et al., 2014:3). Other identified factors include overburdened healthcare facilities, insufficient

health education, sub-optimal knowledge and beliefs, inadequate support structures, unsafe communities and low income (IDF, 2016; Kibirige et al., 2014). However, a major causative factor of poorly controlled diabetes is non-adherence to treatment regimen and recommended lifestyle changes (Aikens & Piette, 2013:1; Davies et al., 2013:9; de Vries et al., 2014:3; Hamine, Gerth-Guyette, Faulx, Green & Ginsburg, 2015:1; Jarab et al., 2014:1; Kassahun, Eshetie & Gesesew, 2016:3). There is a wide range of evidence of non-adherence to treatment among individuals with diabetes, both globally and nationally (Mann, Ponieman, Leventhal & Halm, 2009; Krishna & Boren, 2008; Mbuagbaw et al., 2012; Rwegerera, 2014).

Non-adherence to medical therapy and recommended lifestyle regimen has long been a pressing issue in the South African Primary Healthcare system (Kagee, 2004). Patients are the centre of the healthcare team, and it is crucial to improve their awareness and knowledge on diabetes self-management behaviours (Amod et al., 2012; Mandewo, Dodge, Chideme-Munodwafa & Mandewo, 2014; Dos Santos et al., 2014). Based on this perspective, there is a need for interventions to enhance patients' education and improve their self-management behaviours, self-management skills and ultimately, their health outcomes. Controlled trials of various interventions among diabetic patients to determine their effectiveness in boosting patients' knowledge and self-care behaviours are limited. Diabetes control interventions include educational programmes using various media as well as lifestyle measures (Berg, Dedd & Dodd, 2009; Mash et al., 2012; Schwellnus et al., 2009). However, there is limited documented interventional research available to address the correlates of uncontrolled diabetes in South Africa.

Information and communication technology such as computers, mobile phones, satellite communications and patients' monitors are used to support health services and information exchange (Hamine et al., 2015:1; Wiggins, 2015:88). Mobile technology has the potential to improve the quality, safety and efficiency of healthcare services in almost every aspect of the health sector (Cole-Lewis & Kershaw, 2010; Jemberu, 2013). The World Health Organisation also prioritises the use of new technologies to assist healthcare delivery in resource-limited settings (Joint United Nations Programme on HIV/AIDs, 2005; Kay, Santos & Takane, 2011). The most widely used technology is the use of mobile phones, with evidence of increased uptake in Africa (Lester, Gelmon & Plummer, 2006; Sinha & Barry, 2011). The use of mobile phones has the potential to radically improve healthcare in the most remote and resource-poor environments of the world (Hamspire et al., 2015:1; Marwaha, 2010). Even before phones became mobile, Hyanes et al. (1996) had already posited that communication efforts that would keep the patients engaged in healthcare might be the simplest and most cost-effective strategy for improving adherence to chronic medications. Hall, Fortrell, Wilkinson and Byass (2014) documented the use of mobile phones to improve treatment adherence, appointment compliance, and developing support networks for health workers. Likewise, the use of short message services (SMS) on mobile phones as a means of providing new and innovative opportunities for disease prevention efforts at a low cost is plausible (IDF, 2016).

A number of randomised controlled trials on the use of SMS have been conducted in various parts of the world including Africa (Deglise et al., 2012; Dobson et al., 2016; Ferrer-Roca, Cardenas, Diaz-Cardama & Pulido, 2004; Jemberu, 2013; Islam et al., 2014). It is cost-effective and associated with improvement in self-management behaviour, lifestyle changes, medication compliance and adherence as well as

improved blood glucose control (Deglise et al., 2012; Dobson et al., 2016; Ferrer-Roca et al, 2004; Jemberu, 2013; Islam et al., 2014). However, some scholars have documented mixed effects or no results on treatment outcomes following the use of SMS (Balisa et al., 2010; Capozza et al., 2015; Fairhurst & Sheikh, 2008).

There is a rapid increase in the use of mobile phones in South Africa; these phones have now become affordable and available (Leon, Schneider, Daviaud, 2012:4). In addition, in South Africa, successes have been recorded with the use of mHealth technology among patients with various conditions such as hypertension (Leon, Surender, Bobrow, Muller & Farmer, 2015), sexually transmitted infections and HIV/AIDs (de Tolly, Nambaware & Skinny, 2011:1), malaria (Quan et al., 2014:5) and maternal and child health conditions (Baron et al., 2016:4). Conversely, there is little or no documented interventional studies applying the use of mHealth technology strategy for glycaemic control among individuals with diabetes (Leon, Schneider, Daviaud, 2015:4; Lunny et al., 2014). Diabetes is a chronic condition like hypertension; however, its treatment and management differs from hypertension. The treatment and management of diabetes appear to be more complex as it involves paying keen attention to dietary intake, the use of medications or insulin, and the need for several examinations for complications, including foot care. Thus, there is a need to carry out interventional studies targeting the use of mHealth, particularly among individuals with diabetes.

1.2 PROBLEM STATEMENT

Diabetes mellitus is a disease of significant public health concern and a leading cause of death and disability worldwide (WHO, 2016a). Several countries, both developed and developing, are undergoing an exponential increase in the disease burden (IDF,

2014:2; Seuring, Archangelidi & Suhrcke, 2015:1). Developing nations, including South Africa, are confronted with a rapid increase in the burden of diabetes with close to three-quarters of the individuals living with diabetes (Shen et al., 2016).

There is an exponential increase in diabetes burden and its associated increase in morbidity and premature mortality in South Africa (IDF, 2015). South Africa is ranked second among countries with the highest prevalence of diabetes in Africa, following Ethiopia (IDF, 2017; Guarigata et al., 2013:3). Despite the documented effectiveness of medication therapy and lifestyle modifications in attaining glycaemic control, the high prevalence of diabetes in the country is further complicated by poor glycaemic control (Adeniyi et al., 2016, Daramola et al., 2012; Igbojiaku et al., 2013; Kadima & Tumbo, 2013; Shilubane, 2010). Plausibly, the high rate of sub-optimal control is attributed to the poor level of knowledge and healthcare services, and the low level of adherence to medication and healthy lifestyle behaviours (Adisa & Fakeye, 2014; Bagonza et al., 2015; Booysen & Schlemmer, 2015; Kagee, 2004; Cramer, 2004). Consequently, there is a resultant predisposition to complications development leading to a poor quality of life, disability, premature mortality and excessive burden on the individuals, placing a significant strain on the already overburdened healthcare system.

Mobile health (mHealth) is an emerging, and cost-effective measure proven to be effective in improving patients' self-management behaviours, adherence to therapeutic regimen, compliance with appointments and treatment outcomes. However, the effectiveness of mHealth among individuals with diabetes has been rarely documented in South Africa, and more specifically, in an economically poor region with a high burden of diabetes like the Eastern Cape. Hence, there is the need

for an interventional study to determine the efficacy of mHealth technology besides the usual care in promoting adherence to anti-diabetic therapy, glycaemic control and other treatment outcomes among individuals living with diabetes in low-resource settings of Eastern Cape, South Africa. This study therefore aims to determine the efficacy, the feasibility and the acceptability of the mHealth technology, specifically, Short Message Services (SMS) in promoting adherence to anti-diabetic regimen and glycaemic control among diabetic patients in selected districts of the Eastern Cape Province of South Africa.

1.3 AIM AND OBJECTIVES

The overall aim of this experimental study is to determine the efficacy, acceptability and feasibility of mHealth technology in promoting adherence to anti-diabetic therapy and glycaemic control among individuals with diabetes in low-resource areas of the Eastern Cape Province, in order to inform public health policy direction concerning diabetes control.

The specific objectives of the study are:

- To assess the efficacy of mobile phone SMS in promoting glycaemic control among individuals living with diabetes in the selected districts in the Eastern Cape Province;
- To determine the efficacy of mobile phone SMS in improving diabetes knowledge among individuals living with diabetes in the selected districts in the Eastern Cape Province;
- To assess the efficacy of mobile phone SMS in promoting adherence to medication, physical activity regimen and dietary recommendations among

individuals living with diabetes in the selected districts in the Eastern Cape Province;

- To determine the efficacy of mobile phone SMS in improving the health-related quality of life among individuals living with diabetes in the selected districts in the Eastern Cape province;
- To determine the efficacy of mobile phone SMS in improving self-management behaviour, self-efficacy and diabetes distress among individuals living with diabetes in the selected districts of Eastern Cape Province;
- To assess the efficacy of the use of mobile phone SMS in improving secondary clinical outcomes (blood pressure, body mass index) among individuals living with diabetes in the selected districts in the Eastern Cape Province;
- To assess the efficacy of the use of mobile phone SMS in improving behavioural characteristics (smoking and alcohol use) of individuals living with diabetes in the selected districts in the Eastern Cape Province;
- To determine the efficacy of the use of mobile phone SMS as a clinic appointment reminder among individuals living with diabetes in the selected districts in the Eastern Cape Province; and
- To determine the acceptability of the mobile phone SMS intervention by individuals living with diabetes in the Eastern Cape Province.
- To determine the feasibility of the mobile phone SMS intervention by individuals living with diabetes in the Eastern Cape Province.

1.4 RESEARCH QUESTIONS

The research questions for this study are as follows:

- Would the use of mobile phone SMS be effective in promoting glycaemic control among individuals with diabetes in the selected districts in the Eastern Cape Province?
- Would the use of mobile phone SMS be effective in improving diabetes knowledge among individuals with diabetes in the selected districts in Eastern Cape Province?
- Would the use of mobile phone SMS be effective in promoting adherence to medication, physical activity and recommended diets among individuals with diabetes in the selected districts in the Eastern Cape Province?
- Would the use of mobile phone SMS be effective in improving the health-related quality of life among individuals with diabetes in the selected districts in the Eastern Cape Province?
- Would the use of mobile phone SMS be effective in improving self-management behaviour, self-efficacy and diabetes distress among individuals with diabetes in the selected districts of the Eastern Cape Province?
- Would the use of mobile phone SMS be effective in improving secondary clinical outcomes (blood pressure and body mass index), among individuals with diabetes in the selected districts in the Eastern Cape Province?
- Would the use of mobile phone SMS be effective in improving behavioural outcomes (smoking and alcohol use) among individuals with diabetes in the Eastern Cape Province?
- How effective is the mobile phone SMS as an appointment reminder among individuals with diabetes in the selected districts in the Eastern Cape Province?

- Is the SMS intervention acceptable to individuals living with diabetes in the selected districts of the Eastern Cape Province?
- Will the SMS intervention be feasible among individuals living with diabetes in the selected districts of the Eastern Cape Province?

1.5 RESEARCH HYPOTHESES

The primary research hypothesis framed for the study is that mobile phone SMS intervention, in addition to standard diabetes care, will significantly reduce blood glucose level among diabetic patients attending diabetes clinics in the Eastern Cape Province compared to standard diabetes care alone.

Secondary hypotheses are:

- Participants in the intervention arm will demonstrate significantly improved knowledge compared to those in the control arm.
- Participants in the intervention arm will demonstrate a significantly improved adherence to medication, physical activity and recommended diets compared to those in the control arm.
- Mobile phone SMS in addition to standard care will increase clinic attendance relative to the usual standard diabetes care.
- Participants in the intervention arm will have a better quality of life than participants in the control group.
- Participants in the intervention arm will demonstrate significantly improved secondary clinical outcomes (blood pressure, weight, body mass index) compared to those in the control group.

- Participants in the intervention arm will demonstrate significantly improved behavioural outcomes (reduced smoking and alcohol use) compared to those in the control group.

1.6 SIGNIFICANCE OF THE STUDY

Inadequate knowledge of diabetes and poor adherence to anti-diabetic regimens have been identified as threats to effective glycaemic control as well as prevention of complications among individuals living with diabetes. Improving knowledge and adherence to anti-diabetic therapy will play a key role in improving glycaemic control and in reducing the morbidity and mortality related to diabetes. Also, since diabetes is a chronic disease, patients' involvement in their care, as well as improvement in their self-management behaviour will go a long way in improving their quality of life. It is believed that the SMS has the potential to build awareness and knowledge about the disease, improve self-management and prevent complications in resource-limited settings. Since some of the previously conducted SMS trials have shown to be effective in some countries and for some other diseases, the findings of this study might help to determine if this same measure could apply to those in the resource-limited areas or communities and whether it will yield any positive result. If this intervention proves to be effective in the current study, large-scale implementation across all the diabetes clinics in the province, and the country at large could be undertaken.

Likewise, the findings of this study may assist in ascertaining the standard of care of diabetes in the settings, identify the obvious lapses and assist in determining the area of care requiring more attention. There is a need for such information for strategic planning for the delivery of quality healthcare services. Finally, the findings of this

study will help policy makers to understand the importance of creating healthcare systems which better meets the need of people, and develop prevention and management strategies for diabetes and other chronic diseases using cost-effective, innovative mobile phone technologies at the national level.

1.7 SCOPE AND DELIMITATION

This study is delimited to adults who have been diagnosed with diabetes, receiving anti-diabetic therapy and are attending the selected diabetes clinics in the Eastern Cape Province. Variables of interest are mHealth technology (SMS), diabetes control, adherence to therapy, knowledge, self-management, self-efficacy, diabetes distress and health-related quality of life of the individuals living with diabetes.

1.8 THEORETICAL FRAMEWORK

The Integrated theory of behaviour change will be used as a guide for this study.

1.8.1 The Integrated Theory of Behaviour Change

The integrated theory of behaviour change is based on the assumption that behaviour change is a dynamic and iterative process (Ryan, 2009). This theory suggests that health behaviour change through engagement in self-management behaviours could be enhanced by fostering knowledge and beliefs, increasing self-regulation skills and abilities and enhancing social facilitation (Institute of Medicine, 2001). Engagement in self-management behaviour is often related to a greater likelihood of achieving the desired result. It further shows that desire and motivation are pre-requisites to change, and self-regulation facilitates progress (Lorig, Ritter, Plant, 2005). The theory also highlights that positive social influences power one's interest and willingness, just as positive relationship helps to support and sustain the change. Additionally, it is

assumed that person-centred interventions, which are often aimed at increasing knowledge, beliefs, skills and abilities, are more effective than standardised interventions in promoting health behaviour change. The integrated theory of behaviour change posits there will be more likelihood for an individual to engage in the recommended health behaviours if they are provided with information, and that they will embrace health beliefs consistent with behaviours if they develop self-regulation abilities and experience social facilitation that positively influences and support them (Barlow, Sturt, Hearnshaw, 2002). Several similar studies involving interventions aimed at facilitating behavioural modifications and improving self-management (Ryan, Pumilia, Henak, & Chang, 2009; Toback & Clark, 2017; Wang, Egelandsdal, Amdam, Almli, & Oostindjer, 2016) have successfully adopted the Integrated theory of Behaviour change, thus, considered a good fit for this study. The integrated behaviour change model is shown in Figure 1.1.

1.8.2 Application of the Theory to the Study

Education and engagement in healthy lifestyle behaviour have been identified as key components in the improvement of health and management of chronic conditions. Glycaemic control and prevention of complications associated with diabetes require diabetic individuals to engage in health-promoting behaviours and comply with a therapeutic regimen. Based on the integrated theory of behaviour change, the health status of the diabetic individual, knowledge of diabetes, as well as factors and skills which influence diabetes control will be assessed. Participants' glycaemic level, blood pressure, weight and behavioural characteristics will also be assessed. Based on the findings of the initial assessment, participants will receive text messages tailored to their needs with the aim of increasing their knowledge and enhancing their self-efficacy, self-management behaviour and outcome expectations about their glycaemic

level. As a way to obtain feedbacks, participants will be provided with the opportunity to forward all queries or issues to the cell number that will be provided, if they so desire. At the end of the intervention, the measures of the expected outcome (self-management behaviours, improvement in lifestyle behaviours) and ultimately clinical outcomes (weight, blood pressure, HbA1c, physical activity, smoking and alcohol use) will be assessed.

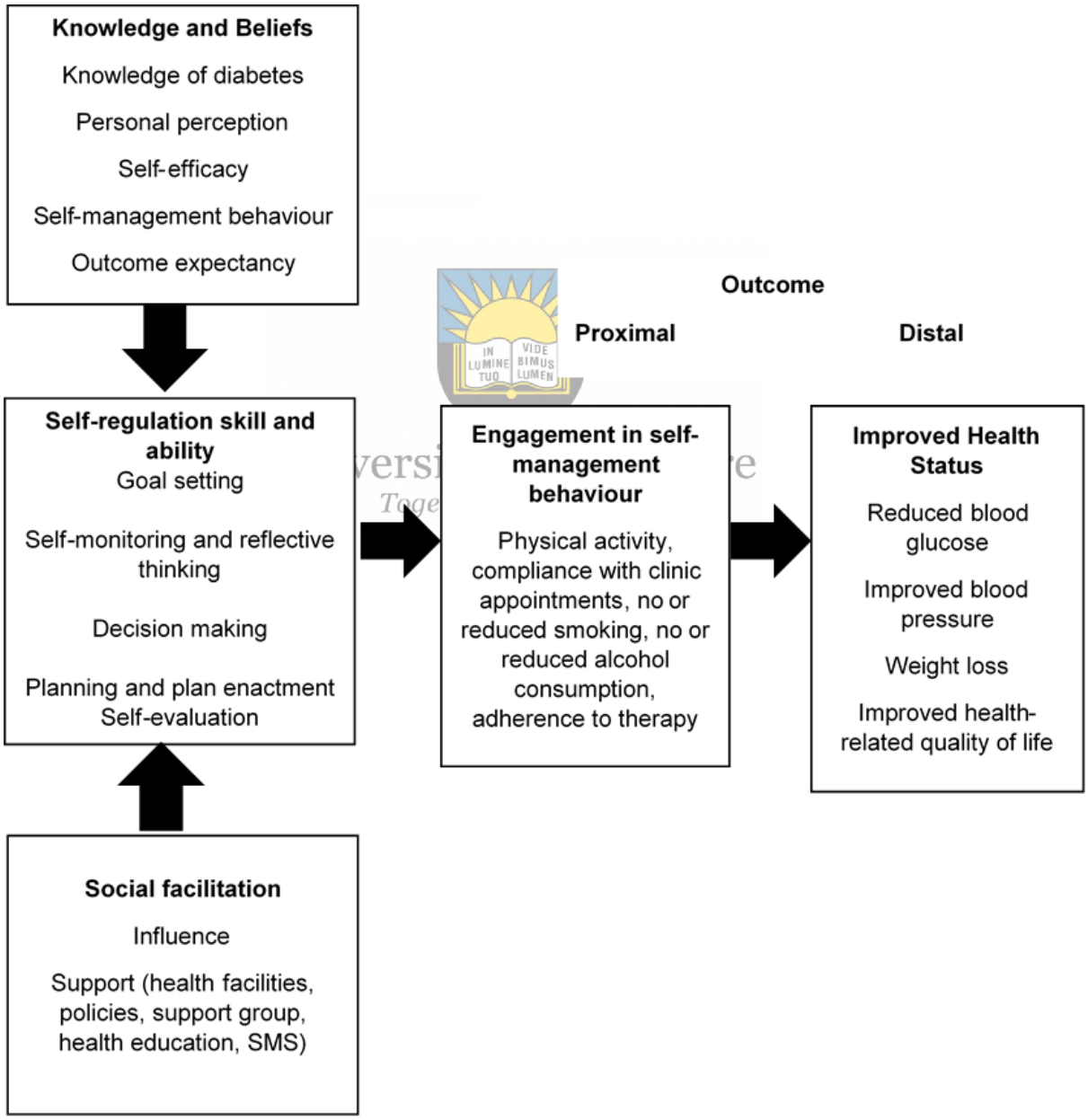

Figure 1.1: Integrated Behaviour Change model

1.9 OPERATIONAL DEFINITION OF KEY TERMS

Efficacy/Effectiveness: Both words are defined as the ability of the mHealth intervention to produce intended results, that is, enhancing self-management, self-efficacy and knowledge, promotion of medication, physical activity and dietary adherence, health-related quality of life, self-management behaviour and glycaemic control among diabetic individuals.

Acceptability: It is defined as the acceptance of the mHealth intervention by diabetic individuals, that is, being satisfied and happy with receiving the text messages and feeling that the SMS is of help.

Feasibility: It is the ability to carry out the mHealth study among diabetic individuals.

Adherence: In this study, adherence means sticking to the prescribed anti-diabetic therapeutic regimen by diabetic individuals.

mHealth: An abbreviation for mobile health. It is the use of mobile devices, specifically, SMS, to support and promote diabetes control.

Glycaemic control: It is the regulation and maintenance of blood glucose levels within normal range.

Therapy: The treatment and management of diabetes mellitus, including medical and lifestyle management.

Anti-diabetic therapy: Administration of drugs, diets and exercise in order to reduce blood glucose level.

1.10 CHAPTER OUTLINE

Chapter 1 presents the background to the study, problem statement, aim, objectives, research questions, research hypotheses, significance of the study, theoretical framework and the definitions of key operational terms. The chapter also describes the division of the study.

Chapter 2 concerns the review of relevant literature. In this chapter, an overview of diabetes, its diagnosis, management, control and its associated factors are presented. Also, the measures of promoting diabetes management and control, adoption of mHealth technology for improving health and the efficacy of mHealth in promoting the various aspects of diabetes management and outcomes are described. Finally, the acceptability and feasibility of text messaging interventions among diabetic patients, possible barriers to the implementation of mHealth interventions and cues for developing an effective text messaging intervention for the management and control of diabetes are analysed.

Chapter 3 describes the research methodology adopted in this study. Aspects such as the design used for the execution of the study, the settings, population, sampling and sample size, randomisation, blinding, SMS development and dispersal, the research instruments, the validity and reliability of the instruments, data collection and ethical considerations are discussed. This is followed by the description of the data analysis approach.

Chapter 4 presents the results of the study and discusses them.

In Chapter 5, a summary of the pertinent findings, together with the limitations and strengths of the study, and what the study adds to the body of existing knowledge are presented. This is followed by the conclusions and recommendations.

CHAPTER TWO

LITERATURE REVIEW

2.1 INTRODUCTION

This chapter focuses on the review of literature on the burden of diabetes, its management, control and associated factors, the role of mHealth technology in healthcare and the potential impact of mHealth on the various components of diabetes management and care. The review also delves into acceptability and feasibility of text messaging interventions among diabetic patients, possible barriers to implementation of mHealth as well as cues for developing an effective text messaging intervention for diabetes control and management. The review of literature and the various components of this chapter was guided by the study objectives and questions. Relevant articles were retrieved from various databases which include EBSCOhost, Google Scholar, Medline, PubMed, PsychINFO, BIOMED Central and Science Direct. The keywords and phrases used for searching for relevant literature were mHealth interventions for diabetes, text messaging interventions for diabetes, randomised controlled trials using text messaging among diabetic patients, text messaging interventions for improving glycaemic control, text messaging interventions for improving adherence and self-management, mHealth interventions among diabetic patients in South Africa, acceptability of mHealth, and feasibility of mHealth.

2.2 DIABETES MELLITUS: AN OVERVIEW

Diabetes mellitus is a metabolic disorder characterised by a high level of blood glucose, resulting from a defect in insulin secretion, insulin action or both (American Diabetes Association [ADA], 2018; Diabetes Australia, 2015; WHO, 2018). Diabetes

mellitus constitutes a significant public health challenge globally and in South Africa (Al-Lawati, 2017; Zimmet, Magliano, Herman & Shaw, 2014; IDF, 2017). It is also a priority disease on various health agendas and its prevalence and associated burden is continually on the increase (Wang et al., 2018; WHO, 2014). The mortality associated with diabetes is higher than those associated with HIV/AIDs, tuberculosis and malaria combined (Amod et al., 2017; IDF et al., 2017). Worryingly, there is a widespread burden of diabetes in both the urban and the rural areas, particularly among the poor, contrary to previous reports of diabetes being a disease of affluence (Hall, Thomsen, Henriksen & Lohse, 2011; Mbanya, Motala, Sobngwi, Assah & Enoru, 2010; Peer et al., 2014; WHO, 2016a). This constitutes a socio-economic threat and imposes a greater burden on the already over-stretched healthcare system in many nations (Nolan, Damm & Prentki, 2011:1).

Low and middle-income countries, including South Africa, are confronted with a high burden of diabetes, a continual increase in prevalence, poor level of control, younger age of onset and inadequate healthcare system (Johnston, Zemenek, Reeve & Grills, 2018). South Africa is ranked second in Africa in terms of diabetes burden (IDF, 2017; Kahn, 2011:1; Nojilana et al., 2016; Peer et al., 2014). Currently, 5.4% of South African adults have diabetes, and as much as 70% are unaware of it (IDF, 2017). The burden of diabetes is more grievous among rural dwellers (Amod et al., 2017).

Various factors underlie the increasing burden of diabetes in South Africa of which obesity is foremost (Manyema et al., 2015:1). Aside obesity, several scholars have also highlighted the contributory role of various modifiable and non-modifiable factors like physical inactivity, poor dietary practices, harmful alcohol use, smoking, age and urbanisation to the growing burden of diabetes (Bhupathiraju & Hu, 2016:1; Gray,

2014; Lun et al., 2013:5; Park, 2011; Schrieks, Heil, Hendriks, Mukamal & Beulens, 2015:6; Subramanian & Chait, 2012:1). The most common form of diabetes is type 2 diabetes found in 90 to 95% of individuals living with diabetes, while just 5 to 10% of them have type 1 diabetes (ADA, 2019; Anik, Catli, G., Abaci, A., Bober, E., 2015; Hope et al., 2016).

2.3 DIAGNOSIS OF DIABETES

There are two basic measures of diagnosing diabetes, based on the South African diabetes management guideline (Amod et al., 2017).

The diagnosis of diabetes mellitus is made and confirmed in the presence of a random plasma glucose ≥ 11.0mmol/l, a fasting plasma glucose ≥ 7.0mmol/l, glycated haemoglobin (HbA1c) ≥ 6.5% or a two-hour oral glucose tolerance test ≥ 11.1mmol/l (Table 2.1), and the manifestation of symptoms such as polyuria, polydipsia, polyphagia, loss of weight, blurry vision and diabetes ketoacidosis. Also, in the absence of symptoms manifestation, two-time tests conducted within a two-week interval revealing the same thresholds for the above tests is confirmatory of diagnosis. However, a discrepancy in the repeated test is confirmed after 3 or 6 months, while the patient is placed on lifestyle modifications.

Table 2.1: Diagnosis of Diabetes

Test type	Threshold and diagnosis	Threshold and diagnosis	Threshold and diagnosis
FPG (mmol/l)	< 5.6 DM excluded	6.0-6.9 Impaired fasting glucose	≥ 7.0 Diabetes
2-hr OGTT (mmol/l)	<7.8 Normal tolerance of glucose	7.8 – 11.0 Impaired glucose tolerance	≥ 11.1 Diabetes
HbA1c (%)	< 6.5 Inconclusive		≥ 6.5% Diabetes
RPG (mmol/l)	< 5.6 Diabetes excluded	5.6-11.0 Inconclusive	≥ 11.1 Diabetes

FPG= Fasting plasma glucose; OGTT= Oral glucose tolerance test; HBA1c: Glycated haemoglobin; RPG= Random plasma glucose; mmol/l= Millimole/Litre.

2.4 MANAGEMENT AND CONTROL OF DIABETES

Diabetes control is highly dependent on the quality of management. This section describes the various approaches to diabetes management as well as diabetes control and its associated factors.

2.4.1 Management

The overarching aim of all diabetes management measures is to bring about a positive change in glycaemic status, ensure the attainment of the set treatment goals, improve health and quality of life as well as prevent or delay the development of complications (ADA, 2018). Various approaches exist in the management of diabetes, owing to its complex nature (Amod et al., 2017). The various measures of managing diabetes involve the use of medical therapy and various lifestyle and behavioural modifications (Inzucchi et al., 2015; Reusch & Manson, 2018:2; Ryde et al., 2013). Irrespective of the management approach, it is important to individualise care, taking into consideration the various characteristics of the patients (Inzucchi et al., 2015; Ryde et al., 2013).

The pharmacological approach to diabetes management varies per disease type due to the various causes associated with the different types of diabetes. In patients with type 1 diabetes, insulin therapy is required to account for the absolute lack of insulin underlying the disease (Home et al., 2014). On the other hand, individuals living with type 2 diabetes might require lifestyle modifications at the initial stage to control the presence of various other risk factors like excess weight, high blood pressure and dyslipidaemia (Inzucchi et al., 2015). In addition, there could be a need for anti-diabetic medications or inclusion of insulin injection for management as the disease progresses (Amod et al., 2017). Recent review and several authors show metformin as the first drug of choice for managing diabetes as a result of its efficacy and minimal side effects (Amod et al., 2017; Bennett et al., 2011; Palmer & Strippoli, 2018:1; Rojas & Gomes, 2013; Wang et al., 2017:1). There are also other available drug options like the sulphonylureas, DPP-4 inhibitors, GLP1 agonists and the SLGT2 inhibitors (Christensen, Rungby & Thomsen, 2016; Fowler, 2010; Hinnen, 2017:3; Hsia, Grove & Cefalu, 2017:1; Khunti, Chatterjee, Gerstein, Zoungas & Davies, 2018; Rositer, 2016; Thule & Umpierrez, 2014:1; van Dalem et al., 2016:3). Often, patients require a combination of drugs to attain the targeted glycaemic status of HbA1c level less than 7%, fasting blood glucose level less than 7mmol/L or a random blood glucose level less than 10mmol/L (Amod et al., 2017).

The non-pharmacological approach entails behavioural or lifestyle modifications, which can be combined with pharmacological treatment to enhance glycaemic control and prevent the development of complications (Inzucchi et al., 2015; de Pablo-Velasco et al., 2014; Ryde et al., 2014). A healthy lifestyle is crucial in the management of diabetes, especially type 2 diabetes, just as it is required for healthy living among the general population (Amod et al., 2017). Such lifestyle modifications include the

adoption of healthy dietary practices, increased activity pattern, weight reduction, and avoidance of alcohol and tobacco use (Miller et al., 2014:2; Raveendran, Chacko & Pappachan, 2018).

Unhealthy dietary practices increase blood glucose level, and non-adherence to healthy dietary choices is a worldwide and significant challenge in the management of diabetes (Miller et al., 2014:2). Some authors have linked high level of unhealthy dietary practices among the populace to cultural beliefs and social factors (Laraia, Leak, Tester & Leung, 2017). This is also a source of concern in South Africa where a large number of the populace care less about the nutritional content of the purchased and consumed food items (Shisana et al., 2013). Likewise, engagement in physical activity is paramount, as it helps to improve insulin sensitivity and other cardiovascular risks, thus promoting glycaemic control (Reiner, Niermann, Jekauc & Woll, 2013; WHO, 2011). Equally, alcohol use predisposes one to the development of other cardiovascular risks and enhances the development of hypoglycaemic episodes or life-threatening conditions like diabetic ketoacidosis among diabetic patients (Kim & Kim, 2012:1). While some scholars argued that the use of alcohol has some protective effects on diabetes (Metcalf, Scragg & Jackson, 2014; Schrieks et al., 2015:6), a recent GBD study pointed at no safety level associated with any degree of alcohol use (GBD Alcohol Collaborators, 2018). Tobacco use also has similar adverse effects, and as such, alcohol and tobacco use are discouraged among diabetic patients to attain the set treatment targets (Park, 2011).

2.4.2 Diabetes control and associated factors

Despite advancement and the demonstrated efficacy of pharmacological and non-pharmacological therapies, the control of diabetes remains a daunting task (Teoh et

al., 2010). Control of diabetes generally seems to be a mirage as several studies across various countries often report a high rate of poorly controlled diabetes worldwide (Camara et al., 2015; Khan et al., 2015; Kibirige et al., 2014; Teoh et al., 2010). Of all the various cardiovascular risks factors, reaching a diabetes treatment target appears to be the most challenging (Willard-Grace et al., 2015). It is reported that 43% of diabetic patients reach their treatment target, against 50% and 83% reaching their blood pressure and lipid targets, respectively, in the United States (Cheung et al., 2009; Egan, Zhao & Axon, 2010; Ford, Li, Pearson, Zhao & Mokdad; 2010).

Glycaemic control in developing nations is not encouraging. A national survey conducted among Chinese adults reported a glycaemic control rate of 39.7% in 2013 (Xu et al., 2013:1), a rate higher than other studies (Li et al., 2013:8; Liu et al., 2016:4) reporting 21% glycaemic control rate among rural Chinese adults. This further buttresses the reported higher burden of diabetes among rural dwellers. Other studies in China also demonstrated a low rate of control among diabetic individuals (Hu et al., 2011; Lv, Pan, Xiang & Wu, 2011; Yang et al., 2012). Studies conducted in India (Singh, Kalaivani, Krishnan, Aggarwal & Gupta, 2012) and Thailand (Porapakkham, Pattaraarchachai & Aekplakom, 2008) also reported low control rates of diabetes, 16.9% and 21.6% respectively. Another study conducted among Bangladeshi adults reported even a lower control rate of 14.2% (Rahman et al., 2015:1).

In South Africa, attaining glycaemic control among individuals living with diabetes appears to be a challenging task for both healthcare professionals and patients (Booysen & Schlemmer, 2015). A study by Adeniyi et al. (2016) in the Eastern Cape province of South Africa reported over 80% of the participants had poorly controlled

diabetes. This is similar to the reported rates of sub-optimal control of diabetes in other provinces of South Africa (Daramola, 2012; Igbojiaku et al., 2013; Kadima & Tumbo, 2013). As a result, there is a resultant predisposition to complications development, leading to poor quality of life, disability, premature mortality and excessive burden on the individuals, thus placing significant strain on the already overburdened healthcare system (ADA, 2018; Ismali-Beigi et al., 2010:1; Jha, Aubert, Yhao, Teagarden & Epstein, 2012; Nasseh, Frazee, Visaria, Vlahiotis & Tian, 2012). Despite the high burden of sub-optimal glycaemic control in South Africa, there are few measures and documented interventions for diabetes control.

Generally, factors affecting diabetes care in majority of the developing nations are patient-related, social or healthcare system-related factors (Venkataraman, Kanna & Mohan, 2009). Patient-related factors include poor level of knowledge of diabetes (Zimmet et al., 2014), while social and healthcare system factors range from shortage of manpower, deficiency in disease management guidelines, poor infrastructures and poverty (Venkataraman, Kanna & Mohan, 2009; Zimmet et al., 2014). More specifically, Li et al. (2013:11) showed that risk factors such as obesity, smoking, physical inactivity, as well as genetics influence the control of diabetes. Poor adherence to medications, poor adherence to recommended lifestyle regimen and poor self-management behaviours of the patients also contribute to the sub-optimal control of diabetes (Adeniyi et al., 2016; Kagee et al., 2004; Liang et al., 2011; Willard-Grace et al., 2015).

Socio-demographic factors also affect glycaemic control. Rahman et al. (2015:8) established an association between younger age, lack of education and poverty, and poor treatment and control of diabetes among Bangladeshi adults. On the contrary,

Liu et al. (2016:4) found no significant association between control of diabetes and risk factors such as age, level of education, family history of diabetes, physical activity, fruit and vegetable consumption and BMI among rural Chinese adults. Diabetes control varies across different socio-economic levels and geographical settings (Liu et al., 2016:4). Studies have shown that individuals with a lower level of income and literacy usually have a higher level of sub-optimal diabetes control (Assari, Moghani, Lankarani, Piette & Aikens, 2017:5; Houle et al., 2016:1; Rahman et al., 2015:8; Sutherland et al., 2018:1). Likewise, participants in the rural areas often have a higher level of sub-optimal glycaemic control compared to urban settings plausibly because of inadequate access to medical practitioners or the quality of the health services rendered (Adeniyi et al., 2015). Li et al. (2013:9) however reported no significant variation in the control of diabetes between urban and rural populations.

2.5 MEASURES OF PROMOTING DIABETES MANAGEMENT AND CONTROL

Attaining the set glycaemic target and achieving glycaemic control are key in the management of diabetes (Ali et al., 2013). In recognition of the pressing need to combat the growing burden of diabetes and its control, several interventional approaches are currently being implemented and evaluated. Previous interventional measures to promote glycaemic control and better management of diabetes aimed at improving the doctor-patient relationship (Mash, Ponieman, Leventhal & Halm, 2012; Olry de Labry Lima et al., 2017). Others were family-oriented interventions where family members and caregivers undergo educational sessions to assist the diabetic patients (Baig, Benitez, Quinn & Burnet, 2015; Garcia-Huidobro, Bittner, Brahm & Puschel, 2011:1).

Diabetes treatment and outcomes are strongly related to health and lifestyle behaviours, psychosocial state and socio-economic status of the patient (Luczynski, Glowinska-Olszewska & Bossowski, 2016:1). Current management of diabetes entails a shift from the disease itself, towards empowering the patient to take responsibility of their care in order to enhance treatment outcomes (Chatzimarkakis, 2010; Tol, Alhani, Shojaezadeh, Sharifirad & Moazam, 2015). Diabetes is a patient-managed disease; hence, the major decisions that foster diabetes management and outcomes are highly dependent on the patient (Luczynski, Glowinska-Olszewska & Bossowski, 2016:2; Tol et al., 2015). Consequently, there is a dire need to educate and empower patients (Grant et al., 2013; White, 2012), provide advocacy and improve knowledge of the patients on the various measures of managing diabetes and achieving better health outcomes (Berg, Dedd & Dodd, 2009; Mash, Ponieman, Leventhal & Halm, 2012; Schwellnus et al., 2009). Such empowerment programmes are crucial because the willingness and the decision to make the recommended changes lies with the patients and these empowerment programmes facilitate such decision (White, 2012).

Empowering patients through health education can enhance their knowledge, self-management behaviours and self-efficacy, and such intervention is a widely recognised practice in healthcare settings (Brunisholz et al., 2014; Powers et al., 2017). However, due to the excessive workload coupled with an inadequate workforce, there are limited opportunities to conduct educational sessions with patients. (Boels et al., 2017:2). Consequentially, the time-limited face-to-face approach of health education is being augmented with new innovative measures using Information and Communication Technology (ICT), with the most commonly used being mHealth technologies (Bodenheimer & Pham, 2010; Forjuoh, Ory, Jiang, Vuong & Bolin, 2014; Ricci-Cabello et al., 2014).

The use of ICT to foster health, even among diabetic patients is premised on the assumption that such measures could improve patient's knowledge, and improvement in knowledge could, in turn, improve self-management behaviours and adherence which could ultimately improve health outcomes (Balsa & Gandelman, 2010). Nonetheless, some individuals are reluctant to embrace ICT measures for empowering patients, especially the use of advanced ICTs, involving the use of internet, particularly among those in the low-income regions and the less educated ones (Balsa & Gandelman, 2010). Similar reluctance is observed on the part of researchers to implement such measures, especially in the developing nations, including South Africa, and among chronic patients, despite the rapid penetration of ICT.

2.6 MHEALTH TECHNOLOGY: A NEW HORIZON FOR HEALTH

Worldwide, there is an exponential growth in telecommunication, both in high and low-income countries, which allows people to communicate across geographical settings, including the rural and inaccessible places (International Telecommunication Union (ITU), 2010). Mobile Health (mHealth) is evolving as a vital and promising tool for addressing health system challenges like inadequate health care workforce, restrained finances, increasing burden of disease, exponential increase in population size and challenges in extending healthcare to the hard-to-reach population groups, even in developing countries (Fjeldsoe, Marshall & Miller, 2009; Lester & Karanja, 2008; Mechael et al., 2010; Pop-Eleches et al., 2011). mHealth has the likelihood of offering accessible health care, bridging the equity gap and generally improving healthcare, even in developing economies (Beratarrechea et al., 2014:8).

The World Health Organisation describes mHealth as a new horizon for health, and the adoption of mobile or wireless technologies promotes the attainment of health goals (WHO, 2011:1). The Global Observatory for eHealth (GOe) of the World Health Organisation described mHealth as public health and medical practice promoted by the use of mobile devices like mobile phones, patient monitoring devices, personal digital assistants and other wireless devices (WHO, 2011). It involves the use of the core utility of voice and short messaging service (SMS) and at times other advanced options such as the general packet radio service (GPRS), third or fourth generation mobile telecommunications (3G and 4G systems), global positioning system (GPS) as well as the Bluetooth technology (Rampatige, Abusayeed & Galappaththi, 2010:2).

The use of mHealth has been shown to have the ability to drive change in the face of health care service delivery globally (WHO, 2011:9). Innovative thinkers are already grabbing the prospect for information access to harness the potential of mobile technologies for public health benefits (Wambugu & Villella, 2014). mHealth is continually changing the lives of people around the globe (Wambugu & Villella, 2014). mHealth generally offers an effective means of improving health care services access, health information and as well reducing the cost of health delivery (Beratarrechea et al., 2014). The exponential rise in the use of mHealth is driven by the unprecedented spread in mobile technologies and applications as well as the continual improvement in mobile cellular network coverage (Betjeman, Soghoian & Foran, 2013:1; Latif et al., 2016:1; WHO, 2011:9).

Currently, more than five billion wireless users exist, and out of this, more than 70% are found in developing countries, with an increase in coverage of wireless signals, reaching up to 85% of the population (International Telecommunication Unit (ITU),

2011; Wallis, Blessing, Dalwai & Shin, 2017). Even more, the rate of penetration of mobile health technologies and network in many developing countries is beyond that of other infrastructures such as roads and electricity (WHO, 2010). As at 2014, estimates showed that the number of mobile connections surpassed the number of people worldwide (MEASURE Evaluation, 2016). The rise in mobile health technologies is positively impacting access, delivery and management of health services and information, which could foster more individualised care, even at a low cost (Campos & Olmstead-Rose, 2012; Stephanie, Hill, Ricks, Bennet & Oriol, 2017:1). If properly implemented, mHealth can reform health outcomes, by providing everyone with access to mobile phones with medical expertise, information and knowledge without delay (WHO, 2011:77).

Globally, various mHealth initiatives include the use of health call centres, mobile telemedicine, emergencies and disasters management, toll-free emergency telephone services, appointment reminders, treatment compliance, mobile patient records, community mobilization and health promotion, information access, monitoring of patients, health surveys and collection of data, health surveillance, health awareness creation, and decision support systems (WHO, 2011:9; Latif et al., 2017:2). The list is not exhaustive as several other measures are being proposed to be added up with time (Health Systems Trust (HST), 2015). Of the 14 mHealth initiatives, the four most offered services across WHO member states are; health call centres, emergency toll-free telephone services, emergencies and disasters management, and mobile telemedicine, in order of utilisation, even though majority of these services are still in their initial piloting stage, except for the health call centres (WHO, 2011:10). In all, the mHealth initiatives are generally divided into three broad categories: mHealth targeted at patients or the populace, mHealth focusing on supporting healthcare professionals,

and mHealth initiatives aimed at supporting health institutions in healthcare delivery (HST, 2015).

The utilisation and coverage of these mHealth initiatives differ across various socio-economic strata, with the developed countries, most especially European countries, documenting more success in adoption and utilisation, while Africa region is still lagging behind (Kay, Santos & Takane, 2011; WHO, 2011:10). One of the greatest barriers to the adoption of mHealth is the conflicting health system priorities where countries are embattled with challenges like several health conditions, shortage of staff and restrained resources or limited budgets (Aamir et al., 2018, Mechael et al., 2010; Saleh, Khodor, Alameddine & Baroud, 2016; Van Velthoven & Car, 2015). As such, there is a need for strong evidence to support the effectiveness of these initiatives through evaluation processes in order to attract the attention of policy makers, administrators and other key stakeholders involved in decision making (Mechael et al., 2010).

Governments are also showing interest in mobile health technologies as a means of strengthening the healthcare systems and attaining the set sustainable development goals in developing countries (ITU, 2010). The use of mHealth spans through various health conditions and programmes such as maternal and child health as well in the management of other forms of diseases associated with poverty such as HIV/AIDs, tuberculosis, malaria and other chronic conditions (Baron et al., 2018:4; de Tolly, Nambaware & Skinny, 2011:1; Leon, Surender, Bobrow, Muller & Farmer, 2015; Quan, Hulth, Kok & Blumberg, 2014:5).

South Africa is no exception in the exponential increase in mHealth initiatives taking place worldwide. As reported in the All Media Products Survey in 2014, 85% of South Africans have access to mobile phones, and all households possess a mobile phone, which makes the use of mobile phone the most pervasive measure of communication in South Africa since 2009 (South African Audience Research Foundation (SAARF), 2017). More importantly, almost all the mobile phone users at least engage the use of SMS and voice (HST, 2015:11). South Africa has more than 76 million mobile phone subscribers with two-thirds of the mobile phone owners in low-income groups and aged 15 years and older (SAARF, 2017; HST, 2015). Owing to this, the mHealth is seen as a facilitator for improved health systems and has a possibility of transforming health care delivery, while producing socio-economic benefits in terms of fostering the effectiveness and efficiency of healthcare (HSR, 2015).

Even though South Africa is fairly better equipped in the area of ICT infrastructure compared to many of the emerging economies in the world, the challenge of high cost of connectivity abounds with few areas still lacking coverage (HSR, 2015). Generally, there is a paucity of local research projects involving mHealth across South Africa (HSR, 2015). The most popular intervention involving the use of mHealth in South Africa is the MOMConnect programme aimed at improving maternal health (Baron et al., 2018:4). Till date, there is hardly any such programme for the management and control of diabetes in South Africa, despite the wide use of this measure for diabetes management globally and the obvious growing need to combat the escalating burden of diabetes in South Africa. This is a pressing concern that warrants attention. The only available mHealth programme related to diabetes in South Africa was recently set up to assess people for diabetes (Chowles, 2016). This could be a step towards improvement. However, this programme might not be accessible to those in resource-

restrained areas and is more beneficial for prevention and diagnosis of diabetes, rather than its management.

Short message service (SMS) is the most commonly used and widely available mHealth technology (Lassica, 2007; Stewart & Quick, 2009). Due to the positive attributes of the SMS such as the direct linkage to the recipient, confidentiality, convenience and the spontaneity of delivery, users find it appealing (Balsa & Gandelman, 2010:1; Gurol-Urganci, de Jongh, Vodopivec-Jamsek, Atun & Car, 2013:4; Milne, Horne & Torsney, 2006). Similarly, text messaging allows for several messages to be sent across a large platform simultaneously (Chen, Fang, Chen & Dai, 2008). Several studies and reviews have already being conducted on the use of mHealth, including text messaging, in improving health outcomes among diabetic patients (Arambepola et al., 2016; Dobson et al., 2018; Dobson et al., 2016; Doodarzi et al., 2012; Quinn et al., 2011; Wu et al., 2017), with only a few focusing on developing countries (Beratarrechea et al, 2014; Johnston et al., 2018), very few in Africa (Pop-Eleches et al., 2011; Shahid et al., 2015), and only a recent online platform for assessing diabetes in South Africa (Chowles, 2016). This is an obvious gap that needs to be addressed as there are differing patients' characteristics, disease profile, and quality of healthcare between different world economies and even across various countries, and as such various interventions or approaches might yield different results in different settings. It is, therefore, paramount to explore this option in more developing countries, especially in South Africa, a country with a significantly high burden of diabetes and sub-optimal control (IDF, 2017). Thus, studies aimed at addressing these gaps, particularly in remote areas with high burden of diabetes and where healthcare is sub-optimal are warranted.

2.6.1 Efficacy of mHealth in promoting glycaemic control

Provision of continual diabetes support forms part of many clinical guidelines, yet, no effective developed strategy for offering such supports and even sustaining the observed changes seems to be in place (ADA, 2018; Arambepola et al., 2016:4; Powers et al., 2017). Goodarzi et al. (2012:1) stated that the glycaemic status of patients could improve by enhancing their knowledge, attitude and self-efficacy. There is growing evidence of the use of mHealth in fostering various components of diabetes care and management and ultimately improving glycaemic control (Dobson et al., 2018:5; Islam et al., 2015:1; Quinn et al., 2011:6). The use of mHealth platforms assists in providing individualised healthcare at the patient's convenience (Bonoto et al., 2017:1). The added model of diabetes care using text messaging has the potential for improving the health outcomes of diabetic patients even in developing countries (Goodarzi, Ebrahimzadeh, Rabi, Saedipoor & Jafarabadi, 2012). However, the use of mHealth in remote areas and among people with low level of education is sparsely studied.

Various studies have examined the effectiveness of various mHealth interventions, including SMS, on diabetes care and outcomes. Liang et al. (2011:1) documented a 0.5% statistically significant reduction in mean HbA1c levels of diabetic individuals following mobile phone interventions over an average of six months, specifically among those with type 2 diabetes. Similarly, a systematic review conducted by Wu et al. (2017:1) on twelve clinical trials involving the use of technological applications documented a significant reduction in glycaemic status measured by HbA1c, a mean difference of 0.48%, with minimal side effects. According to this review, the effect or reduction observed was more pronounced among individuals with type-2 diabetes. The review of six clinical trials by Bonoto et al. (2017:1) also reported similar findings

of a significant reduction in HbA1c in the group which took part in the mHealth interventions. Unlike the study by Wu et al. (2017), the observed improvement in HbA1c found in the meta-analysis by Bonoto et al. (2017:1) showed that the recorded improvement did not vary, irrespective of the type of diabetes. In spite of the documented reduction in glycosylated haemoglobin reported in the various studies, the HbA1c levels attained in the studies included in the meta-analysis was still below the acceptable standard regarded as good glycaemic control (7.0%), as all the studies had an average of 8.3% (Charpentier et al. 2011; Bonoto et al., 2017). Irrespective of the significance level, a slight improvement in glycaemic status, as low as 1% reduction in HbA1c is associated with a 35% decrease in the risk of developing vascular complications (Charpentier et al., 2011).

Pertaining to the use of SMS, a systematic review conducted by Dobson et al. (2017:1) recorded mixed findings. Even though there were some positive influences recorded on glycaemic control among diabetic patients, the use of SMS services as a proxy for improving glycaemic control among those with poorly controlled diabetes showed mixed and unclear results. The pooled data from ten intervention studies by Safari et al. (2014:1) showed a significant reduction in HbA1c among those offered text messages, an effect size of 44%. However, the combined use of internet and text messaging showed a significant increase in effect size to 86%. A systematic review and meta-analysis by Arambepola et al. (2016:1) also recorded an overall positive impact on HbA1c, a -0.53% reduction among those who were offered the SMS services for diabetes in thirteen clinical trials. Several studies also recorded positive impacts on change in HbA1c following text messaging (Abebe et al., 2013:1; Goodarzi et al., 2012). Of note, majority of the studies included in these reviews and meta-analysis were conducted in developed countries, thus, raising questions on the proven

efficacy of mHealth in settings where the healthcare system is not optimal, like the African settings.

Asides the various systematic reviews and meta-analysis, examining individual studies, Quinn et al. (2011:6) in their randomised trial conducted in the United States for twelve months also demonstrated a significant improvement in HbA1c among diabetic individuals who received text messages, a decline of 1.9% compared to 0.7% in the control arm. Similarly, another trial conducted in a developing country, Bangladesh precisely, demonstrated a significant improvement in HbA1c levels among diabetic patients who received daily SMS for six months compared to those who did not receive the SMS; the mean difference was -0.66 (Islam et al., 2015:1). However, there was a greater improvement among women, participants with HbA1c level higher than 8% as well as participants with a shorter duration of illness. The study by Shetty et al. (2011) is also in agreement with these findings of improved glycaemic status following a one-year intervention for diabetic patients, using SMS. Many of the interventions were rarely conducted in rural settings and do not solely utilise text messages, and are at times combined with other measures such as clinicians or patients' feedback or the addition of web-based programmes (Goodarzi et al., 2012; Noh et al., 2010; Tamban, Isip-Tan & Jimeno, 2013:5; Quinn et al., 2011). There is a possibility that the added measures could have positively impacted the health outcomes (Kitsiou, Pare, Jaana & Gerber, 2017). However, the use of the extra added measures to the SMS might be a challenging task among rural dwellers, as many do not have access to smartphones or computers that could perform such tasks. This raises another question on the reported efficacy of the mHealth in rural areas, which warrants investigation. A study conducted among rural Pakistanis adults showed a significant improvement in blood glucose level in the intervention arm at the different

study periods (Shahid, Mahar, Shaikh & Shaikh, 2015). This study, however, included the use of phone calls bimonthly for feedback and support and did not conduct a between-group analysis; they only assessed the difference in the different measures in the two arms, a within-group analysis.

On the contrary, Capozza et al. (2015:5) reported an improvement in HbA1c in both arms of their trial, with no significant difference between those who received the SMS and those who did not. They ascribed this to a possible general improvement in the standard of care at the various primary health care clinics from where patients were recruited. Another SMS intervention conducted among diabetic patients attending emergency services also documented similar findings of improvement in both arms, with no significant difference (Arora, Peters, Burner, Lam & Menchine, 2014:1). Similarly, Kollman, Riedl, Kastner, Schreier and Ludvik (2007:10) reported no significant improvement in fasting blood glucose level following SMS intervention among diabetic patients.

Generally, there are conflicting findings on the efficacy of mobile technology in improving glycaemic control, and this warrants further investigation. Although developing countries are beginning to embrace the use of mHealth to foster diabetes care, South Africa still appears to be lagging behind in this aspect. Studies have rarely been conducted on the efficacy of mobile technology in improving diabetes care in South Africa. This present study, therefore, seek to implement an mHealth-based intervention for diabetes management and evaluate its effectiveness.

2.7 COMPLIANCE AND ADHERENCE TO TREATMENT AMONG DIABETIC PATIENTS

Treatment success is highly dependent on the level of adherence and compliance among the patients (Jimmy & Jose, 2011:1). Non-adherence to treatment constitutes a significant challenge to both the patients and the healthcare system (Polonsky & Henry, 2016:2). Non-adherence or non-compliance with medication therapy is often associated with poor treatment outcomes, high healthcare cost, poor quality of life, worsening of the health of the individuals, development of complications and if care is not taken, could lead to death (daCosta et al., 2014; Egede et al., 2014; Egede et al., 2012; Jha et al., 2012; Jimmy & Jose, 2011; Nasseh et al., 2012; Polonsky & Henry, 2016:2; Roebuck, Liberman, Gemmill-Toyama & Brennan, 2011). Generally, patients suffering from chronic conditions are reportedly non-adherents with only half of them adhering in developed nations and a far lower number in developing nations (Cramer et al., 2008; Osterberg & Blaschke, 2005). As important as adherence is, interventional studies which target improvement in medication adherence is currently preferred even to improvement in medical therapies, in terms of its general effect on health (Thakkar et al., 2016). Among diabetic patients, adherence and compliance to treatment and other recommended therapies are quite important in achieving treatment targets, yet, reports show a low level of adherence among these patients (Eaddy et al., 2012; King et al., 2009). Notably, adherence to treatment goes beyond medical therapy; it also includes other forms of management like prescribed behavioural modifications, appointments, among others (Garcia-Perez, Alvarez, Dilla & Gill-Guilan, 2013:2).

Various barriers to adherence have been identified and these include poor communication between the healthcare provider and the patient, poor knowledge of the disease condition and the therapy, duration of drug use, age, complexity of the

regimen, fear of side effects, costs of medication, lack of trust in the physician and lack of conviction on the need for treatment (Coleman et al., 2012; de Vries et al., 2014; Eaddy et al., 2012; Garcia-Perez et al., 2013; Gadkari & McHorney, 2010; Kirkman et al., 2015; Polonsky & Henry, 2016:4; Walz et al., 2014). Socio-demographic factors also contribute to poor adherence rates among diabetic patients, and these include younger age, low level of education and low level of income (Curkendall et al., 2013; Kirkman et al., 2013).

2.7.1 Efficacy of mHealth technology in promoting compliance and adherence to treatment

The need for a more convenient measure of assisting patients in adhering to treatment is of utmost importance (Nieuwlaat et al., 2014), and the use of mobile health technologies in improving health has emerged (WHO, 2011). According to WHO, the use of mHealth in promoting treatment compliance includes the use of phone calls, voice or SMS for transmitting reminder messages, promoting compliance to treatment, eradicate of diseases and scale the issues of challenges with drug resistance (WHO, 2011). This has been demonstrated among individuals with various health conditions. For instance, in Europe, the use of mHealth was used as a measure for promoting treatment compliance among individuals with chronic illnesses such as diabetes, tuberculosis and HIV/AIDS, obesity, asthma, and chronic obstructive pulmonary disease (Holtz & Whitten, 2009; Liu et al., 2011:4; Quinn et al., 2011). The same measure was also adopted in Czech Republic for reminding women to take their oral contraceptive pills, using SMS (Corker, 2010). Also, this measure has been employed in New Zealand for smokers in the widely acclaimed and effective study called Txt2Quit, where smokers were sent support messages towards their attempts to quit smoking (Li, 2009). The programme recorded success in terms of the number of new

individuals attracted to it monthly and was recently adopted in Canada (STOMP-TELUS, 2018). The same measure has been adopted and documented in Africa and other resource-restrained settings and among different socio-economic groups (Islam et al., 2015; Pop-Eleches et al., 2011). However, there exists a gap in this regard in South Africa.

Concerning the use of SMS reminders as a measure of promoting medication adherence among diabetic patients, Vervloet et al. (2012:1) documented a significant improvement in medication adherence among diabetic patients in the Netherlands following six months of sending SMS reminders. Arora et al. (2014), however, showed a non-significant improvement in medication adherence among low-income Latino diabetic patients following a unidirectional text messaging intervention. In the same vein, another study conducted among Asian-Indian diabetic patients showed a non-significant improvement in the number of annual check-up and adherence with dietary prescriptions (Shetty et al., 2011:1). This is also similar to the findings of Sugita, Shinohara, Yokomichi, Suzuki and Yamagata (2017:6) among Japanese diabetic patients. Obviously, there are conflicting results on the impact of text messaging on adherence and compliance to therapy, and more importantly so, there is a definite gap in knowledge on this measure in African settings, including South Africa. Variation in study methodology could be a contributing factor to the varying results on the efficacy of mHealth technology in promoting adherence. For example, Shetty et al. (2011:1) made use of real-time monitoring where reminders were sent when patients forget to use their medications, while other studies send a random reminder message, these variations could impact results.

2.8 COMPLIANCE WITH APPOINTMENT AMONG DIABETIC PATIENTS

Appointment reminder is a crucial health initiative as missed appointments often have significant health, financial and operational cost implications (Schectman, Schorling & Voss, 2008). Missed appointments are responsible for inefficient healthcare services, delayed diagnosis and treatment as well as poor treatment outcomes (Berg et al., 2013; Fischer et al., 2017; Gurol-Urganci et al., 2013:1; Hwang et al., 2015). There are several factors responsible for the missed appointments phenomenon among patients, and these include forgetfulness, employment and family competing demands, ill-health, mix-up in date, transportation issues, poor healthcare provider attitude or patient-healthcare provider relationships and poor experiences during clinical visits (Crosby et al., 2009; Crutchfield & Kistler, 2017:1; Gurol-Urganci et al., 2013:1; Guy et al., 2012; Youssef, 2014:1).

Chronic illnesses, including diabetes, require a long-term commitment to therapy and appointment schedules to maximise the health benefits (Low et al., 2016). Studies have highlighted a high rate of non-adherence to clinic appointments among diabetic patients (Low et al., 2016; Nuti et al., 2012; Schetman, Schorling & Voss, 2008). Among diabetic patients, non-adherence to appointment confers significant threat, disrupts continuity of care and affects the management of the patients, thus preventing the patients from attaining an optimal level of care and outcome (Nwabuo, Dy, Week & Young, 2014; Schetman, Schorling & Voss, 2008; WHO, 2012). There is a high rate of sub-optimal control among diabetic patients who miss appointments, and there is a lower chance of prompt diagnosis and identification of complications onset and adjustment of treatment, which contributes to poor treatment outcomes (Akinniyi & Olamide, 2017; Nuti et al., 2012).

Aside the impact of non-adherence to appointments among diabetic patients, other patients suffer from the adverse effects of poor clinic attendance among the diabetic patients (Nwabuo et al., 2014). This can be attributed to the fact that in majority of the clinics, the few staff spend more time resolving issues related to patients missing appointments or unscheduled appointments, thus, affecting the efficiency of the health care system (Brandenburg, Gabow, Steele, Toussaint & Tyson, 2015). A study conducted by Ngwenya, Van-Zyl and Webb (2009) among diabetic patients in South Africa also documented forgetfulness as the most stated reasons for non-adherence to appointments among their patients.

2.8.1 Efficacy of mHealth technology as an appointment reminder

A reminder can be compared to a stop sign at a busy intersection which reminds an individual how to react next (Schewebel & Larimer, 2018). Even before the advent of mobile phones, people acknowledged the importance of reminders and used tools like alarm clocks, calendars and timers to achieve such purpose (Prochaska et al., 1994). A mobile phone is now an available tool which serves this same purpose by combining all the listed tools and measures through which people set reminders (Madden, Lenhart, Duggan, Cortesi & Gasser, 2013). As highlighted by the World Health Organisation, the use of mHealth as an appointment reminder is one of the four initiatives of mHealth which involves the use of voice or text messages to fix an appointment for a patient to enable them to attend (WHO, 2010:10).

A systematic review conducted by Schwebel and Larimer (2018) of 93 studies on the use of SMS as a measure of promoting compliance with medical treatment as well as an appointment reminder, documented an aggregate positive impact of the SMS as a means of reminder in almost all the studies, with a high level of acceptability. The use

of mHealth as appointment reminders is already being documented for immunization reminders, communicating treatment results, and even for fixing or making a post-appointment follow-up (Branson et al., 2013; Stockwell et al., 2014). Even though the use of telephones have been in place for a while, although with limited access in resource-limited settings, the use of mobile phones are gradually replacing such measures, both in developed and developing countries (Chung et al., 2015). A large percentage of WHO member countries have shown a preference for the use of SMS as an appointment reminder measure, supported with the use of voice, e-mail reminders and online scheduling (Baker et al., 2015). The use of such other support measures might, however, be limited among the rural populace.

Studies conducted on the efficacy or effectiveness of mHealth as appointment reminders among diabetic patients have demonstrated mixed results. A randomised controlled trial conducted by Fairhurst and Sheikh (2008) showed no significant improvement in non-attendance rates sequel to receiving SMS reminders. This is similar to the report of Balsa and Gandelman (2010) conducted among diabetic patients in Uruguay. In contrast, Da Costa, Salomai, Martha, Pisa & Sigulem (2010) documented an increase in attendance rate following web-based SMS reminders at four medical clinics in Sao Paulo, Brazil. Also, Guy et al. (2011), in their review, reported a positive influence of SMS reminders in promoting clinic appointment attendance. A review by Beratarrechea et al. (2014) on studies conducted in low and middle-income countries not only showed improved attendance rates but also indicated improvements in other clinical outcomes, including health-related quality of life. Likewise, a Cochrane review conducted by Gurol-Urganci et al. (2013:1) also reported a positive influence of SMS reminders on clinic attendance.

2.9 KNOWLEDGE OF DIABETES AND ITS IMPACT ON GLYCAEMIC CONTROL

Knowledge is said to be power, and in addition to attitude makes critical markers of awareness (Fatema et al., 2017:1). Knowledge has been identified as the greatest weapon in the fight against diabetes (Khan et al., 2015:1). Knowledge of diabetes, self-care management and its complications among diabetic patients influence their health-seeking behaviours and better management of diabetes and its complications (Uchenna et al., 2009:5). Improved knowledge, good attitude and consequently improved awareness play a key role in the prevention of diabetes complications as they facilitate prompt detection and prevention (Fatema et al., 2017:1). These attributes all contribute to self-care, health-seeking behaviour and the quality of life of the individuals (Hjelm & Mufunda, 2010; Mufunda, Ernerson & Hjelm, 2018:1; Moodley & Moodley, 2007).

Poor knowledge of diabetes among its sufferers is a major setback towards attaining glycaemic control (Basu et al., 2017:1). Education of diabetic individuals has long been reported to bring about an improvement in HbA1c (Norris et al., 2002) and is advocated for by various international organisations (ADA, 2018). Sankar, Lipska, Mini, Sarma and Thankappan (2015) suggested the need to prioritise interventions focused on enhancing patients' knowledge in promoting medication adherence. This was further reinforced by Carratala-Munuera et al. (2015) who reported significant improvement in adherence to therapy following better patient information. However, Ajzen et al. (2011) argued that knowledge and patients' behaviour are not dependent on each other; they further asserted that having a good knowledge does not guarantee positive health behaviour while poor knowledge, on the other hand, also does not connote consequent negative health behaviour. There is usually a variation in the level of

knowledge and awareness of diabetes across various cultures and socio-economic strata (Reza, Heel, Chowdhury & Wragg, 2014).

According to Moodley et al. (2007), there is a generally low level of knowledge of diabetes globally, despite its documented importance. Several scholars have pointed at the poor level of knowledge among diabetic patients in Africa and other developing countries (Al-Maskari et al., 2013; Ayele, Tesfa, Abebe, Tilahun & Girma, 2012; Islam et al., 2014; Mufunda, Ernerson & Hjelm, 2018:1; Okolie, Ehiemere, Peace & Ngozi, 2009). A large study conducted among over eighteen thousand individuals in Bangladesh showed that a major part of the populace (68%) only had average knowledge of diabetes (Fatema et al., 2017:5). Another large study conducted among various population groups, including health workers in Saudi Arabia showed a poor level of knowledge and awareness of diabetes among the cohort (Alanazi et al., 2018:3). A study conducted in a rural part of Islamabad also showed that majority of its participants had limited or no knowledge about diabetes (Ulvi et al., 2009). Unsurprisingly, many are also not knowledgeable or even aware of the various aspects of the care and management of diabetes (Foma et al., 2013:6; Muninarayana, Balachandra, Hiremath, Iyengar & Anil, 2010). It also appears there is a gender variation in the knowledge of diabetes with several authors documenting men to be more knowledgeable about diabetes compared to women, although women seem to have better self-care or attitude towards it (Al-Maskari et al., 2013; Fatema et al., 2017:5; Islam et al., 2014; Saleh, Mumu, Ara, Hossain & Ahmed, 2012).

Similarly, studies conducted in South Africa also showed a low level of knowledge among diabetic patients in the Free State and Limpopo province (Le Roux, Walsh, Reid & Raubenheimer, 2018:6; Vorster, 2013; Oloyede, 2013:8). These same studies

opined that a lower level of knowledge is often found among the poor who usually have a higher burden of the disease and among those with low level of literacy as indicated in studies conducted in other parts of South Africa (Roux et al., 2018:6; Vorster et al., 2013). Ntontolo, Lukanu, Ogunbanjo, Fina and Kintaudi (2017:1) also documented a lower level of knowledge among women, those with a lower level of education, as well as those with a shorter duration of the illness. They, however, showed no difference in the level of knowledge across the different socio-economic level. It will, therefore, be worthwhile to ascertain measures and the potential of mHealth technology, including SMS in fostering knowledge of diabetic patients in this setting.

2.9.1 Efficacy of mHealth technology in creating awareness and improving knowledge

mHealth is not only used for appointment reminders, health promotion or community mobilisation, it also has the potential for creating awareness and boosting the knowledge of individuals about various health conditions (WHO, 2011:27). Several studies have employed the use of mHealth technology in disseminating information in order to boost patients' knowledge (Hamsphire et al., 2015:1; Marwaha, 2010), and it has proven effective in promoting knowledge and adherence to medications in several conditions (Leon et al., 2015; Quan, Hulth, Kok & Blumberg, 2016), including diabetes (Deglise, Suggs & Odermatt, 2012; Dobson et al., 2016). A programme organised by Internet Sexuality Information Services in collaboration with San Francisco Department of Health, named SEXINFO, geared towards providing information on sexual health, owing to the increasing rate of gonorrhoea, showed positive outcomes (Levine, McCright, Dobkin, Woodruff & Klausner, 2008).

With regards to the use of mHealth in creating awareness and health education among diabetic patients, mHealth technology has also been shown to bring about significant improvement in knowledge and management of diabetes among diabetic individuals, as well as improved clinical outcomes (Deglise, Suggs & Odermatt, 2012; Hall, Fortrell, Wilkinson & Byass, 2014; Marwaha 2010). Other studies shared contrasting views in which they showed a non-significant improvement in knowledge and awareness following SMS intervention (Goodarzi et al., 2018:4; Van Olmen et al., 2017). Saffari, Ghanizedeh and Koenig (2014) pointed out in their review that the use of mHealth intervention to bring about improvement in knowledge is more realistic when there is a combination of internet-based mHealth programmes in addition to text messaging and when there is an avenue for patients' feedback.

2.10 SELF-MANAGEMENT BEHAVIOUR AND SELF-EFFICACY OF DIABETIC PATIENTS

Self-management behaviour and self-efficacy are integral components of chronic disease management, including diabetes (De Jongh, Gurol-Urganci, Vodopivec-Jamsek, Car & Atun, 2012:7). Given the chronic nature of diabetes, the complexity of its management, contributing factors like increasing urbanisation and the associated lifestyle modifications, self-management of diabetes and self-efficacy on the part of patients become highly important (Avasthi, 2010; Varma & Gupta, 2008).

Diabetes self-management entails making effective and healthy dietary choices, participating in physical activity, proper self-monitoring of blood sugar, and adherence to prescribed therapeutic regimens (Sharma, Nazareth & Petersen, 2016). Diabetes self-management promotes knowledge and self-efficacy, provides the skills and capacity required for self-care, and also helps an individual with diabetes to implement

and maintain the required behaviours essential for the management of their conditions (Beck et al., 2017:1). Diabetes self-management education and support have the potential to minimise the risks of developing diabetes-related complications and improve clinical outcomes, including glycaemic status (Pal et al., 2018:1; Powers et al., 2016). Chrvala, Sherr and Lipman (2015:1) documented a significant reduction in HbA1c level following diabetes self-management educational programmes, particularly when it lasts for more than 10 hours.

Factors contributing to poor self-management behaviour among chronic patients include poor level of understanding or knowledge, lack of confidence or motivation, poor attitude and low self-efficacy (Goodarzi et al., 2012). As such, equipping patients with the required skills and knowledge and the confidence for the management of their conditions through health educations or coaching is crucial (Ghorob, 2013). This helps to improve disease management, heighten metabolic control, and finally reduce disease-associated burdens (Bonoto et al., 2017:1; Goodarzi et al., 2012:6).

Traditionally, the service of professionals such as nurse specialists and diabetes educators is often employed in fostering the diabetes patients' self-management behaviours and consequently, glycaemic control. Educating the patients on diabetes self-management education often involves a usual face-to-face interaction (Bodenheimer & Pham, 2010; Forjuoh et al., 2014; Ricci-Cabello et al., 2014). However, owing to the continual increase in the number of individuals with diabetes, insufficient human workforce and excessive workload, opportunities for such face-to-face interactions are limited (Boels et al., 2017:2). Consequently, the number of contact sessions are limited, and as such, patients are bombarded with series of information which can be overwhelming (Bodenheimer & Pham, 2010; Forjuoh et al.,

2014; Ricci-Cabello et al., 2014). In the face of these pitfalls, the need for a more feasible and cost-effective measure of delivering such educational interactions becomes imperative.

2.10.1 Efficacy of mHealth technology in promoting self-management behaviour and self-efficacy

Various alternative measures of improving diabetes self-management include a variety of programmes, ranging from distribution of brochure as well as evolving new and innovative measures such as mHealth (Hunt, 2015). mHealth programmes such as text messaging, phone calls or web-based programmes are capable of delivering such educational contents promptly and even at a low-cost (Free et al., 2013:1; Van Olmen et al., 2016:2). The most acclaimed mHealth measure is the use of SMS (Gurol-Urganci et al., 2013:4). Text messaging is a powerful tool with the potential of bringing about behaviour change as a result of its gross availability, spontaneity and cost-effectiveness (Cole-Lewis & Kershaw, 2010).

Diverse self-management issues have been covered using text messaging programmes. An example of such programme currently being undertaken in South Africa is the MomConnect. The programme is undertaken by the South African Department of Health, and it involves the use of text messages to register pregnant mothers and the provision of stage-based text messages to such mothers until the child clocks one year (Barron et al., 2018; SADoH, 2019). Another initiative is the United Kingdom National Health Service mHealth programme tagged SmokefreeTXT, which assist smokers in ceasing smoking (Squiers et al., 2016). A similar programme aimed at smoking cessation is also in place in the United States, organised by the United States National Cancer Institute (National Cancer Institute, 2019). These

programmes assist in providing health information to individuals, irrespective of their geographic location or social status, and thus foster their self-management behaviours.

A review conducted by Gurman, Rubin and Roess (2012) documented a rapid uptake of mHealth as a tool to foster behaviour change in developing countries, particularly in Africa and mostly on health topics like HIV/AIDs and family planning or pregnancy. Even so, the use of mHealth for other conditions such as non-communicable diseases (NCDs) is not lacking (Bloomfield et al., 2014). This could stem from the high-level meeting held by the United Nations in 2011, where mHealth was highlighted as a vital tool for combating NCDs (WHO, 2011). South Africa, however, is still lagging in this regard.

There are variants in the outcomes of the impact of mHealth on self-management behaviours of patients with chronic illnesses, including diabetes. A study conducted in the United States showed promise regarding the use of mHealth in boosting self-management behaviours of chronic patients with regards to their activity levels (Plow & Golding, 2017:1). A family-oriented intervention which entails educational sessions, group discussions, home visit and phone follow-ups demonstrated a significant improvement in the self-efficacy, self-management behaviours of the diabetic patients, which also showed a potential for improving glycaemic status and health-related quality of life (Wichit et al., 2017:7). In addition to glycaemic control, Bonoto et al. (2017) also revealed that educating diabetic patients through mobile apps brought about an improvement in the patients' self-care through the provision of more information. This corroborates the findings of Berndt et al. (2014); Rossi et al. (2013) and Rossi et al. (2010) and demonstrates a great potential for health promotion as

highlighted by international organisations, such as the International Diabetes Federation (IDF, 2011). Van Olmen et al. (2017:6), however, reported contrary findings whereby no significant improvement in self-management was recorded following mHealth intervention.

Generally, as documented in the review conducted by De Leon, Fuentes and Cohen (2014:1), text messaging which is considered a form of prompt for patients, shows great potential in fostering behavioural changes, such as, quitting tobacco use, increasing activities pattern and even sticking to recommended dietary regimen. Tamban, Isip-Tan and Jimeno (2013:5) also documented similar findings concerning dietary practices and physical activity. Likewise, a review conducted by Fjeldsoe, Marshall and Miller (2009) recorded similar improvement in behavioural outcomes in terms of the cessation of smoking, and self-management behaviours of the diabetic patients in thirteen of the fourteen included studies. The review by Head, Noar, Iannarino and Harrington (2013:1) involving 19 trials also documented similar findings. They highlighted that the use of individualised messages, tailored according to the patient's health requirements or recommendations, is highly efficacious and that having an irregular or varying frequency of the messages improved the efficacy. Notwithstanding, the efficacy of SMS alone, a tool that might be feasible among those in the lower social class and in resource-limited settings in promoting self-management of diabetes remains unclear.

2.11 PSYCHOSOCIAL IMPACTS OF DIABETES

The management of diabetes goes beyond medication use, and its presence affects the lives of the individuals and their family members and as a result, has serious psychosocial impacts (Debono & Cachia, 2007:1). Diabetes is the most

psychologically demanding of all the various chronic diseases with an increasing burden (Bajwa, Sarowa & Bajwa, 2015:1). The psychosocial impacts of diabetes have been identified as a leading predictor of mortality among individuals with diabetes (Bajwa, Sarowa & Bajwa, 2015: 4). Worryingly, these challenges are sometimes overlooked or missed (Tareen & Tareen, 2017:1).

Diabetes has long been associated with various psychological or psychosocial factors or symptoms (Lustman & Gavard, 1995; Rubin & Peyrot, 2002). For some years, attention has shifted from medical factors as the underlying mechanism for poor glycaemic control to various psychosocial factors (Serrano-Gil & Jacob, 2010). Such psychosocial factors include coping skills, psychological distress, social or family support which might give rise to symptoms like depression, anxiety, eating disorders, personality disorder and cognitive impairments (Bener, Al-Hamaq, & Dafeeah, 2011; Khuwaja et al., 2010; Kota et al., 2012; Ramkisson, Pillay & Sartorius, 2016:1). Sometimes, these clinical symptoms are even confused with symptoms associated with hypoglycaemic episodes or other comorbidities (Balhara, 2011).

The impact of psychosocial factors on the management of diabetes cannot be overemphasised. Psychosocial factors can affect the adherence level of the patients, health-related quality of life, self-management behaviours of the patient, which all impact the glycaemic control (Avasthi, 2010; Gupta, Bhadada, Shah & Mattoo, 2016:1; Varma & Gupta, 2018; Young-Hyman et al., 2016). The consequential poor health behaviours accompanying the psychosocial challenges among diabetic patients result from the associated feeling of hopelessness, lack of motivation, support and energy, as shown in Figure 2.4 (Tareen & Tareen, 2017: 3). Given this, assessing diabetic individuals for psychosocial factors is paramount in attaining the set glycaemic target

and quality of life (Bajwa, Jindal, Kaur & Sing, 2011; Pyatak, Sequeira, Peters, Montoya & Weigensberg, 2013). This was also highlighted in the first Diabetes Attitudes, Needs, and Wishes (DAWN) study conducted across 13 countries, involving more than 5,000 diabetic patients and more than 3,000 healthcare providers (Skovlund, 2004).

2.11.1 Diabetes distress

One of the psychosocial issues which confront individuals living with diabetes is diabetes distress. Unlike the widely known issues such as depression and anxiety disorders, diabetes distress is an emerging phenomenon among diabetic individuals, though now common (Fischer et al., 2012; Fisher, Glasgow & Strycker, 2010; Nicolucci et al., 2013). It is also regarded as a part of quality of life challenges and sometimes also gets missed or goes unnoticed by healthcare providers and even the individuals themselves (Tareen & Tareen, 2017:5). Diabetes distress, which is an affective malady rather than a psychiatric disease often results from the patient's regular fear or worry regarding medication use, glucose monitoring, lifestyle modifications, stress, burnout or even anger, as shown in Figure 2.4 (Fisher et al. 2012; Tareen & Tareen, 2017:6). It also influences diabetes treatment outcomes and self-management behaviour of the patients negatively (Driscoll & Young-Hyman, 2014; Fisher, Hessler, Polonsky & Mullan, 2012; Fisher et al., 2010; Nam, Chesla, Stotts, Kroon & Janson, 2011; Nicolucci et al., 2013).

Delahanty et al. (2007) had earlier indicated that the level of diabetes distress is higher among diabetic patients in the younger age groups, those with weight issues and those taking insulin, irrespective of the duration of illness (Hagger, Hendrieckx, Sturt & Spieght, 2016). On the other hand, polytherapy, comorbidity level or educational

qualifications do not influence diabetes distress development (Delahanty et al., 2007). The higher the level of diabetes distress, the more the chances of not complying with treatment; the poorer the clinical outcomes, the lower the diabetes empowerment and the health-related quality of life (Delahanty et al., 2007; Joensen, Tapager & Willaing, 2013). Diabetes education is an established means of assisting patients in dealing with diabetes distress. During such educational sessions, they are provided with insights on the care of the disease, support and these improve their coping skills (Young-Hyman, 2016:7).

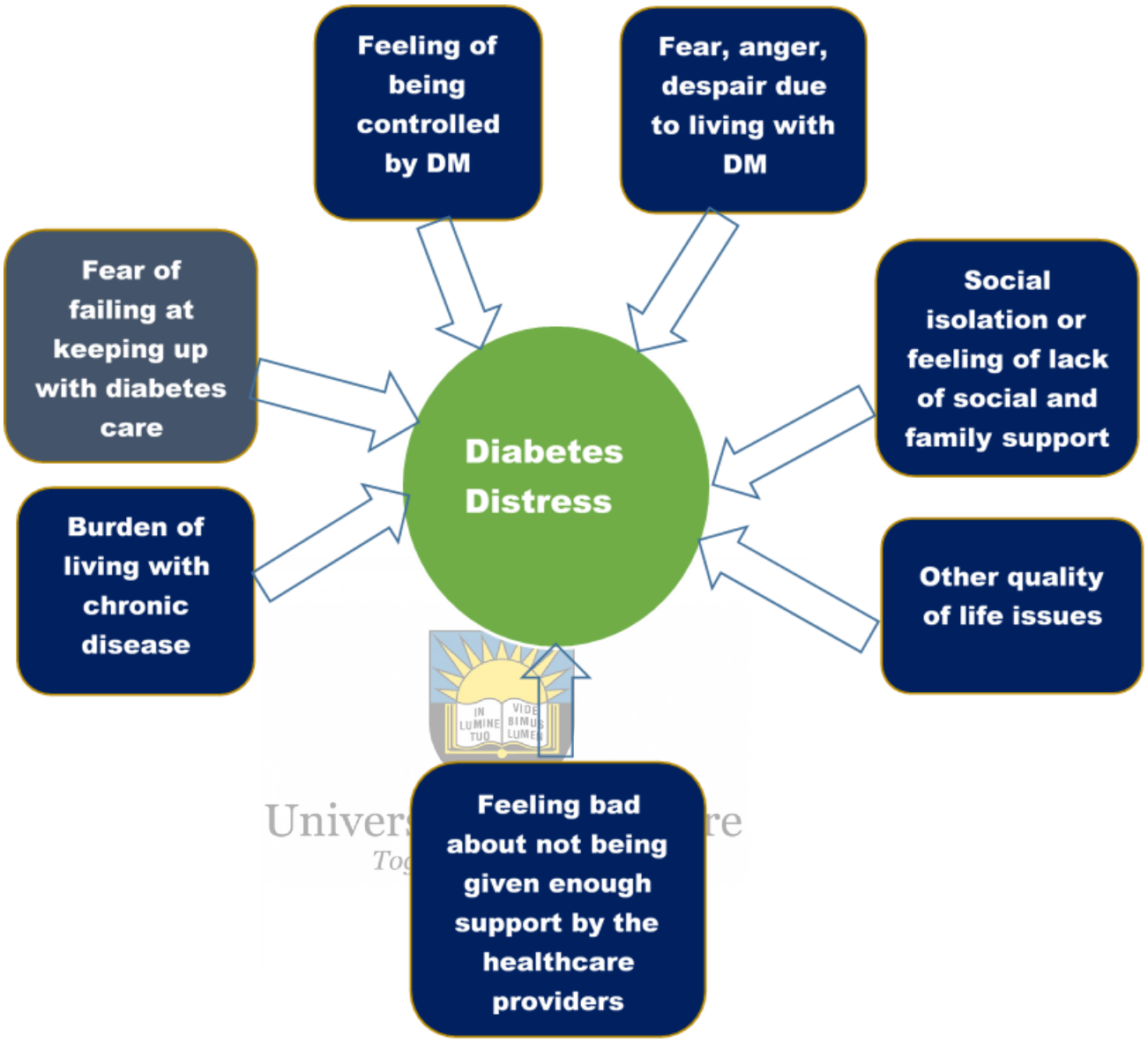

Figure 2.1: Schematic presentation of diabetes distress

Source: Tareen and Tareen (2017)

2.11.2 Quality of life

Another psychosocial issue related to diabetes is the health-related quality of life. Health-related quality of life according to the World Health Organisation is defined as the perception of an individual of the position in life, with regards to the cultural and value system where they live in, regarding their aims, expectations, concerns and

standards (WHOQol Group, 1993). This definition encompasses the various dimensional concepts of the individual's health physically, his or her psychological condition, social interactions, beliefs, as well as the environment (Bajwa, Saroha & Bajwa, 2015). Simply, health-related quality of life is said to be the effect an illness imposes on a patient, based on the patient's beliefs, expectations and perception (Rwegerera et al., 2018:1).

Diabetes greatly impacts on the quality of life of its sufferers and diabetic individuals are said to have a worse health-related quality of life compared to those without chronic illnesses (Al-Khaledi et al., 2018:2). The quality of life of many diabetic patients is often dependent on the complications related to the disease and sometimes on other psychosocial and demographic factors (Rwegerera et al., 2018). There is usually an association between the health-related quality of life of diabetic patients and their self-management behaviour (Nawaz, Malik & Batool, 2014). The better the diabetes self-management behaviour is, the better the health-related quality of life (Al-Khaledi et al., 2018:2). There is also an association between the psychosocial wellbeing of a patient, their self-care and the health-related quality of life (da Mata, Alvares & Diniz, 2016; Speight, Reaney & Barnard, 2009). The perceived quality of life of a patient plays a crucial role in the level of glycaemic control; the better the perceived health-related quality of life of a diabetic patient, the better the level of glycaemic control (Al-Khaledi et al., 2018).

Several studies have documented varying levels of quality of life. The DAWN2 study recorded quality of life ranging from 7.6% to 29.3% among their study participants in Denmark and Japan respectively (Peyrot et al., 2005; Skovlund, 2004). With regards to the various domains of the quality of life measure, diabetes impacted almost all the

domains negatively among the DAWN study participants (Skovlund, 2004). Another study in India also reported the poor quality of life among diabetic patients (Kalra et al., 2013). Not only that, diabetes also influences the psychological wellbeing of individuals, with an associated high perception of social burdens and personal distress (Kalra et al., 2013; Ramkisson, Pilllay & Sartorius, 2016). Owing to these reasons, there is a constant need for social support, psychological therapy, promotion of physical activity level, and proper nutrition education, in addition to medical therapy, in the management of diabetes (Bhajwa, Saroha & Bajwa, 2015). Ramkisson, Pillay and Sartorius (2016:1) recommend the need to include the treatment of psychosocial issues as a component of standard diabetes care. They further stated that family members need to be carried along and involved in the care of their loved ones living with diabetes. Likewise, healthcare providers need to move towards patient-centred care where the patients' role as part of the treatment plan is emphasised, and patients' satisfaction is prioritised (Powers et al., 2017).

2.11.3 Efficacy of mHealth technology in improving psychosocial aspects of diabetes

Information technology is currently an available medium for improving the clinical outcomes of diabetes patients, including those with psychosocial challenges (Schwebel & Larimer, 2018). With the innovative approaches, newly developed protocols for diabetes can be implemented and tailored to the patient's care and needs, while fostering interaction and effective and prompt delivery of health information (Kaufman, 2010). Interventions aimed at improving diabetic patients' knowledge through education have been highlighted to have the potential to improve the various domains of their health-related quality of life (Faria et al., 2013).

Previous studies conducted on the impacts of mHealth, including text messaging, on improving the psychosocial effects of diabetes showed mixed results. Some scholars showed no significant improvement in diabetes distress and depression symptoms (Arora et al., 2014; Burner, Menchine, Kubicak, Robles & Arora, 2014; Quinn et al., 2011). Regarding changes in the quality of life, there appear to be mixed findings. Berndt et al. (2014), Rossi et al. (2013) and Rossi et al. (2010) documented a significant reduction in the health-related quality of life of participants in the intervention arm. In contrast, Drion et al. (2015); Holmen et al. (2014) and Kirwan et al. (2013) reported no significant reduction in the health-related quality of life of both the intervention and control groups. The few studies which examined the impact of mHealth on diabetes distress and depression showed no significant improvement (Arora et al., 2014; Burner et al., 2014; Dobson et al., 2018; Quinn et al., 2011). A review conducted by Johnston et al. (2018) however reported that majority of the studies on the impact of mHealth among diabetic patients in developing nations rarely put into consideration the behavioural aspect, an obvious shortcoming in previous studies.

2.12 EMPIRICAL EVIDENCE ON THE EFFICACY OF MHEALTH IN PROMOTING SECONDARY CLINICAL OUTCOMES

Considering the complexity of diabetes management and its associated inter-relationship with other clinical outcomes such as the body weight, blood pressure, physical activity pattern and dietary practices, assessing these secondary outcomes in diabetes interventions becomes essential.

2.12.1 Efficacy of mHealth interventions in improving blood pressure

Most diabetic patients usually develop hypertension at one point or the other (Obrien et al., 2013) and this increases their risk of developing target organ damage and other microvascular and macrovascular complications (Bonifonte et al., 2015:1; James et al., 2014:1; Willaims, 2013). An improvement in blood pressure level, even as low as a 10mmHg drop is associated with a significant improvement in stroke, other cardiovascular diseases and all-cause mortality among diabetic patients (Brunstrom & Calberg, 2016; Emdin et al., 2015). As a result, various measures of bringing about improvement in blood pressure level of diabetic patients through medical therapy and lifestyle modifications are advocated (Amod et al., 2017).

Previous mHealth interventions also assessed its effectiveness in improving blood pressure among diabetic patients. Review studies conducted by Cui, Wu, Mao, Wang and Nie (2016:10), Marcolino, Maia, Alkmin, Boersma and Ribeiro (2013) and Liang et al. (2011) showed no significant improvement in the mean systolic and diastolic blood pressures following text messaging. Several others documented similar findings of no significant improvement in blood pressure following mHealth interventions (Orsama et al., 2013; Quinn et al., 2011; Rossi et al., 2013; Rossi et al., 2010). On the contrary, few other studies recorded a significant improvement in blood pressure of diabetic patients, following a text-messaging intervention (Bell, Fonda, Walker, Schmidt & Vigersky, 2012; Noh et al., 2010; Yoo et al., 2009). There is often a positive association between blood pressure and blood sugar in which an increase in blood sugar could increase the blood pressure and vice versa (Heianza et al., 2015; Lv et al., 2018:5). However, an intervention which documents significant improvement in blood glucose might not show an equivalent significant improvement in blood pressure (Quinn et al., 2011). Irrespective of that, a small improvement in blood pressure often

recorded in many of the interventions is of clinical significance, whether it is statistically significant or not (Brunstrom & Calberg, 2016; Emdin et al., 2015).

2.12.2 Efficacy of mHealth interventions in improving blood lipid

Another treatment target for diabetes management is the blood lipid level. Dyslipidaemia, which encompasses a reduction in high-density lipoprotein cholesterol, increase in low-density lipoprotein cholesterol and increased triglycerides, is a common risk factor among diabetic patients (The Emerging Risk Factor Collaboration, 2015). Abnormal blood lipid level is a leading risk factor for diabetes-related complications (Fox et al., 2015; The Emerging Risk Factor Collaboration, 2015). As such, an improved level of blood lipid is targeted among diabetic patients (Amod et al., 2017).

With regards to the effectiveness of mHealth in promoting blood lipid level, similar findings of no significant improvement were recorded for change in total cholesterol and high-density lipoprotein in many studies (Quinn et al. 2011; Rossi et al., 2013; Rossi et al., 2010). Abebe et al. (2013) and Noh et al. (2010) however, demonstrated an improvement in lipids level following their text messaging interventions. There is a similar metabolic pathway for change in blood glucose and other clinical outcomes such as blood pressure and lipids and as such, an improvement in one could bring about an improvement in the other factors (Lv et al., 2018). Even studies which documented no significant improvement showed a change in the blood lipid level, although not significant (Quinn et al. 2011; Rossi et al., 2013; Rossi et al., 2010).

2.12.3 Efficacy of mHealth interventions in promoting weight loss

Apart from the blood glucose, blood pressure and blood lipid targets among diabetic patients, a modest weight loss is also encouraged, and can be achieved through continual engagement in physical activities and healthy dietary practices (May in Amod et al., 2017). Various benefits of weight loss include improved blood glucose and other cardiovascular risk factors and improvement in the psychological impacts of diabetes, such as depression (Bramante, Lee & Gudzune, 2017:1; Rublin et al., 2014; Wing & Look Ahead Research Group, 2010; Wing et al., 2011).

Essential healthy behaviours that can bring about improvement in weight status such as engagement in physical activities and healthy dietary practices are often a challenge among diabetic patients (Amod et al., 2017; Milner et al., 2014:2). Factors which influence these negative behaviours include low socio-economic level, cultural values and beliefs (Laraia, Leak, Tester & Leung, 2017). Similar challenges exist among South African adults (Shisana et al., 2013). Even though some scholars highlighted the important role of health educating the patients to improve their knowledge and subsequently their practices (Van Wyk, 2015; Yannakoulia, Poulia, Mylona & Kontogianni, 2007:2), it is not clear if text messaging can bring about the expected changes, more especially, among those in the lower socio-economic group and settings, who often engage in such unhealthy behaviours.

Literature shows varying results on weight change following SMS intervention, which are often mixed. While Arambepola et al. (2016)'s systematic review and meta-analysis showed no significant improvement in weight following SMS intervention, Siopis, Chay and Allman-Farinelli (2015) recorded a significant improvement in weight. Keating and McCurry (2015) and Shaw and Bosworth (2012) in their reviews

conducted generally on the impact of SMS on weight loss among general adults reported no significant improvement. Pertaining to change in body mass index (BMI), many scholars recorded no significant improvement in BMI following SMS interventions among diabetic patients (Lim et al., 2011; Noh et al., 2010; Tamban, Thiele-Tan & Jimeno, 2014; Waki et al., 2014; Yoo et al., 2009). Furthermore, changes in other behavioural patterns, particularly dietary practices and physical activity patterns following SMS interventions also showed a mixed effect. While Arora et al. (2014); Burner et al. (2014) and Shetty et al. (2011) found no significant improvement among their study participants, Goordarzi et al. (2012) and Tamban, Thiele-Tan and Jimeno (2014) reported significant improvement in dietary practises and physical activity levels of their study participants. A change in lifestyle behaviour is often a complex issue especially among those who are significantly embedded in their traditional and cultural beliefs; it is unknown if text messaging only can bring about a positive change in this regard.

2.13 ACCEPTABILITY AND FEASIBILITY OF MHEALTH INTERVENTIONS

The acceptability of any intervention aimed at empowering patients is of great importance. Chatziemarkakis (2010) posited that interventions aimed at empowering patients and those which involve extra routines or commitment on the part of the patient that are not acceptable by them might be ineffective. Such is the SMS intervention, which requires the patient to expect, receive and read empowering and educating messages daily. It is, therefore, imperative to assess the acceptability of such measures when implemented. Generally, there seems to be a high rate of acceptability of various text message-based interventions for diabetes. Several scholars have indicated that the use of SMS for boosting behaviour change was highly accepted by diabetic patients in their studies (Abebe et al., 2013; Arora et al., 2014;

Burner et al., 2014; Capozza et al., 2015; Shetty et al., 2011). In contrast, Noh et al. (2010) showed a very low rate of acceptability, which was related to the web-based interface used for sending the messages, which the participants considered unfriendly. Shetty et al. (2011:1) also documented a high level of acceptability and feasibility of the mobile phone SMS in promoting adherence and improving glycaemic, blood pressure and blood lipid control. Equally, a review by Wei, Hollin and Kachnowski (2011:1) showed a high rate of acceptance and efficacy of the SMS in improving clinical and behavioural outcomes. It is thus necessary to ascertain the acceptability of mHealth interventions among diabetic patients in South Africa, particularly among those in the resource-limited settings.

Some authors have associated the acceptability of the text messaging programme as a proxy for improving health to its ease of use (Orsama et al., 2013; Waki et al., 2014; Yoo et al., 2009). In addition to this, authors have shown the feasibility of text messaging across various population groups (Dick et al., 2011:1; Haddad et al., 2014:1; Herbert, Mehta, Monaghan, Cogen & Streisand, 2014:1). Many of the mHealth acceptability and feasibility studies were conducted in developed nations and among the more educated fellows (Dick et al., 2011:1; Herbert et al., 2014:1; Orsama et al., 2013), thus, warranting a further investigation among those in the lower social class, with low literacy level and in disadvantaged settings.

2.14 BARRIERS TO THE IMPLEMENTATION OF MHEALTH

Despite the various success records of the mHealth, the presence of challenges or barriers is inevitable. The identification of potential barriers to the implementation of mHealth, its adoption and utilisation is essential in planning and resource allocation (Zayyad & Toycan, 2018). Globally, the four most documented challenges across

various socio-economic strata as highlighted by the World Health Organisation include countries competing health priorities, lack of adequate infrastructures such as poor network coverage, cost-effectiveness and inadequate knowledge on mHealth applications and health outcomes (WHO, 2011). As a result, the need for evaluation studies is highly recommended and vital. The identified barriers vary across regions and are more pronounced in developing regions, most especially Africa (WHO, 2011).

Some studies identified technical issues as some of the challenges of mHealth (Wambungu & Villella, 2016; 10; Woodard, Weinstock & Lesher, 2014); some information could be lost or breached due to the use of unsecured networks (Woodard, Weinstock & Lesher, 2014). This corroborates the report of Sanner, Roland and Braa (2012) which indicated that many SMS messages sent to participants involved in the DHIS2 study were lost. Perosky et al. (2015) also buttressed the claim by saying that only 52% of about 8000 text messages sent to their participants were successfully transmitted.

Another identified barrier to mHealth is the users' behaviour challenges. Such behaviours include paying less attention to the use of the mobile device, imputing wrong data, and even care-free handling or loss of the devices (Leon, Schneider & Daviaud, 2012; Medhanyiie et al., 2015). These issues are more paramount in mHealth programmes involving the use of mobile applications, or initiatives involving people inputting data on a mobile device and are less of a concern for mHealth programmes involving simple measures like the SMS, except for phone loss (Leon, Schneider & Daviaud, 2012; Medhanyiie et al., 2015; Sanner, Roland & Braa, 2012).

Language barrier is another downside to the use of mHealth. Some of the mobile applications and devices use English while the users' preferred language of choice might be different from the programmed language and this can influence the usability of the programme (Gurupur, Thomas & Wan, 2017:2). It is preferable to provide interventions or mHealth services in the users' language of choice in order to overcome the language barrier. This can be challenging as it requires translation and validation of the translation (MEASURE Evaluation, 2016:6). Back translation, whereby the new translated message is translated back to the original by an independent translator while ensuring simplicity, is a measure of ensuring consistency in the translated message (MEASURE Evaluation, 2016: 6).

2.15 CUES TO DEVELOPING AN EFFECTIVE TEXT MESSAGING PROGRAMME

It is often reinforced that the theoretical basis of content is essential while designing a prevention programme (Fry & Neff, 2009). The use of text messages as a measure of delivering health prevention information is often based on theoretical standpoints such as the health belief model or even theory of planned behaviour (Cole-Lewis & Kershaw, 2010). Even so, the use of text messaging almost automatically involves constructs such as the cues for action, social or emotional support and reinforcement, which are core components of many behavioural theories, even without being consciously planned by the researcher (Fry & Neff, 2009). It is opined that prompts and reminders are active ways of promoting and reinforcing healthy behaviours (Schewebel & Larimer, 2018). Thus, regular communication, accountability and reinforcement produced through texts have the potential of increasing the chances of remembering the expected or required changes (Powers et al., 2017).

Also, the Centre for Disease Control and Prevention (2012)'s guide to writing for social media suggested that for SMS intervention to foster behaviour change, its content should be simple, concise, short, readable, engaging, timely and devoid of abbreviations. Besides, the frequency of feedback, effective guidance and support, and interpretation by the patients also play a crucial role in the effectiveness of a text messaging programme (Hood, Hilliard, Piatt & Levers-Landis, 2015:1). Other factors as highlighted by Hood et al. (2015:2) are literacy, available infrastructures in the community, family and social support system and dietary and psychological issues like mood changes.

Furthermore, based on the tool kit designed for text messaging interventions by the Centre for Research in Implementation Science and Prevention (CRISP), determining and understanding the need of the participants in designing the SMS content and approach is important (CRISP, 2013). They further mentioned the need to determine the frequency of the messages, bearing in mind the desired outcomes and usually using a theory or evidence-based approach. According to this group, they also stated the need to ensure privacy, both on the part of the researcher and the patient, especially when the phone gets to another hand. Likewise, they advised that the SMS content should be developed in a manner that limits personal information and also advised that patients use a means of security either through the use of a password or a personal identification number. Lastly, it is essential for researchers to provide an option for participants to either opt-in or out of the SMS intervention (Hawkins, Kreuter, Resnicow, Fishbein & Dijkstra, 2008; Rothman, Bartels, Waschin & Salovey, 2006).

In summary, diabetes mellitus constitute a significant public health and socio-economic challenge and many countries, including South Africa, are faced by its

exponential increase. Diabetes mellitus as a disease has various impacts and affects almost every organ of the body. It is a complex disease and requires a multifaceted care approach. In spite of all the advances in diabetes care and management, its treatment outcomes are often poor, and control is most times sub-optimal. Patients are central in the management of diabetes; as such, they play a significant role in the management of the disease. As a result, it is important to empower the patients in order to attain the set objectives. There is a continual need for interventions with the potential of empowering patients and improving diabetes health outcomes. mHealth is an emerging, cost-effective measure with a potential for improving health and its use has been implemented in several countries, most especially, in developed countries. However, there is a continual need to evaluate the mHealth programmes and determine their effectiveness. Many studies, mostly conducted in developed countries, have documented diverse results on its effectiveness and impact on diabetes health and outcomes. Studies which showed significant improvements were rarely conducted in resource-poor settings and less often among those in the lower social stratum who bear the most burden of the diseases and are at greater risk. Intervention studies among individuals with diabetes, using mHealth technology are completely lacking in South Africa, a country with a high burden of diabetes and sub-optimal glycaemic control. There is, therefore, a need to implement an intervention involving the use of mHealth and determine its effectiveness, feasibility and acceptability.

CHAPTER THREE

RESEARCH METHODOLOGY

3.1 INTRODUCTION

The overall aim of this experimental study is to determine the efficacy, acceptability and feasibility of mHealth Technology (SMS) in promoting adherence to anti-diabetic therapy and glycaemic control among diabetic patients. This chapter describes the methodology adopted to achieve the set aim and objectives.

3.2 RESEARCH DESIGN

This was a quantitative, experimental study which utilised a multi-centre, two-arm, parallel, randomised-controlled design to determine the efficacy, acceptability and feasibility of mHealth technology (SMS) in promoting adherence to anti-diabetic therapy and glycaemic control among diabetic patients in the Eastern Cape Province. The study was designed to compare a six-month mobile phone-based SMS intervention, in addition to the standard diabetes care, as a tool for promoting adherence and health outcomes among diabetic patients receiving treatment in selected diabetes clinics in the province. While the study design followed the 2013 Standard Protocol Items: Recommendations for Interventional Trials statement (Chan et al., 2013), the description of the intervention followed the Consolidated Standard for Reporting Trials (CONSORT) checklist (Eysenbach & CONSORT E-Health Group, 2011).

3.3 STUDY SETTING

The study was conducted at diabetes clinics in two randomly selected districts in the Eastern Cape Province of South Africa. The Eastern Cape Province was created in

1994, and include areas from the Xhosa homelands of the Transkei and Ciskei, as well as part of the Cape Province. The Eastern Cape Province is one of the poorest provinces in South Africa (Business Tech, 2016; StatsSA, 2011). The Eastern Cape Province is made up of two metropolitan municipalities: Buffalo City and the Nelson Mandela Bay Metropolitan Municipalities and six districts: Alfred Nzo, Amathole, Chris Hani, Joe Gqabi, OR Tambo and Sarah Baartman (StatsSA, 2011). The study was conducted at the out-patient departments of six selected primary healthcare centres in Buffalo City Municipality and Amathole Districts, in the Eastern Cape Province, South Africa.

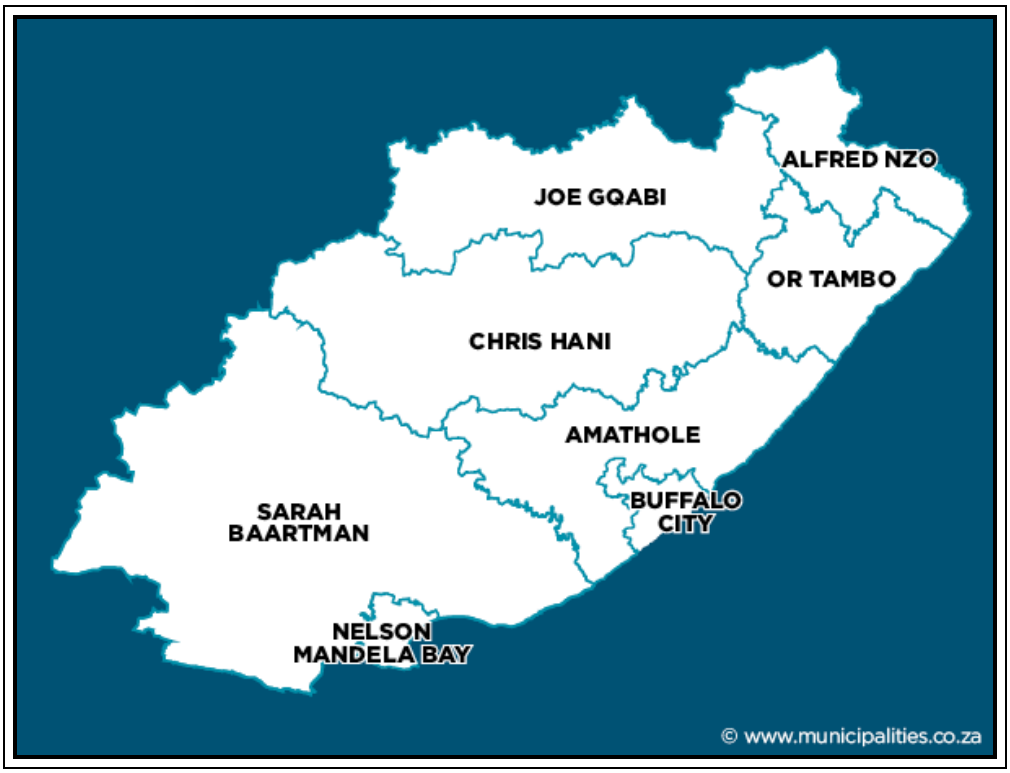

Figure 3.1: Map of the Eastern Cape Province.

3.4 STUDY POPULATION

The target population were adults with uncontrolled diabetes attending the diabetes clinics in the Eastern Cape, South Africa.

3.4.1 Inclusion Criteria

The inclusion criteria were age 18 years and above; diagnosed of diabetes mellitus not less than 6 months prior to the time of recruitment; currently receiving treatment at the selected clinics; on a stable medication for at least three months prior to recruitment; have a random blood glucose ≥10mmol/L, or a HbA1c level > 7.0% where available; possession of a personal mobile phone; ability to read SMS or have an available relative willing to assist in reading the SMS; readiness to receive SMS daily for the duration of the study; not planning to relocate in the next six months; and ability to communicate in either English or isiXhosa. Participants with poorly controlled diabetes were selected because they pose greater risk for complications development and thus require more attention and interventions. Also, only those who have been diagnosed of diabetes for over six months were considered as the diagnosis of diabetes must have been confirmed among them, they are expected to be on stable medications as well as must have adapted well to diabetes management and be able to participate in the study. Finally, those who might be relocating within the period of study might be difficult to follow-up, therefore, only those who have verbalised stability for the period of the study were included.

3.4.2 Exclusion Criteria

Participants were excluded from the study if they have psychiatric disorders, cognitive impairment, visual impairment or any other form of impairment that could hinder the use of a mobile phone or the ability to read and comprehend SMS content. Also,

pregnancy or planning to get pregnant within the next 6 months, being debilitated or handicapped in such a manner that obtaining anthropometric measurements will be difficult, and inability to answer few questions such as demographic characteristics and contact address were additional exclusion criteria.

3.5 STUDY SAMPLE AND SAMPLING TECHNIQUE

3.5.1 Sample size calculation

The previously reported mean HBA1c in the setting was 10.6% and standard care for diabetes using metformin has been reported to reduce HbA1c by 1% (11 mmol/L) (Amod et al., 2012; Govender, Gathiram, & Panajatovic, 2017). Assuming the intervention adds an extra 0.5% and considering a standard deviation of 1 and an alpha error level of 5%, the two-tailed calculation gives a power of over 90% with only 84 participants in each of the control and intervention group. If 20% loss of participants to follow-up is anticipated (Islam et al., 2014), a total of 108 participants is required in each group.

The required sample size was calculated using an online clinical trial sample size calculator (Kane, 2019) which utilises the formula below:

$$K = n_2 \div n_1 = 1$$

$$n_1 = \frac{(\sigma^2_1 + \sigma^2_2 / K)\,(z_{1-\alpha/2} + z_{1-\beta})^2}{\Delta^2}$$

Where,

Δ = |μ2-μ1| = absolute difference between two means
σ1, σ2 = variance of mean #1 and #2
n1 = sample size for group #1
n2 = sample size for group #2
α = probability of type I error (usually 0.05)
β = probability of type II error (usually 0.2)
z = critical Z value for a given α or β
k = ratio of sample size for group #2 to group #1

$$n_1 = \frac{(11^2+11^2/\ 1)\ (1.96 + 1.28)^2}{5.5^2} = 84$$

$$n_2 = K * n_1 = 84$$

3.5.2 Randomisation

The guideline for the management of diabetes is the same across all the primary health care facilities in South Africa (Amod et al., 2017). Thus, all clinics are considered eligible; although the quality of care might vary across various health facilities because of the available infrastructures as well as the available human resources and the experiences of the care providers. Of all the eight health districts, two were conveniently selected: Buffalo City Metropolitan Municipality and Amathole District. In each selected health district, the diabetes clinics were assessed for available facilities such as human resources, blood glucose testing kits and available diabetes support programmes. Information was obtained from the various district health departments and facility heads. The information was scored, and the diabetes clinics were stratified into two levels: average and low-resourced clinics. All the clinics were assigned an identification number hidden from the study statistician. One average-resourced and

two low-resourced clinics were selected from each of the two selected districts, summing up to 6 clinics; 4 low-resourced and 2 average-resourced clinics.

Demographics and other basic information, including random blood glucose measurements, were obtained from diabetic patients at the selected clinics in order to screen for eligibility. From the sample size calculation, 108 participants were required in each arm of the study, summing to 216 participants. Therefore, 36 participants were required from each of the six selected clinics. After screening for eligibility, using simple randomisation technique, 36 participants were randomly selected from the list of eligible participants from each clinic using computer-generated random numbers, adjusting for age and mean duration of diabetes. The selected participants were then randomly allocated to the intervention and control group at a ratio of 1:1. The flowchart for the recruitment, randomisation, allocation and retention of study participants is shown in Figure 3.2.

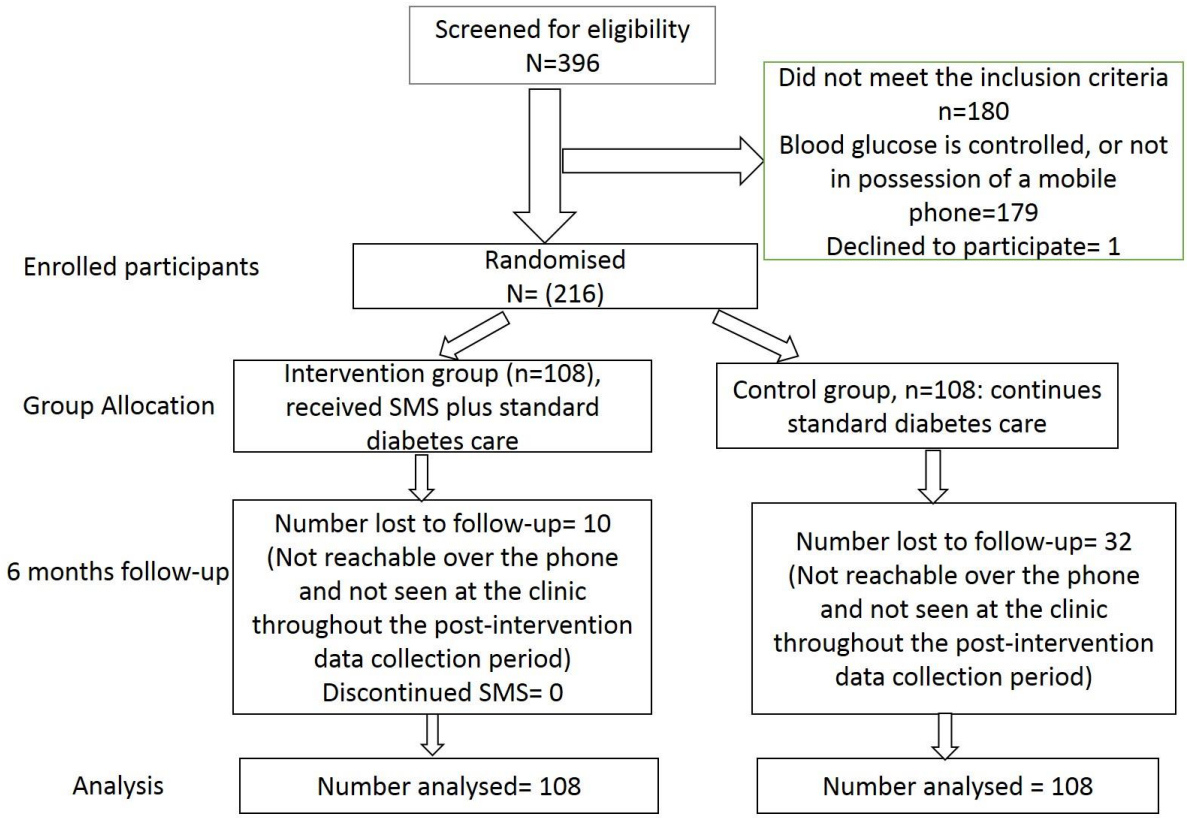

Figure 3.2: Flowchart of the study participants

3.5.3 Blinding

In order to avoid bias, the study statistician involved in the randomisation was blinded to every identifying information. Due to the nature of the study, it was impossible for the research staff conducting the SMS intervention as well as the participants in the intervention arm to be blinded to the intervention, however, participants in the control arm were blinded to the intervention. The participants involved in the intervention were privately contacted after randomisation to remind them of the intervention process and aim. Also, the primary outcome, random blood glucose, as an objective measure, and all other measures were blinded to treatment allocation.

3.6 DATA COLLECTION AND INTERVENTION

3.6.1 Data collection

Data were collected at baseline, and six months after the intervention. Baseline data were collected after screening for eligibility and the random selection of the study participants. Baseline data included demographic characteristics (gender, income, employment status and the duration of diabetes), lifestyle behaviours (smoking, physical inactivity, dietary practices, and alcohol use), diabetes knowledge, health-related quality of life, medication adherence, self-efficacy, self-management behaviour, and biochemical (random blood glucose), blood pressure and anthropometric (weight and height) measurements.

3.6.1.1 Demographic characteristics

Demographic characteristics such as age, gender, marital status, employment status and average income were obtained using the modified WHO STEPwise questionnaire.

3.6.1.2 Primary outcome measure

The primary outcome measure was a change in glycaemic control from baseline to six months post-intervention, which was measured as change in random blood glucose. This was measured with an Accu-Chek Active glucometer (Roche, Switzerland) which analysed a drop of the fingertip capillary blood.

3.6.1.3 Secondary outcome measures

The secondary outcome measures were assessed at baseline and six months. The secondary outcome measures include:

- Knowledge of diabetes obtained with the validated Simplified Diabetes Knowledge Test Questionnaire-2 (Fitzgerald et al., 2016).

- Medication adherence assessed with the 8-item Morisky Medication Adherence Scale (Morisky, Ang, Krousel-Wood & Ward, 2009).
- Health-related quality of life assessed with the EQ-5D-5L quality of life questionnaire (Devlin & Brooks, 2017).
- Diabetes self-management behaviour assessed using the Diabetes Self-management questionnaire (Schmitt et al., 2013; Schmitt et al., 2016).
- Diabetes self-efficacy assessed with Michigan Diabetes Empowerment scale (Anderson, Funnell, Fitzgerald & Marrero, 2003).
- Co-morbid outcomes (hypertension and obesity) obtained through blood pressure measurement and anthropometric measurements (body weight and height), which followed standard protocols; and
- Behavioural characteristics (smoking, alcohol use and physical activity), using the WHO STEPwise approach (ANNEXURE 1).

Other clinical records such as the HbA1c value, appointment dates and compliance were retrieved from the clinic folders where available, or the participants' clinic notes as appropriate.

3.6.1.4 Other variables

- Acceptability of the SMS intervention was determined using the participants' feedback obtained through some self-designed questions.
- Feasibility of the study was assessed by the recruitment and the retention rates

3.6.2 Description of data collection instruments, Validity and Reliability

3.6.2.1 Knowledge of diabetes

Participants' diabetes knowledge was assessed with the simplified Diabetes Knowledge Test, SDKT-2, the true/false version (Fitzgerard et al., 2016). The simplified version of the questionnaire is easier to comprehend and administer. However, it has been shown to be less sensitive to some aspects of diabetes care such as behaviour change (Fitzgerard et al., 2016). The SDKT-2 questionnaire contains 20 items in both sections. The first part of the questionnaire which contains 18 items concerns all the diabetic patients, while the second section containing 2 items solicits information from diabetic patients on insulin therapy only. The instrument assessed patients' general knowledge on diabetes, diets, physical activity and their self-efficacy. Every incorrect response as well as a 'don't know' was considered a knowledge deficit. Individual participant's calculated overall knowledge score was the average of the scores of completed questions. An average score of 50% or more indicates good knowledge of diabetes (Jarab et al., 2014). In this study setting, the diabetes knowledge scale showed high internal consistency. The reliability test of the scale yielded a Cronbach alpha value of 0.94.

3.6.2.2 Medication adherence

The validated 8-item Morisky Medication Adherence Scale (MMAS-8) was utilised for assessing the participants' level of medication adherence (Morisky et al., 2009). The instrument addressed diverse measures through which medication users omit their medications. Such measures include forgetfulness, carelessness, or sudden discontinuation of medication use on assumption of improved health or deterioration of health or users' feelings. Each of the items had a 'Yes' or 'No' answer, and the last item had a dichotomous response as well as a 5-point Likert scale (Morisky et al.,

2009). All the items were reverse coded, in which a 'Yes' answer connoted a score of 0 and 'No' was coded as 1, except for question 5 "Did you take your medication yesterday?", where a Yes response connotes a score of 1. A cut-off value of 6 was used. Adherence level was divided into; low adherence, a score of less than 6, moderate adherence, a score of 6 to 7, while high adherence was defined as a score of 8 (Morisky et al., 2009).

The reliability of the Morisky Medication Adherence scale using Cronbach alpha was 0.55. The same scale was modified to assess adherence to physical activity and dietary recommendation. The modified scale consisted of seven items, and the alpha coefficient value was 0.68 for the physical activity scale and 0.64 for the diet scale. Apart from the alpha coefficient level of the scale, the face, content and construct validity of the scale provided an acceptable level of validity and reliability of the scales as measures of adherence in the various aspects of recommended healthcare regimen.

3.6.2.3 Health-related quality of life

The participants' health-related quality of life was assessed with the EQ-5D-5L questionnaire developed by the Europe Quality of Life (EUROQOL) group in the United Kingdom. The instrument has been used and validated in several countries (Devlin & Brooks, 2017). This concise instrument is a standardised measure of describing and valuing health status for clinical and economic assessment.

The EQ-5D-5L questionnaire contains two sections. The first section is a descriptive part divided into five domains with five levels in each domain. The five domains were

mobility, self-care, usual activities, pain or discomfort and anxiety/depression. In each of the domains, the five levels were described as:

- Level 1: No problem
- Level 2: Slight problem
- Level 3: Moderate problem
- Level 4: Severe problem
- Level 5: Extreme problem

A state of unique health was described as obtaining a mark of 1 in all the domains, which indicated no problem. However, a score of 2 to 5 in any of the domains was an indication of a health problem.

The second section of the tool was a visual assessment scale (VAS), which measured the participants' self-reported health on the day of assessment. The VAS has two endpoints, which ranged from 0 to 100. The '0' end was described as a state of worst health, while the other end of the continuum indicated the best state of health (Van Reeven & Jansen, 2015).

A reliability test was conducted to ascertain the internal consistency of the tool for assessing the health-related quality of life among the participants. The EQ-5D-5L quality of life scale yielded an alpha coefficient of 0.58 based on the responses of the study participants. Although the alpha coefficient value was slightly low, the face and construct validity of the scale added a level of confidence for using this scale as a measure of health-related quality of life among diabetic patients in this setting.

3.6.2.4 Diabetes self-management behaviour

Diabetes self-management behaviour of the participants was assessed with the validated 4-Likert-scale Diabetes Self-management Questionnaire (Schmitt et al., 2013; Schmitt et al., 2016). The questionnaire addressed four core areas that influence diabetes treatment outcome. It comprised 16 items divided into four sub-scales; glucose management (items 1, 4, 6, 10 and 12), dietary control (items 2,5,9 and13), physical activity (items 8,11 and 15) and health care utilisation (items 3,7 and 14), and a final section that is a sum scale, whereby an overall rating of self-care is assessed (item 16 only). The participants were required to rate their self-care behaviour over the past eight weeks (Nathan et al., 2008). The ratings ranged from 'applies to me very much' (score of 3), 'applies to me to a considerable degree' (score of 2), 'applies to me to some degree' (score of 1) to 'does not apply to me' (score of 0). Of these 16 items, seven were in a positive direction while the remaining nine were in a negative direction.

The scores of the subscales ranged from 0 to 10 after being transformed. The transformation was done using the formula:

(Raw score ÷ theoretical maximum score) × 10.

The theoretical maximum score is 15. Therefore, a transformed score of 10 is the highest self-rating of the particular behaviour assessed. An option was provided for the participants to state if the item in the question was not required as part of their treatment. As such, if that option was chosen, the computation of the scale score was adjusted by reducing the theoretical maximum score by 3. In cases where more than half of the items on a scale were missing, no scale score was computed. The

negatively worded questions were reversed in such a manner that higher values deduced more effective self-care. The overall self-management behaviour was determined by summing up the scores, dividing by the theoretical maximum score of 48 and then multiplying by 10. The higher the DSM score, the better the participant's self-management behaviour.

The scale showed a high level of internal consistency in this setting with an alpha coefficient level of 0.81. Given this, and in combination with its face and construct validity, the scale was considered to be a valid and reliable scale for assessing self-management among diabetic patients in this study setting.

3.6.2.5 Diabetes self-efficacy

Participants' diabetes self-efficacy, that is, the ability to complete a task and to reach goals, was assessed with the short form of the Michigan Diabetes Empowerment scale (DES-SF). This validated tool assesses the overall diabetes-related psychosocial self-efficacy of diabetic individuals (Anderson et al., 2003). It is a five-point Likert scale ranging from strongly disagree (score of 1) to strongly agree (score of 5). The scale consists of eight items and was scored by averaging the scores for all the completed items.

The self-efficacy scale demonstrated a high level of reliability among this study population, with a Cronbach Alpha of 0.94. Based on the alpha coefficient as well as the face, content and construct validity of the scale, it was considered a valid and reliable scale for assessing self-efficacy of diabetic patients in this study setting.

3.6.2.6 Diabetes distress

The level of participants' diabetes distress was assessed using the shorter version of the diabetes distress scale, which consists of four items and was validated by Fisher et al. (2008). The average score of the four items formed the diabetes distress score. According to Fisher et al. (2008), a score of 3 or more was considered a level of distress that is worth clinical attention.

The diabetes distress scale had a fairly good alpha coefficient of 0.66 based on the responses of the study participants. Based on the alpha coefficient as well as the face and construct validity of the scale, the scale was considered a valid and reliable scale for assessing diabetes distress in this study setting.

3.6.3 Study intervention procedure

Prior to the commencement of the intervention, both the intervention and the control groups proceeded with their usual care, including all medical visits, routine tests and counselling, medications pick-up and diabetes support programmes. During the intervention period, the intervention group received short message services (SMS) at an agreed time of the day, tailored to their needs, care plan and goals. Participants also received motivational and support messages, and advice on lifestyle behaviours such as diets, physical activity, smoking cessation and medication reminders. One SMS was sent daily, including weekends, and every participant received an average of 184 SMSs for the period of the study. Core messages which provided a general motivation and educative messages on diabetes were sent thrice a week and messages specifically focusing on dietary aspects were sent twice a week. Messages selected randomly from the various other sections were sent once a week. In this setting, appointments are fixed for every 28 days, thus, individualised reminders for

appointments were sent once a month, based on the date of the next appointment provided by the patients. In addition, the few patients who verbalised taking alcohol and smoking were sent messages regarding alcohol use and smoking once every weekend. The SMSs were sent through an online bulk SMS platform named Zoomconnect. The platform allows several messages to be sent at once and scheduled when needed. The platform also provided information on the delivery status of the messages. Participants in the intervention arm were formally informed of the plan to discontinue the daily messages at the end of the six months of intervention and both groups continued with their usual care.

3.6.4 SMS development and dispersal

The principal investigator, supervisor, family physician and a nurse developed the contents of the SMS. The team followed the SEMDSA guideline for the management of diabetes, the health education materials from the National Diabetes Education Programme, and some sample SMS from previously conducted studies which were documented to be efficient and effective (Dobson et al., 2018; Islam et al., 2015). The health care needs of the participants were also not neglected. In addition to that, some gaps in diabetes management in the setting, as observed in the baseline data also influenced the SMS contents. Finally, the opinions of the clinicians and other healthcare workers involved in the management of the patients were put into consideration. The SMS was developed in English and translated to isiXhosa by a professional translator. The two versions of the messages were then pre-tested by sending them out to various people, including those with little or no level of education, to ascertain whether it was easy, simple and clear. Modifications were made using various feedbacks received. Samples of the SMS contents are provided in Annexure

8. Messages were sent at the patient's preferred time and language as indicated during baseline data collection and the record of the SMS sent and received was kept.

3.7 ETHICAL CONSIDERATIONS

University of Fort Hare Research Ethics Committee granted the ethical approval (Reference number: GOO171OWA01) for this study (Annexure 2). Approvals were also obtained from the Eastern Cape Departments of Health (Annexure 3), the two selected health districts and the clinic managers (Annexure 4 and 5). Verbal and written informed consents were obtained from the participants prior to the commencement of the study. Rights to anonymity and confidentiality were ensured throughout the study, and participants consented to referral to further care in case of detection of abnormal findings.

3.8 DATA ANALYSIS

Statistical analysis followed the Intention-to-Treat Analysis, whereby all the randomised participants were analysed, and analysed in their original group, irrespective of any change or drop-out after the randomisation. Descriptive statistics were used to summarise the demographic and baseline characteristics. Continuous variables were summarised as numbers of observed values, means, standard deviation, minimum and maximum. Categorical variables were described as frequency and percentages. Chi-square and Fisher's exact test were used to assess the difference between groups for categorical baseline variables. For continuous variables, analysis of variance was used to assess the difference in the baseline characteristics of the study participants between the intervention and control group. The effect of the intervention on the primary outcome between the two groups and at

the two periods was assessed using the mixed-effect model analysis. Adjustment was made for type of diabetes, and the baseline outcome measures.

Regression was used to assess the effect of the intervention on secondary outcome measures between the groups and two periods; linear regression was used for continuous variables while binary logistic regression was used for categorical variables. The assumption underlying the analysis of missing variables was that the data were missed at random. Missing data were inputted for both the primary and secondary variables using the mean of the variables assessed. Sensitivity analyses were performed on assumptions that missing data were not missed at random and the worst case scenarios. All statistical tests were two-sided at 5% significance level. A p-value less than 0.05 was considered statistically significant. The Statistical Package for Social Sciences (SPSS) version 23 was used for data analysis (SPSS Inc., Chicago, IL, USA).

CHAPTER FOUR

RESULTS AND DISCUSSION

This chapter presents the results of the study as well as the discussion of findings. The results are presented in tables, charts and figures, as appropriate.

4.1 BASELINE RESULTS

4.1.1 Demographic characteristics

Table 4.1 presents the demographic characteristics of the study participants at baseline. Of the 216 participants in the study, 108 were in the intervention arm and 108 in the control arm. For both groups, the majority of the participants were females, 83.30% and 85.20% for the intervention and control groups, respectively. For both the intervention and control groups, over half of the study participants had grade eight to twelve level of education (58.30% vs 58.30%), and the majority had no form of employment (78.70%; 88.90%).

Overall, the mean age of the participants was 60.64 (SD± 11.58) years. For the intervention group, the mean age was 60.12 (SD ± 11.20) years, while the mean age for the control group was 61.16 (SD ± 11.97) years, with no significant difference (p=0.512). With regards to the level of income, the participants earned below 14,200 Rand. The average income was 1551.68 (SD ± 1720.54) Rand. The mean income for the intervention group was 1719.52 (SD ± 2285.46) Rand, and was 1373.56 (SD ± 724.87) Rand for the control group, with no significant difference (p=0.154).

Table 4.1 : Demographic characteristics of study participants by study groups

Variables	Intervention n (%)	Control n (%)	p-value
Age (Years)			
35-50	22 (20.40)	18 (16.80)	0.612
51-70	66 (61.10)	64 (59.80)	
71-87	20 (18.50)	25 (23.40)	
Gender			
Male	18 (16.70)	16 (14.80)	0.426
Female	90 (83.30)	92 (85.20)	
Level of education			
No formal schooling	3 (2.80)	2 (1.90)	0.965
Grade 1-7	39 (36.10)	41 (38.00)	
Grade 8-12	63 (58.30)	63 (58.30)	
Tertiary	1 (0.90)	1 (0.90)	
Post-graduate	2 (1.90)	1 (0.90)	
Marital status			
Never married	16 (15.20)	31 (29.00)	0.018
Married	55 (52.40)	47 (43.90)	
Single mom	0 (0.00)	4 (3.70)	
Divorced	6 (5.70)	2 (1.90)	
Widowed	28 (26.70)	23 (21.50)	
Employment status			
Government employee	2 (1.90)	0 (0.00)	0.209
Non-government employee	7 (6.50)	3 (2.80)	
Self-employed	5 (4.60)	2 (1.90)	
Student	0 (0.00)	1 (0.90)	
Retired	9 (8.30)	6 (5.60)	
Unemployed	85 (78.70)	96 (88.90)	
Average monthly Income (Rand)			
0-1500	39 (37.50)	24 (24.50)	0.032
1501-14200	65 (62.50)	74 (75.50)	

n= Frequency. For intervention group, n=108; while for control group, n=108

Information regarding diabetes treatment and clinical characteristics of the study participants are presented in Table 4.2. For both the intervention and control groups, majority of the study participants had Type 2 diabetes (97.20% vs 90.70%), were on oral pills (76.90% vs 74.10%), had concomitant hypertension, (80.60% vs 85.50%) and were receiving treatment for hypertension (75.00% vs 86.80%). Only a small percentage of the participants had no health comorbidity, 27.80% and 16.70% for the intervention and control groups, respectively.

Concerning the duration of diabetes, overall, the mean duration of diabetes was 9.06 (SD ± 7.38) years, while the duration of diabetes treatment was 8.81 (SD ± 7.20) years.

Stratified by the study groups, the mean duration of diabetes treatment was 8.67 (SD ± 7.56) years for the intervention group, and 9.46 (SD ± 7.22) years for the control group, with no significant difference (p=0.429). For the duration of treatment, the mean duration for the intervention group was 8.22 (SD ± 7.22) years, while the control group was 9.40 (SD ±7.18) years. There was no significant difference in the mean duration of treatment between both groups (p=0.231).

Table 4.2 : Diabetes and treatment characteristics by study groups

Variables	Intervention n (%)	Control n (%)	p-value
Type of diabetes			
Type 1	3 (2.80)	10 (9.30)	0.041
Type 2	105 (97.20)	98 (90.70)	
Type of treatment			
Oral pills	83 (76.90)	80 (74.10)	0.740
Insulin	14 (13.0)	18 (16.70)	
Both	11 (10.20)	10 (9.30)	
Number of therapy			
Monotherapy	63 (58.30)	66 (61.70)	0.359
Dual therapy	45 (41.70)	41 (38.30)	
Type of medication used			
Metformin only	46 (42.60)	43 (40.20)	0.197
Metformin and others	47 (43.50)	39 (36.40)	
Insulin	14 (13.00)	19 (17.80)	
Gliclazide or glibenclamide only	0 (0.00)	3 (2.80)	
Glibenclamide and other	1 (0.90)	0 (0.00)	
Daonil	0 (0.00)	1 (0.90)	
Daonil and Others	0 (0.00)	2 (1.90)	
Type of comorbidity			
None	30 (27.80)	18 (16.70)	0.196
Diabetes and hypertension	62 (57.40)	73 (67.60)	
Diabetes, hypertension and HIV/AIDS	4 (3.70)	7 (6.50)	
Diabetes, hypertension and heart issues	2 (1.90)	3 (2.80)	
Diabetes, hypertension and anti-depressants	2 (1.90)	0 (0.00)	
Diabetes, hypertension and Asthma	7 (6.50)	3 (2.80)	
Diabetes, hypertension and Epilepsy	0 (0.00)	1 (0.90)	
Diabetes and cancer	1 (0.90)	0 (0.00)	
Diabetes, hypertension and dyslipidaemia	0 (0.00)	1 (0.90)	
Diabetes and HIV/AIDs	0 (0.00)	1 (0.90)	
Diabetes, hypertension and stroke	0 (0.00)	1 (0.90)	
Duration of diabetes (Years)			
1-6	58 (53.70)	50 (46.30)	0.723
7-12	22 (20.40)	24 (22.20)	
13-20	19 (17.60)	22 (20.40)	
21-34	9 (8.30)	12 (11.10)	
Duration of treatment (Years)			
1-6	60 (55.60)	50 (46.30)	0.553
7-12	22 (20.40)	24 (22.20)	
13-20	17 (15.70)	23 (21.30)	
21-34	9 (8.30)	11 (10.20)	

Have you been told by a doctor or other health professional that you have hypertension?			
Yes	79 (80.60)	65 (85.50)	0.260
No	19 (19.40)	11 (14.50)	
Are you currently receiving any treatment for hypertension in the past two weeks?			
Yes	81 (75.00)	92 (86.80)	0.021
No	27 (25.00)	14 (13.20)	
Does any of your family members have diabetes?			
Yes	60 (55.60)	49 (45.40)	0.087
No	48 (44.40)	59 (54.60)	

n= Frequency. For intervention group, n=108; while for control group, n=108

4.1.2 Behavioural characteristics of the study participants

Table 4.3 presents tobacco use among the study participants. For both the intervention and control groups, majority of the study participants never smoked any tobacco product; 98.10% and 94.40% for the intervention and control group participants, respectively. Also, secondary smoking was not prevalent among the study participants, 95.20% and 92.50% for the intervention and the control group, respectively.

Table 4.3: Pattern of tobacco use among the study participants

Variables	Intervention n (%)	Control n (%)	p-value
Have you ever smoked any tobacco product?			
Yes	2 (1.90)	6 (5.60)	0.140
No	106 (98.10)	102(94.40)	
Do you currently smoke any tobacco product?			
Yes	2 (100.00)	3 (50.00)	0.357
No	0 (0.00)	3 (50.00)	
If you no longer smoke, when did you stop smoking (years)?			
1	1 (100.00)	0 (0.00)	0.223
15	0 (0.00)	1 (50.00)	
30	0 (0.00)	1 (50.00)	
If you still smoke tobacco, so you currently use tobacco daily?			
Yes	2 (100.00)	2 (66.70)	0.600
No	0 (0.00)	1 (33.30)	
Type of tobacco product used			
Manufactured cigarette	1 (50.00)	2 (66.70)	0.700
Hand-rolled cigarette	1 (50.00)	1 (33.30)	
How many of the tobacco product you use do you take per day?			
1	1 (50.00)	0 (0.00)	0.261
4	0 (0.00)	1 (50.00)	
6	1 (50.00)	0 (0.00)	
10	0 (0.00)	1 (50.00)	

During the past 7 days, did any one smoke in your home or at your workplace?			
Yes	5 (4.80)	8 (7.50)	0.297
No	100 (95.20)	99 (92.50)	

n= Frequency. For intervention group, n=108; while for control group, n=108

As shown in Table 4.4, the majority of the participants in the intervention (88.00%) and control group (87.00%) never used alcohol. The only few participants who reported current alcohol use often do so once in a month, 100.00% and 60.00% for the intervention and control group participants, respectively.

Table 4.4: Alcohol use among the study participants

Variables	Intervention n (%)	Control n (%)	p-value
Have you ever consumed alcohol			
Yes	13 (12.00)	14 (13.00)	0.500
No	95 (88.00)	94 (87.00)	
Do you currently use alcohol			
Yes	10 (83.30)	11 (84.60)	0.672
No	2 (16.70)	2 (15.40)	
Have you ever consumed alcohol in the last 30 days?			
Yes	6 (75.00)	10 (83.30)	0.535
No	2 (25.00)	2 (16.70)	
If you no longer take alcohol, when did you stop (years)?			
1	1 (100.00)	1 (50.00)	0.667
30	0 (0.00)	1 (50.00)	
During the past 30 days, how frequently have you had at least one alcoholic drink?			
Daily	0 (0.00)	2 (20.00)	0.362
5-6 times a week	0 (0.00)	1 (10.00)	
1-3 times per week	0 (0.00)	1 (10.00)	
Less than once a month	6 (100.00)	6 (60.00)	
During the past 30 days, how many times did you have for men, 5 or more or for women, four or more alcoholic drink in a week?			
1-4 times	6 (75.00)	3 (75.00)	0.764
5-7 times	2 (25.00)	1 (25.00)	

n= Frequency. For intervention group, n=108; while for control group, n=108

The results obtained from the participants regarding their dietary practices (Table 4.5) indicated that more than half of the study participants both in the intervention group (66.40%) and in the control group (67.30%) had been taught about the required diets for diabetes. With regards to adherence to recommended dietary regimens, 92.50%

of participants in the intervention group and 87.00% of those in control group, had a low level of adherence. A large number of the study participants, 68.80% and 79.60% for the intervention and control group respectively, did not comply with the recommended dietary regimen because they felt the diets are expensive and they could not afford it.

Table 4.5: Dietary practices of the study participants

Variables	Intervention Group n (%)	Control Group n (%)	p-value
Has anyone taught you about required diets for diabetes?			
Yes	71 (66.40)	72 (67.30)	0.500
No	36 (33.60)	35 (32.70)	
Are you familiar with the diabetes diet portions?			
Yes	48 (44.40)	57 (52.80)	0.138
No	60 (55.60)	51 (47.20)	
How often do you adhere to your recommended dietary regimen?			
Always	9 (8.30)	13 (12.00)	0.112
Sometimes	86 (79.60)	90 (83.30)	
Not at all	13 (12.00)	5 (4.60)	
If you do not comply, what is/are your reason(s) for not complying?			
Diet is not palatable	19 (20.4)	9 (9.7)	0.061
Diet is expensive and I cannot afford it	64 (68.8)	74 (79.6)	
Diet does not improve my condition	0 (0.00)	3 (3.20)	
Diet is not palatable	2 (2.20)	4 (4.30)	
Lack of knowledge	7 (7.50)	3 (3.20)	
No specific reason	1 (1.10)	0 (0.00)	
Adherence to diet regimen			
Low	99 (92.50)	94 (87.00)	0.177
Medium	7 (6.50)	14 (13.00)	
High	1 (0.90)	0 (0.00)	

n= Frequency. For intervention group, n=108; while for control group, n=108

Concerning the physical activity pattern of the participants, for both the intervention and the control groups, majority (88.00%; 86.10%) stated that they engage in a form of moderate exercise or the other. However, applying the adherence scale, almost all the participants exhibited low adherence to physical activity regimens, 93.5% for both the intervention and the control groups. More than half of the participants in both groups verbalised being active enough (52.80; 61.40%) despite majority indicating they engage in exercise sometimes, 83.30% and 81.50% for the intervention and

control groups. Lack of time was the most cited reason for not following the recommended physical activity pattern (Table 4.6).

Table 4.6: Physical activity pattern of the study participants

Variables	Intervention n (%)	Control n (%)	p-value
Do you participate in physical activities like running, walking, gardening			
Yes	95 (88.00)	93 (86.10)	0.420
No	13 (12.00)	15 (13.90)	
Do you think you are active enough?			
Yes	56 (52.80)	62 (61.40)	0.135
No	50 (47.20)	39 (38.60)	
How often do you comply with the recommended physical activity level?			
Always	13 (12.00)	15 (13.90)	0.921
Sometimes	90 (83.30)	88 (81.50)	
Not at all	5 (4.60)	5 (4.60)	
What are your reasons for non-compliance with recommended physical activity pattern?			
Lack of time	43 (59.70)	52 (61.20)	0.651
Lack of equipment for exercising	12 (16.70)	16 (57.10)	
Lack of motivation	1 (1.40)	1 (1.20)	
It does not improve my condition	1 (1.40)	1 (1.20)	
I do not know the benefits	0 (0.00)	2 (2.40)	
Lack of equipment and it does not improve my condition	14 (19.40)	11 (12.90)	
Lack of equipment and I do not know its benefits	1 (1.40)	0 (0.00)	
Lack of time and lack of equipment	0 (0.00)	1 (1.20)	
In a typical day, how many hours do you spend sitting down or reclining			
1-7	93 (97.90)	87 (95.60)	0.321
8-10	2 (2.10)	4 (4.40)	
Adherence with the recommended physical activity level			
Low	101 (93.50)	101(93.50)	0.608
Moderate	7 (6.50)	7 (6.50)	
High	0 (0.0)	0 (0.0)	

n= Frequency. For intervention group, n=108; while for control group, n=108

4.1.3 Clinical measures or skills that contribute to glycaemic control

Concerning the knowledge of diabetes among the study participants, there was a generally low level of knowledge across both groups. At baseline, the participants' diabetes knowledge score using the Michigan Diabetes Knowledge Test instrument ranged from as low as 3 to 17 out of 20. Their average score was 7.59 (SD ± 2.05)

(Table 4.10). The mean score for the intervention group was 7.67 (SD ± 2.13), while that of the control group was 7.56 (SD ± 1.96), with no significant difference (p=0.842).

Figure 4.1 displays the medication adherence level among the study participants at baseline. There was no significant difference in the medication adherence between both groups at baseline (p=0.989). In the intervention arm, 41.70% had a high level of adherence to medication (score of 8 out of 8), another 40.70% had a moderate level of adherence (score of 6 to 7), while 17.60% had a low level of adherence (score less than 6). A similar pattern was recorded in the control group. On a scale of 1 to 8, the mean medication adherence level for both groups was 6.88 (SD ± 1.33); 6.90 (SD ± 1.34) for the intervention group and 6.87 (SD ± 1.32) for the control group. There was no statistical difference between the mean medication adherence levels of both arms of the study (p= 0.878).

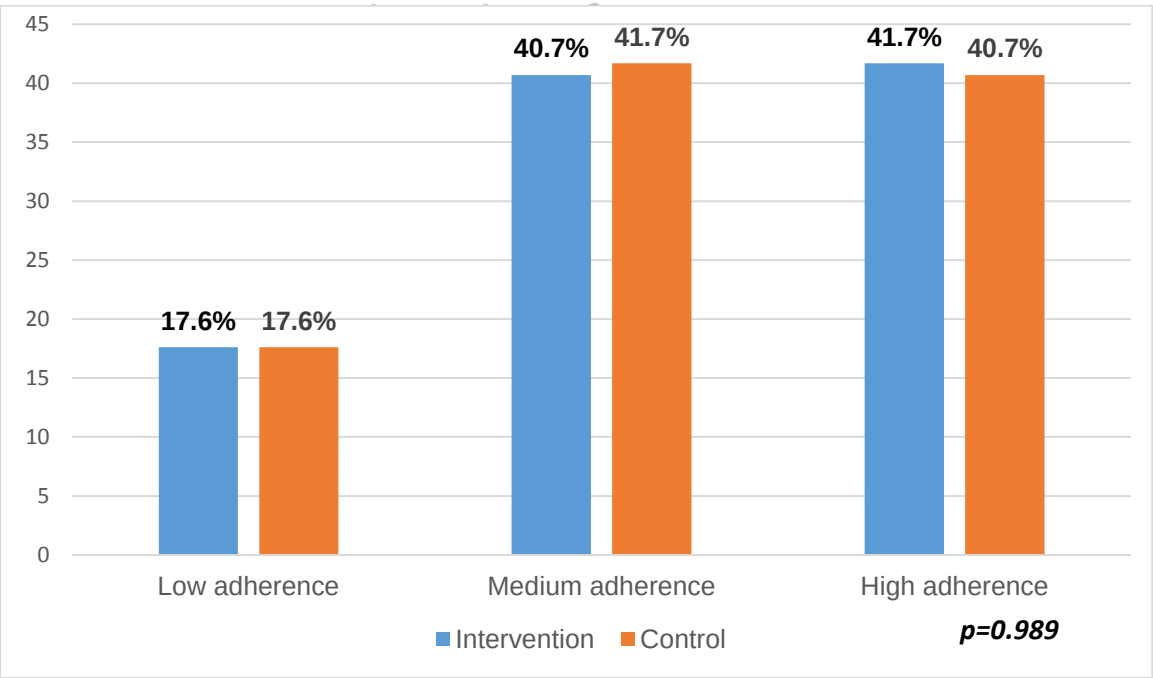

Figure 4.1: Medication adherence among study participants

The mean quality of life score for all the participants in all the various aspects of health was 7.08 (SD ± 2.40), which ranged from 5 to 17. When asked to rate their health on a scale of 100, the average quality of life rating was 70.09 (SD±16.06) percent, which ranged from 30% to 100% for both groups. There was no significant difference in the average quality of life between the study groups at baseline (p= 0.497) as well as the overall quality of life rating on the day of assessment (p=0.896).

Shown in Table 4.7, is the quality of life of the study participants in the various aspects of health. The rating of quality of life was categorised into two, those without problems and those with problems which could be either slight, moderate, severe or very severe problems in various health aspects. Overall, only one-third of the participants had no problem in their overall quality of life with no significant difference across the groups (p=0.280). However, in the various aspects of health, a large number of participants generally reported having no problems except in the pain or discomfort aspect, where close to half of the participants reported having a level of pain or the other. In the pain or discomfort quality of life, 46.30% of the participants in the intervention arm had a form of pain or discomfort, while 40.7% in the control arm also had a form of pain or discomfort.

Table 4.7: Baseline distribution of participant's quality of life

Variables	Intervention n (%)	Control n (%)	p-value
Overall quality of life			
No problem	32 (29.60)	37 (34.30)	0.280
Problems	76 (70.40)	71 (65.70)	
Quality of life in various aspects of health			
Mobility			
No problems	71 (65.70)	71 (65.70)	0.557
Problems	37 (34.30)	37 (34.30)	
Self-care			
No problems	99 (91.70)	96 (88.90)	0.328
Problems	9 (8.30)	12 (11.10)	
Usual activities			
No problems	80 (74.10)	86 (79.60)	0.210

Problems	28 (25.90)	22 (20.40)	
Pain or discomfort			
No problems	58 (53.70)	64 (59.30)	0.246
Problems	50 (46.30)	44 (40.70)	
Anxiety/depression			
No problems	89 (82.40)	86 (79.60)	0.364
Problems	19 (17.60)	22 (20.40)	

n= Frequency. For intervention group, n=108; while for control group, n=108

Diabetes self-management is rated on a scale of 10. The higher the diabetes self-management score, the better. The diabetes self-management score for all the participants ranged from 1.88 to 10.00, with a mean diabetes self-management score of 5.75 (SD ± 1.69). There was no statistically significant difference in the diabetes self-management of participants across the two study arms (p=0.854). For the participants in the intervention arm, the mean self-management score was 5.73 (SD ± 1.73), while those in the control arm had a self-management score of 5.77 (SD ± 1.66) (Table 4.10).

Considering the self-efficacy level of diabetic patients, scores from 3.8 to 5.0 are considered high; scores from 2.40 to 3.79 are moderate self-efficacy, while scores between 1 and 2.39 are considered a low level of self-efficacy. The mean self-efficacy of the participants was 3.82 (SD ± 0.85), and the score ranged from 1 to 5. For those in the intervention group, mean diabetes self-efficacy score was 3.74 (SD ± 0.84), while that of the control group was 3.90 (SD ± 0.87), with no significant difference (p=0.179). The participants' diabetes self-efficacy was further divided into groups: high, moderate and low. Over half (55.60%) of the participants in the control arm had high self-efficacy. Close to half (46.20%) of the study participants in the intervention arm have high self-efficacy (Figure 4.2).

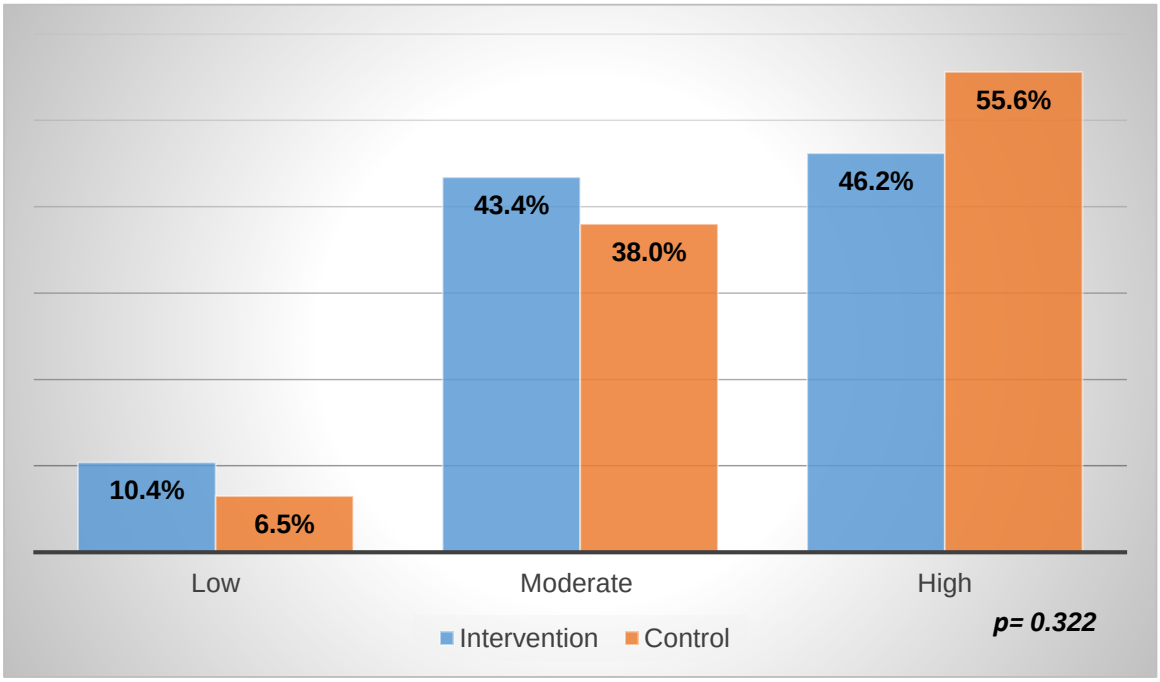

Figure 4.2: Diabetes self-efficacy

The level of diabetes distress is illustrated in Figure 4.3. Low level of diabetes distress is a score less than 3, while a score of 3 and above is considered high, which represents a level of clinically significant diabetes distress. Diabetes distress differed significantly between the two study groups. High level of diabetes distress was found among 12.10% of the participants in the intervention arm and 23.10% in the control group, with a significant difference (p= 0.026). The mean diabetes distress score for both the intervention arm and the control arm (2.17 vs 2.37) were below the level considered to be clinically significant distress. Overall, the mean diabetes distress score was low, 2.27 (SD ± 0.85).

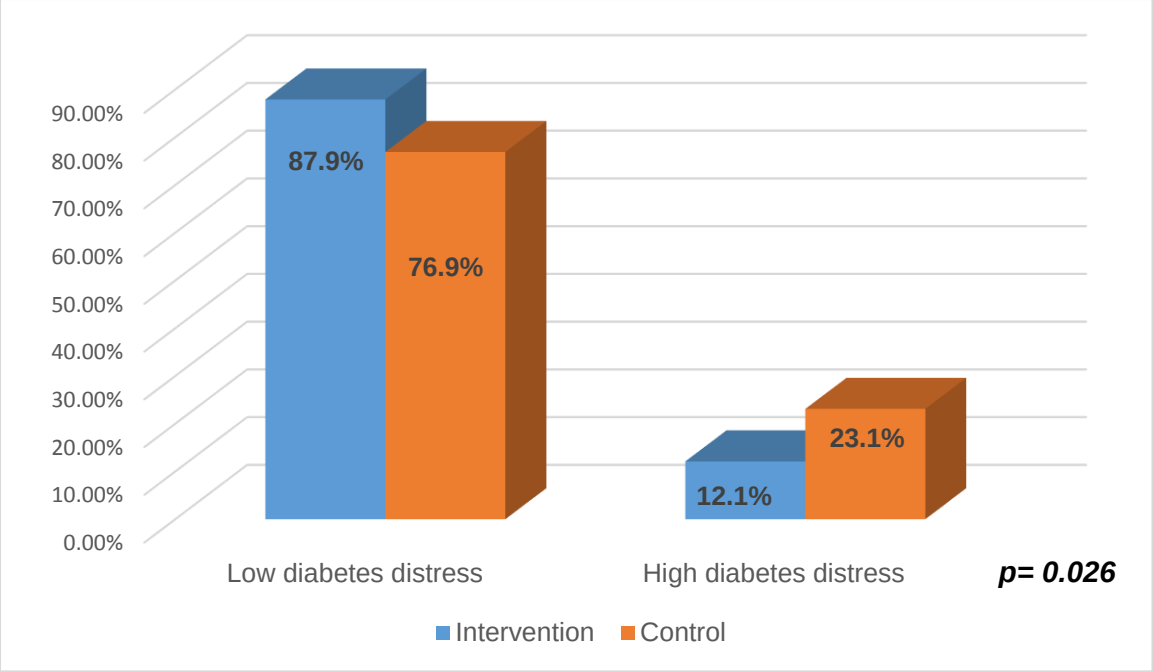

Figure 4.3: Diabetes distress among study participants

4.1.4 Healthcare utilisation

Table 4.8 indicates that all the patients had visited the clinic in the last six months. Majority of the patients rarely had cause to visit the emergency room, private doctor, or be admitted at the clinic or hospital in the past 6 months, for both groups.

Table 4.8: Healthcare utilisation by the study participants

Variables	Intervention n (%)	Control n (%)	p-value
Have you visited the clinic in the last 6 months?			
Yes	108 (100.00)	108 100.00)	
No			
Have you visited the emergency room in the last six months?			
Yes	4 (4.40)	6 (8.20)	0.245
No	87 (95.60)	67 (91.80)	
Have you visited the private doctor in the last six months?			
Yes	2 (2.20)	3 (4.20)	0.394
No	87 (97.80)	68 (95.80)	
Did you have cause to sleep overnight in the clinic or the hospital in the last six months?			
Yes	3 (3.30)	10 (13.50)	0.017
No	87 (96.7)	64 (86.50)	

n= Frequency. For intervention group, n=108; while for control group, n=108

4.1.5 Quality of diabetes care

The quality of diabetes care rendered to the study participants in terms of conducting the required health screening shows that the most frequent screening or observations conducted for most patients were the blood glucose and blood pressure which were mostly checked every month (Table 4.9). Apart from the blood glucose and blood pressure observations, for both the intervention and the control groups, though at a lower level than expected, blood lipid screening (23.40% vs 17.60%) and screening for renal complications (20.60% vs 14.80%) were the other screenings conducted. Rarely was feet examination, and cardiovascular examinations done for most patients.

Table 4.9: Quality of healthcare in terms of health screenings

Variables	Intervention n (%)	Control n (%)	p-value
Have you checked your blood sugar in the last 12 months?			
Yes	106 (98.10)	106 (98.10)	0.689
No	2 (1.90)	2 (1.90)	
If yes, how often?			
Every month	102 (96.20)	95 (89.60)	0.281
Daily	0 (0.00)	1 (0.90)	
Twice a year	1 (0.90)	5 (4.70)	
Every two months	3 (2.80)	4 (0.90)	
Four times a year	0 (0.00)	1 (0.90)	
Have you checked your blood pressure in the last 12 months			
Yes	107 (99.10)	107 (99.10)	0.751
No	1 (0.90)	1 (0.90)	
If yes, how often?			
Every month	102 (95.30)	100 (93.50)	0.568
Twice a year	0 (0.00)	2 (1.90)	
Every two months	4 (3.70)	4 (3.70)	
Four time a year	1 (0.90)	1 (0.90)	
Have you checked your blood lipid in the last 12 months?			
Yes	25 (23.40)	19 (17.60)	0.190
No	82 (76.60)	89 (82.40)	
If yes, how often?			
Every month	1 (4.20)	1 (5.00)	0.761
Once a year	14 (58.30)	10 (50.00)	
Twice a year	4 (16.70)	3 (15.00)	
Thrice a year	1 (4.20)	0 (0.00)	
Four times a year	4 (16.70)	6 (30.00)	
Have you screened for eyes complications in the last 12 months?			
Yes	14 (13.10)	11 (10.20)	0.327
No	93 (86.90)	97 (89.80)	

If yes, how often?			
Every month	1 (7.10)	0 (0.00)	0.319
Every two months	0 (0.00)	1 (9.10)	
Once a year	6 (42.90)	6 (54.5)	
Twice a year	3 (21.40)	0 (0.00)	
Four times a year	4 (28.60)	4 (36.40)	
Have you screened for feet complications in the last 12 months?			
Yes	3 (2.80)	1 (0.90)	0.307
No	104 (97.20)	107 (99.10)	
If yes, how often?			
Every month	3 (75.00)	0 (0.00)	0.400
Once a year	1 (25.00)	1 (100.00)	
Have you screened for kidney complications in the last 12 months?			
Yes	22 (20.60)	16 (14.80)	0.177
No	85 (79.40)	92 (85.20)	
If yes, how often?			
Every month	0 (0.00)	1 (6.30)	
Once a year	17 (81.00)	14 (87.50)	0.557
Twice a year	2 (9.50)	1 (6.30)	
Thrice a year	1 (4.80)	0 (0.00)	
Four times a year	1 (4.80)	0 (0.00)	
Have you ever screened for cardiovascular complication?			
Yes	8 (7.50)	8 (7.40)	0.594
No	99 (92.50)	100 (92.60)	
If yes, how often?			
Once a year	5 (71.40)	6 (75.00)	0.566
Twice a year	0 (0.00)	1 (12.50)	
Thrice a year	1 (14.30)	1 (12.50)	
Four times a year	1 (14.30)	0 (0.00)	

n= Frequency. For intervention group, n=108; while for control group, n=108

Table 4.10: Mean values of various clinical, health and behavioural measures

Variables	Intervention Mean (±SD)	Control Mean (±SD)	p-value
Health-facilitating behaviours and skills			
Medication adherence	6.90 (1.34)	6.87 (1.32)	0.878
Dietary regime adherence	1.52 (1.62)	1.69 (1.73)	0.479
Physical activity adherence	1.48 (1.58)	1.46 (1.49)	0.930
Knowledge of diabetes	7.67 (2.13)	7.56 (1.96)	0.842
Quality of life	7.19 (2.57)	6.97 (2.22)	0.479
Overall self-rated quality of life	69.95 (15.74)	70.24 (16.45)	0.896
Diabetes self- management score overall	5.73 (1.73)	5.77 (1.66)	0.854
Diabetes glucose management score	6.24 (1.71)	6.35 (1.63)	0.646
Diabetes dietary control self-management	5.69 (2.15)	5.89 (2.04)	0.482
Diabetes physical activity self-management	4.98 (2.48)	4.98 (2.41)	1.000
Diabetes healthcare use self-management	6.47 (2.04)	6.28 (1.93)	0.470
Diabetes self-efficacy	3.74 (0.84)	3.90 (0.87)	0.179
Diabetes distress	2.17 (0.65)	2.38 (0.83)	0.044
Number of missed appointment from the previous six appointments	1.12 (1.60)	1.16 (1.49)	0.857
Hours spent sitting down or reclining daily	3.15 (1.88)	3.59 (4.34)	0.361
Clinical outcomes			
Weight	83.76 (15.30)	82.09 (17.24)	0.451
Waist circumference (Cm)	98.52 (20.21)	100.23(15.67)	0.487
Hip circumference (Cm)	109.88 (18.98)	111.69(21.43)	0.513

Systolic blood pressure (mmHg)	144.28 (21.15)	146.26(23.84)	0.519
Diastolic blood pressure (mmHg)	82.28 (10.25)	82.75 (15.07)	0.793
Random blood glucose (mmol/L)	14.29 (4.39)	14.39 (3.41)	0.851
Body mass index (Kgm^{-2})	32.21 (5.63)	32.14 (7.16)	0.933

n= Frequency. For intervention group, n=108; while for control group, n=108; Cm= Centimetres; mmol/L= Millimole per Litre; mmHg=Millimetres of Mercury, Kgm^{-2} = Kilogram per metre-sqaure.

4.1.6 Acceptability of the mHealth intervention

Regarding the acceptability of the text messaging, the majority of the participants (98; 90.74%) who completed the post-intervention survey indicated the helpfulness of the SMS (Table 4.11).

The participants who completed the post-intervention data collection were further asked to highlight ways through which the SMS helped them. Of the 98 participants, 43% maintained that the SMS provided more information about their health and the required diet for health promotion. Furthermore, 24.7% stated that the SMS was a form of reminder to take medications, while 15.5% said the SMS provided more information, served as reminders to take their medications and was a source of motivation to them.

When asked about the timing of SMS delivery, almost all of the participants (98%) were satisfied with the timing of the SMS delivery. Almost all of the participants (95.9%) declared their readiness to continue receiving the SMS even after the completion of the study should the researcher decide to continue with the SMS. None of the participants had any suggestion as to what changes they would like to see in the SMS intervention should the researcher decide to continue.

Table 4.11: Acceptability of the text messaging intervention

Variables	Frequency (n)	Percentage (%)
Did you receive the daily SMS?		
Yes	98.00	100.0
No	0.00	100.0
Do you think the SMS was helpful?		
Yes	98.00	100.00
No	0.00	0.00
In what way did the SMS help you?		
It gives me more information about my health and more especially about my required diets	42.00	43.30
Reminds me to take my medication and go for my appointments	24.00	24.70
It motivates me	3.00	3.10
Reminds me to take my medication, and taught me about the required diet	13.00	13.40
It reminds me to use my medications, teaches me about the required diets and helps me to stay motivated	15.00	15.50
Did the SMS stress you in any way?		
Yes	1.00	1.00
No	97.00	99.00
Are you satisfied with the timing of the SMS?		
Yes	96.00	98.00
No	2.00	2.00
If we decide to continue, would you like to continue?		
Yes	94.00	95.90
No	4.00	4.10

4.2 RESEARCH OBJECTIVES AND HYPOTHESES TESTING

4.2.1 Impact of intervention on the primary outcome

4.2.1.1 Impact of daily text-messaging on glycaemic control

As shown in Table 4.12, the mean difference in blood glucose from baseline to six months post-intervention for the intervention group was – 1.58 (SD ± 5.29), while that of the control group was – 1.95 (SD ± 4.69). The mean difference in the change in blood sugar between the two groups from baseline to post-intervention was 0.51 (-0.80 to 1.82), with no significant difference (p=0.441). After adjusting for baseline blood glucose, diabetes type and treatment type, the mean difference was 0.26 (-0.81 to 1.32), with no significant difference (p=0.634).

Based on the findings, the primary hypothesis which stated that mobile phone SMS intervention in addition to the standard diabetes care would significantly reduce blood glucose level among diabetic patients compared to standard care alone is therefore rejected.

Table 4.12: Impact of SMS on glycaemic control

	Intervention Mean (SD)	**Control** Mean (SD)	**Unadjusted mean difference (95% CI)**	**p for difference**	**Adjusted mean difference (95% CI)**	**p for difference**
Baseline	14.30 (4.40)	14.40 (3.42)				
Change from baseline at 6 months	-1.58 (5.29)	-1.95 (4.69)	0.51 (-0.80 to 1.82)	0.441	0.26 (-0.81 to 1.32)	0.634

*Random effects mixed model with and without adjustment for baseline blood glucose, type of diabetes, treatment type. Measurements are in mmol/L. P-value < 0.05 is statistically significant.

4.2.2 Impact of intervention on secondary outcomes

4.2.2.1 Impact of daily text messaging on diabetes knowledge

The effect of the SMS intervention on the participants' diabetes knowledge is displayed in Table 4.13. Both the intervention and the control arm showed an increase in knowledge. However, there was no significant difference in the mean change in the knowledge score (p=0.567) from baseline to six months post-intervention across the two groups, mean change -0.04 (-0.59 to 0.32).

The hypothesis, which stated that the participants in the intervention arm would show greater improvement in diabetes knowledge than those in the control arm is thus rejected.

Table 4.13: Impact of daily SMS on diabetes knowledge

Secondary outcomes	Intervention n= 108		Control n= 108		Adjusted mean difference (95% CI)	p-value
	Baseline Mean (SD)	Post-intervention Mean (SD)	Baseline Mean (SD)	Post-intervention Mean (SD)		
Diabetes knowledge	7.67(2.13)	8.14 (1.75)	7.56 (1.96)	8.04 (2.09)	-0.04 (-0.59 to 0.32)	0.567

*Linear regression model adjusted for baseline knowledge score, type of diabetes and duration of illness. P <0.05 is statistically significant

4.2.2.2 Impact of daily text messaging on adherence

Table 4.14 shows the effect of daily SMS on participants' medication adherence level from baseline to six months post-intervention between the two study groups. The adjusted mean change in the medication adherence level was 0.02 (-0.32 to 0.44). There was no significant difference in the mean change in the patients' medication adherence level between the intervention and the control groups (p=0.757). Thus, the hypothesis that participants receiving the daily SMS will show greater improvement in medication adherence than those not receiving text messages is rejected.

There was generally a low level of adherence to dietary recommendations, and physical activity in both groups and both groups demonstrated a slight increase from baseline to follow-up period. Nonetheless, there was no significant difference in the mean change in dietary adherence (p= 0.978) and physical activity adherence (p=0.992) between those in the control arm and those in the intervention arm.

Table 4.14: Impact of SMS intervention on participants' adherence level

Secondary outcomes	Intervention n= 108		Control n= 108		Adjusted mean difference (95% CI)	p-value
	Baseline Mean (SD)	Post-intervention Mean (SD)	Baseline Mean (SD)	Post-intervention Mean (SD)		
Medication adherence	6.90 (1.34)	6.88 (1.67)	6.87 (1.32)	6.96 (1.51)	0.02 (-0.32 to 0.44)	0.757
Diet adherence	1.52 (1.62)	2.22 (1.85)	1.69 (1.73)	2.25 (1.63)	-0.00 (-0.42 to 0.43)	0.978
Physical activity adherence	1.48 (1.58)	1.69 (1.45)	1.46 (1.49)	1.78 (1.60)	-0.00 (-0.36 to 0.37)	0.992

*Linear regression model adjusted for baseline adherence and type of diabetes. P <0.05 is statistically significant

4.2.2.3 Impact of daily text messaging on health-related quality of life

The health-related quality of life of the study participants was assessed with the EuroQol-5D-5L instrument, while the EuroQOl Visual Assessment Scale measured the participants' self-rating of their quality of life on the day of assessment. As shown in Table 4.15, the overall health-related quality of life of the participants in the control arm increased from baseline to post-intervention, while those in the intervention had a slight reduction. However, in the self-rated health-related quality of life, participants in the intervention showed more improvement compared to those in the control arm.

With regards to the effect of the intervention on the health-related quality of life, the adjusted mean change from baseline to six months was 0.06 (-0.32 to 0.81). There was no significant difference in the mean change in health-related quality of life from baseline to six months post-intervention between the participants who received the daily SMS and those who did not (p=0.394). The adjusted mean change in the self-rated health-related quality of life from baseline to six months post-intervention was -0.10 (-7.40 to 1.00). Similarly, there was no significant difference in the mean change

in self-rated health-related quality of life of participants in both the control and intervention arm (p= 0.134).

Therefore, the hypothesis that participants who receive the daily SMS will show greater improvement in their health-related quality of life than those who do not receive daily SMS is rejected.

Table 4.15: Impact of SMS intervention on health-related quality of life

Secondary outcomes	**Intervention n= 108**		**Control n= 108**		**Adjusted mean difference (95% CI)**	**p-value**
	Baseline Mean (SD)	Post-intervention Mean (SD)	Baseline Mean (SD)	Post-intervention Mean (SD)		
Overall QOL	7.19 (2.57)	7.00 (2.51)	6.97 (2.23)	7.22 (2.15)	0.06 (-0.32 to 0.81)	0.394
Self-rated QOL	69.95 (15.74)	80.52 (15.32)	70.24 (16.44)	75.97 (19.58)	-0.10 (7.40 to 1.00)	0.134

*Linear regression model adjusted for baseline measure and type of diabetes. P <0.05 is statistically significant; QOL: Health-related quality of Life

4.2.2.4 Impact of daily text messaging on diabetes self-management

As shown in Table 4.16, there was a general reduction in the overall self-management behaviour of the study participants across the two study arms. Likewise, there was a reduction in mean scores from baseline to post-intervention across the various self-management subscales, except for the diet self-management which slightly increased in the intervention arm, from 5.67 (SD±2.15) to 5.93 (SD±1.62). Overall, there was no significant difference in the mean change in diabetes self-management behaviours between the participants who received the daily SMS and those who did not (p=0.821).

Therefore, the hypothesis which stated that participants in the intervention arm would show greater improvement in self-management behaviour compared to those in the control arm is rejected.

Table 4.16: Impact of daily SMS on participants' self-management behaviour

Secondary outcomes	Intervention n= 108		Control n= 108		Adjusted mean difference (95% CI)	p-value
	Baseline Mean (SD)	Post-intervention Mean (SD)	Baseline Mean (SD)	Post-intervention Mean (SD)		
Overall DSM	5.73 (1.73)	5.29 (0.58)	5.77 (1.66)	5.28 (0.56)	-0.02 (-0.15 to 0.12)	0.821
Glucose management	6.24 (1.71)	6.08 (0.73)	6.35 (1.64)	6.01 (0.73)	-0.05 (-0.24 to 0.12)	0.505
Diet control management	5.67 (2.15)	5.93 (1.62)	5.88 (2.04)	5.80 (1.52)	-0.05 (-0.52 to 0.25)	0.482
Physical activity self-management	4.98 (2.48)	3.16 (1.08)	4.98 (2.41)	3.22 (0.96)	0.05 (-0.16 to 0.34)	0.469
Healthcare use	6.47 (2.04)	6.17 (1.08)	6.28 (1.93)	6.21 (1.25)	0.02 (-0.25 to 0.34)	0.759

*Linear regression model adjusted for baseline self-management and type of diabetes. P <0.05 is statistically significant; DSM: Diabetes self-management.

4.2.2.5 Impact of daily text messaging on Diabetes self-efficacy and distress

The self-efficacy scores of the study participants at baseline and six months post-intervention are displayed in Table 4.17. The participants in both the intervention and control groups demonstrated an improvement in their self-efficacy from baseline to the post-intervention period. However, there was no significant difference in the mean change in diabetes self-efficacy, -0.03 (-0.19 to 0.11) (p=0.609), between the participants who received the SMS and those who did not. A similar result was obtained on the participants' diabetes distress level. Both groups had a reduction in their diabetes distress, but there was no significant difference in the mean change, 0.03 (-0.12 to 0.18), between the two groups (p=0.669).

As such, the hypothesis which stated that participants who receive the daily SMS would show better improvement in their self-efficacy than those who do not receive the SMS is therefore rejected.

Table 4.17: Impact of daily SMS on diabetes self-efficacy and diabetes distress

Secondary outcomes	Intervention n= 108		Control n= 108		Adjusted mean difference (95% CI)	p-value
	Baseline Mean (SD)	Post-intervention Mean (SD)	Baseline Mean (SD)	Post-intervention Mean (SD)		
Diabetes self-efficacy	3.74 (0.84)	4.60 (0.59)	3.90 (0.87)	4.50 (0.69)	-0.03 (-0.19 to 0.11)	0.609
Diabetes distress	2.17 (0.66)	1.59 (0.61)	2.38 (0.83)	1.66 (0.62)	0.03 (-0.12 to 0.18)	0.669

*Linear regression model adjusted for baseline self-efficacy, diabetes distress and type of diabetes. P <0.05 is statistically significant

4.2.2.6 Impact of daily text messaging on other clinical outcomes

The effect of the SMS intervention on other clinical outcomes including the body mass index, systolic blood pressure and diastolic blood pressure was examined. There were reductions in all the clinical outcomes in both the intervention group and the control group. However, there was no significant difference in the mean change in weight, 0.02 (-1.84 to 2.92) (p= 0.654), body mass index, 0.03 (-0.54 to 1.24) (p= 0.439), systolic blood pressure, -0.03 (-4.98 to 2.93) (p=0.610) and diastolic blood pressure, -0.04 (-2.68 to 1.40) (p= 0.535) between the two groups (Table 4.18).

Owing to the non-significant difference in mean change in all the secondary clinical outcomes, the hypothesis which stated that participants receiving daily SMS would show better improvement in their secondary clinical outcomes compared to those who do not receive SMS is therefore rejected.

Table 4.18: Impact of daily text messaging on secondary clinical outcomes

Secondary outcomes	Intervention n= 108		Control n= 108		Adjusted mean difference (95% CI)	p-value
	Baseline Mean (SD)	Post-intervention Mean (SD)	Baseline Mean (SD)	Post-intervention Mean (SD)		
Weight (Kg)	83.76 (15.30)	82.34 (14.49)	82.09 (17.24)	81.66 (16.42)	0.02 (-1.84 to 2.92)	0.654
Body mass index (Kgm-^{2})	32.32 (5.63)	31.49 (5.29)	32.14 (7.16)	31.96 (7.06)	0.03 (-0.54 to 1.24)	0.439
Systolic BP (mmHg)	144.27 (21.15)	137.03 (17.06)	146.27 (22.50)	135.46 (16.17)	-0.03 (-4.98 to 2.93)	0.610
Diastolic BP (mmHg)	82.29 (10.25)	80.70 (8.39)	82.75 (15.07)	79.59 (9.04)	-0.04 (-2.68 to 1.40)	0.535

*Linear regression model adjusted for baseline measure and type of diabetes. P <0.05 is statistically significant; BMI: Body Mass Index; BP: Blood pressure; mmHg= Millimetre of Mercury, Kgm^{-2}, Kilogram per meter-square.

4.2.2.7 Impact of daily text messaging on appointment compliance

The impact of daily SMS on appointment compliance (Table 19), indicated a reduction in the average number of missed appointments across the two study groups. However, there was no significant difference between the improvement observed in both the intervention and control groups (p=0.564).

Table 4.19: Impact of text messaging on appointment compliance

Secondary outcomes	Intervention n= 108		Control n= 108		Adjusted mean difference (95% CI)	p-value
	Baseline Mean (SD)	Post-intervention Mean (SD)	Baseline Mean (SD)	Post-intervention Mean (SD)		
Number of appointment missed in the last 6 months	1.15 (1.63)	0.25 (0.65)	1.38 (1.65)	0.35 (0.86)	0.04 (-0.12 to 0.22)	0.564

*Linear regression model adjusted for baseline appointment compliance and type of diabetes. P <0.05 is statistically significant.

4.2.2.8 Impact of daily text messaging on behavioural characteristics

In this study, very few participants use tobacco and consume alcohol. As shown in Table 4.20, participants in the control arm reduced their alcohol use. However, the

daily SMS had no significant impact on the behavioural characteristics of the study participants, mean change: 0.30 (0.41 to 4.42), p= 0.632.

Table 4.20: Impact of text messaging on behavioural characteristics

Secondary outcomes	**Intervention n= 108**		**Control n= 108**		**Adjusted change in frequency (95% CI)**	**p-value**
	Baseline (n)	Post-intervention (n)	Baseline (n)	Post-intervention (n)		
Smoking	2	2	3	2	0.35 (0.04 to 3.17)	0.326
Alcohol use	10	9	11	4	0.30 (0.41-4.42)	0.632

*Binary logistic regression model adjusted for baseline behavioural measures and type of diabetes. P <0.05 is statistically significant.

4.3 DISCUSSION

4.3.1 Impact of the study intervention on the primary outcome

Sub-optimal glycaemic control is a significant threat to the health of individuals living with diabetes and contributes significantly to the development of microvascular and macrovascular complications (Asif et al., 2014:1; Deshpande, Harris-Hayes & Schootman, 2008; Kirkmman et al., 2012:3). The use of mHealth technologies to foster health and behavioural modifications has been widely documented in different populations with varying results (Bonoto et al., 2017:1; Deglise et al., 2012; Hall et al., 2014; Plow & Eysenbach, 2017:1; Schwebel & Larimer, 2018). This study assessed the impact of daily text messaging in addition to standard care on improving adherence to anti-diabetic therapy and glycaemic control among low-income, black diabetic patients in resource-poor settings in the Eastern Cape province of South Africa. The study was conducted at primary healthcare clinics, with often-limited resources and human power, yet, where the majority of patients living with chronic illnesses, including diabetes, are managed.

At baseline, the average blood glucose level of participants in the intervention arm was 14.29 (± 4.39) mmol/l, while that of the control group was 14.39 (± 3.41) mmol/l, with no significant difference between both arms. At six months post-intervention, both the participants who received the SMS and those who did not receive the SMS showed improvement in their blood glucose level without any significant difference, even after adjusting for diabetes type, treatment type and baseline blood glucose. A similar finding among a small sample of diabetic patients (90 patients in both arms) in India, showed a decline in the blood glucose level of participants in the control and intervention groups without any significant difference in the mean change between both groups; however, contrary to this present study, there was more decline among

those in the intervention arm (Adikusama & Qiyaam, 2017). Kollman et al. (2007:10) also documented no significant improvement in fasting blood sugar following an SMS intervention among Type 1 diabetic patients in Austria. Studies assessing the impact of text messaging on glycaemic control often use the HbA1c test as a measure of glycaemic control and have also reported mixed findings. Some studies showed statistically significant improvement in glycaemic control (Dobson et al., 2018:5; Goodarzi et al., 2012:4; Islam et al., 2015:1; Quinn et al., 2011:6), yet, others reported no statistically significant improvement in glycaemic control (Arora et al., 2014:4; Capozza et al., 2015:1; Kollman et al., 2007:10).

In this setting, access to HbA1c testing which is often recognised as a gold standard for assessing glycaemic control is limited, and preliminary studies conducted in this study showed that majority of the patients had not checked their HbA1c level even in the past six months, contrary to the diabetes management guideline recommendations. As such, using the HbA1c measure in this setting is not feasible; perhaps, a more feasible measure would be the random blood sugar, which is the usual practice and clinical measure at these clinics. Other studies have also adopted the use of fasting blood sugar (Abbas, Fares, Jabbari, Dali & Orifi, 2015:1; Adikusama & Qiyaam, 2017; Kollman, Riedl, Kastner, Schreier & Ludvik, 2007:10) or 2 hours post-prandial blood glucose (Kim, 2007:1) as they deemed fit as measures of glycaemic control.

Although the use of text messaging as an adjunct could be of help to patients and could improve health outcomes, it is imperative to consider the interplay of several factors. As explained by Arora et al. (2014:5), the majority of the SMS interventions that have documented improvement in glycaemic control among study participants

utilised bi-directional text messaging. The authors further stated that SMS interventions anchored on facilitating continual linkage of the patients to their health care providers or physicians concerning the communicated blood sugar readings tended to yield significant improvements in glycaemic control. For instance, a RCT among 60 diabetic patients requesting patients to send their blood sugar readings to a web-based platform and to relate with physicians showed a significant improvement in glycaemic control (Kim, 2007:1). A similar finding was reported by Quinn et al. (2011:6) who adopted the use of bi-directional messages augmented by enhanced clinical care. Thus, the extra measures which were adopted in the previous studies could have had an impact on the positive outcome recorded. The use of such extra measures might however not be feasible among those in the resource-poor settings who do not check their blood glucose regularly and might not be able to send such feedbacks, considering their low level of literacy and socio-economic status.

Furthermore, the methodological issue of sample size selection in some of the studies documenting significant improvement might be another contributing factor. Generally, recruitment of diabetic patients is often a challenging task. Dobson et al. (2018) reported a similar challenge, and it is more daunting in this setting where there are no clinical records of the patients receiving healthcare in most of the facilities. The small sample size in this study might have contributed to the insignificant difference in the glycaemic changes between both groups. Although the quality of diabetes care generally appears to be poor in the setting, the improvement in the glycaemic status in both arms of the study could be an indication of improvement in the diabetes care, without the SMS adding a significant contribution.

It is well established that various factors underpin glycaemic control, which ranges from adherence to recommended therapy, adequate knowledge, positive self-management behaviour and self-efficacy as well as the quality of care rendered (Li et al. 2013:1; Williard-Grace et al., 2015:1). As such, a multi-faceted approach is required to foster improved health outcomes. Notably, the current study was conducted among patients with uncontrolled diabetes and with low-income earnings. Low socioeconomic status, particularly low level of income and low literacy level has been associated with low levels of adherence and poorer health outcomes, including sub-optimal glycaemic control (Assari, Moghani, Lankarani, Piette & Aikens, 2017:5; Houle et al., 2016:1; Rahman et al., 2015:8; Sutherland et al., 2018:1). Besides, the factors underlying the poor glycaemic status among this cohort of participants are not clear. Intuitively, it can be inferred that the variables influencing the poor glycaemic status of the participants in this present study could not be necessarily improved on by text messaging alone.

Even though the use of text messaging is promising, unidirectional SMS interventions will require several other modifications to effectively improve glycaemic control. For instance, good self-management behaviour, knowledge, increase healthcare providers relationship as well as general improvement in healthcare services rendered could drive this expected change (Kim, 2007:1; Quinn et al., 2011:6). As observed in the baseline data in this study, majority of the patients in this study had rarely undergone the recommended screenings for complications of diabetes in the past 6 months, which in a way reflects the quality of the diabetes healthcare services rendered in this study setting.

4.3.2 Impact of text messaging on secondary outcome measures

This study further explored the impact of the daily text messaging on secondary health outcomes such as medication adherence, dietary adherence, participation in physical activities, health-related quality of life, diabetes self-management, diabetes self-efficacy, diabetes distress, alcohol use, smoking and other secondary clinical outcomes.

4.3.2.1 Impact of text messaging on diabetes knowledge

Knowledge is one of the greatest weapons in the fight against diabetes (Khan et al., 2015:1). Knowledge of diabetes, its management and complications among diabetic patients often influences their health-seeking behaviours and their attitude towards its management (Uchenna et al., 2009:5). Patients with improved knowledge of diabetes are more likely to engage in activities that facilitate prompt detection and prevention of diabetes complications, which would in turn improve their health-related quality of life and self-care behaviours (Fatema et al., 2017:1).

The need to educate diabetic patients and organise interventions aimed at improving patients' knowledge is being constantly advocated (Carratale-Munuera et al., 2015; Sankar et al., 2015). mHealth technology is a recognised measure of disseminating information and improving the knowledge of patients, and several studies have documented its ability to improve diabetic control and knowledge (Aikens, Zivin, Trivedi & Piette, 2014; Deglise et al., 2012; Goordaazi et al., 2012:4; Hamsphire et al., 2015; Marwaha, 2016; Leon et al., 2015; Quan et al., 2016). Some scholars, however, hold a contradictory view (Balsa & Gandelman, 2010; Van Olmen et al., 2017:5).

In this study, there was generally a low level of diabetes knowledge among the study participants. The overall knowledge score was usually 20, and the average level of knowledge of the study participants in both the control and intervention arms was below 10, 7.67 in the intervention arm and 7.56 in the control arm, with no statistical difference (p=0.842). After the text messaging intervention for six months, there was an increase in the knowledge level of both the intervention group and the control group. Surprisingly, there was no significant difference in the mean change in knowledge score between the two groups (p=0.567), mean change was -0.04 (-0.59 to 0.32). This corroborates the findings of Van Olmen et al. (2017:5) among diabetic patients in DR Congo and Cambodia but contradicts the findings of Goordarzi et al. (2018:4) among a smaller group of patients in Iran.

Since both groups showed a slight improvement in knowledge, the increase in knowledge in both arms could plausibly be attributed to the effect of prior exposure to the same set of questions by both groups, and less likely to the unidirectional text messaging. Saffari, Ghanizedeh and Koenig (2014) in their review stressed that the use of mHealth intervention in advancing improvement in knowledge is more realistic when there is a combination of internet-based mHealth programmes in addition to text messaging, and when there is an avenue for patients' feedback. This was however not the case in this present study, and the suggested measures might be challenging to the participants in this present study, considering their age, low level of education and lack of adequate resources. Nonetheless, the slight improvement in their knowledge level is clinically significant as Azar et al. (2015) indicated that even such slight improvement in knowledge could bring about a reduction in weight and risk for cardiovascular complications.

The low level of literacy among the participants might have impacted on the low level of knowledge and the insignificant improvement recorded and as such, a longer period might be required to bring about a significant improvement in knowledge. Kanduna et al. (2009) already showed a learning gap between various literacy levels, with those with lower levels of literacy learning less and slower than those with higher levels of literacy. Another plausible explanation for the insignificant improvement in knowledge could be that those in the intervention arm paid little attention to the contents of the messages or did not assimilate them well enough. Probably, the use of visual aids rather than SMS or in combination with SMS, as utilised by Goodarzi et al. (2018), could better improve knowledge among diabetic patients. Also, it is plausible that their previous experiences might have influenced their answers and not based on what they were taught. For instance, a diabetic patient who often complies with recommended diets, yet with an uncontrolled glycaemic status might indicate that healthy diets do not help, based on previous experiences, though this study did not confirm this assumption.

There is an urgent need to deal with the low level of knowledge in this setting, considering the negative impacts on health-seeking behaviour, management of diabetes as well as the outcomes. Further interventional measures to promote diabetes knowledge that better suit this population and setting should be adopted and evaluated in order to bridge this knowledge gap.

4.3.2.2 Impact of text messaging on medication adherence

Successful diabetes treatment outcomes are highly dependent on the level of adherence and compliance to recommended therapies among patients (Jimmy & Jose, 2011:1). Poor level of adherence and compliance among patients constitutes

significant threat to the patients and healthcare system (Polonsky & Henry, 2016:2). This is often because of its association with poor treatment outcomes, increased healthcare cost, poor health-related quality of life and health deterioration (daCosta et al., 2014; Egede et al., 2014; Egede et al., 2014; Jimmy & Jose, 2011; Polonsky & Henry, 2016:2). Patients suffering from chronic diseases, especially those in the developing nations, have a low level of adherence to therapy (Cramer et al., 2008). This study thus evaluated the impact of daily text messaging on adherence.

Concerning medication adherence among this study population, on average, there was a moderate level of adherence to medication use among the study participants. On the other hand, adherence to dietary regimen and physical activity was extremely low among the study participants in both the intervention and control arms. This is a source of concern as both pharmacotherapy and lifestyle modifications are required to attain good health outcomes and adequate glycaemic control. This shows that poor lifestyle behaviour, especially regarding diet and activity pattern, is the probable missing link in the management of diabetes in this setting, hence, the high level of sub-optimal glycaemic control, which was persistent even after the SMS intervention. The reasons for poor adherence to dietary regimen and physical activity were further explored in this present study, and the most cited reasons were poor level of knowledge, high cost of healthy diet, and lack of time to engage in physical activity. This again points to the significant impact of socio-economic status, particularly the level of income and literacy on diabetes outcomes. Addressing these socio-economic, behavioural and demographic issues could positively influence the glycaemic status of the patients.

There was no significant change in medication adherence following the SMS intervention; however, there was a slight increase in dietary adherence and physical activity adherence in both the intervention and control groups following the intervention. Nevertheless, this observed change did not differ significantly between the two groups ($p = 0.757$ for medication adherence, 0.978 for adherence to recommended diets and 0.992 for physical activity adherence). Arora et al. (2014:6) also reported an improvement in medication adherence following SMS intervention, which was not significantly different between both groups. Sugita et al. (2017:6) documented a similar result in a pilot study conducted among diabetic patients in Japan as well as Islam et al. (2015:1) among diabetic patients in Bangladesh. This is, however, contrary to the findings of Vervloet et al. (2012:1), which recorded a significant difference in the medication adherence between both groups. The methodological approach adopted by Vervloet et al. (2012) is incompatible to the approach used in this present study. Vervloet et al. (2012) used real-time medication adherence monitoring, and text messages were sent each time the patient forgets to use medication, while the other group did not receive SMS reminders. Likewise, the use of self-reported measure of adherence rather than a more objective measure such as the use of the Medication Electronic Monitoring System (MEMS) might have introduced bias in the reported medication adherence rate.

Irrespective of this, the improvement in dietary and physical activity adherence is laudable; and can play a significant role in the management of diabetes if intervention continues for a longer period, and more attention is paid to the cultural beliefs of the patients, and their socio-economic status. This is evidenced by the participants' responses to the SMS intervention, stating lack of funds to purchase healthy diets, inability to change their regular diets, as well as lack of adequate education. There is

a need to develop interventions that will take into account various modifications in lifestyle behaviour and dietary practices without necessarily deviating significantly from the culture and tradition of the people. For instance, it would be challenging to instruct a typical South African to desist from eating *mealie* meal, their staple diet. Rather, an approach that aims at educating such patients, including practical guides, on how to combine the mealie meal with other classes of food in the right proportion could be more acceptable, but this may take a longer time and could be more tasking than communicating via a text message.

4.3.2.3 Impact of text messaging on diabetes self-management

Self-management behaviour describes the continuous and active involvement of patients in their care and management and constitutes a core component of chronic disease management (De Jongh et al., 2012:7). It is an essential skill for all patients living with diabetes in order to facilitate proper glucose monitoring as well as to make the necessary behavioural changes (Huang et al., 2014). In this study, the overall self-management behaviour level among the study participants in both the intervention and control arm was only slightly above average, 5.73 and 5.77 respectively, on a scale of 10, with some having a score as low as 1.88. Worryingly, this low level of overall self-management further declined over the six months study period in both arms of the study, which is concerning, given the significant role self-management plays in diabetes management and treatment outcomes. Furthermore, the unidirectional text-messaging programme did not bring about a significant improvement in the overall self-management behaviour of the participants over a period of six months. This corroborates the findings of Van Olmen et al. (2017) among diabetic patients in DR Congo and Cambodia.

Several studies have highlighted patients' inertia in implementing behavioural modifications (Heineman, 2008; Klonoff, 2009; Watson, 2009) required for self-management. Several factors have been purported to contribute to this. Foremost, there is an association between literacy, knowledge and self-management (Huang et al., 2014). Given that a majority of the study participants rarely have more than secondary level of education and also demonstrated a low level of knowledge, these might have impacted on their self-management and empowerment levels.

In addition, some authors opined that patients' health decisions and behaviours are influenced in several ways and by several factors, which are sometimes beyond the control of the healthcare provider or an interventional measure (Beckerle, 2013; Wagner, 2011). Such factors include knowledge, coping strategy, social and emotional support, motivation and their problem-solving skills or approach. According to Beckerle (2013), even when health interventions, including mobile health technology interventions, are conducted effectively, they might not significantly influence patients' competing demands and conditions which influence their behaviours. For instance, while patients might see or understand the need to make lifestyle changes following an intervention, factors such as poor socio-economic level, lack of required healthy diets, ill-health impeding physical activity and inadequate support might make the implementation of such required self-management behaviours challenging (Huang et al., 2014, Wagner, 2011). These constraining factors further limit their willingness to make changes or make required decisions.

Specifically, with regards to the various aspects of self-management such as the glucose management, physical activity, dietary practices and healthcare use, participants' self-management in these various segments was also low, and self-

management behaviour regarding physical activity was the lowest. This further buttress the aforementioned point that the intervention had little or no ability to control certain situations or conditions that influence self-management behaviour. Considering the average age of the participants and the level of comorbidities among them, engaging in physical activities could be challenging, given their compromised health and age and this was not improved by text messaging, even though they were encouraged to do activities they could tolerate.

Also, in the face of poor socio-economic status, glucose monitoring, another aspect of diabetes self-management could be a great challenge among this group. Even at the clinics, evidence gathered during this study showed a significant challenge in conducting basic investigations, including blood glucose testing, for the patients at this level of care as a result of inadequate resources. Probably, intervention measure, which include the provision of resources for glucose testing could bring about significant improvement in this aspect of self-management in this setting. For instance, Chen et al. (2013) showed that their study participants improved in their glucose management behaviour due to the provision of test strips and participants were not willing to continue in the intervention when they were informed the incentive could be withdrawn. Provision of such incentives might not be a short-term feasible measure in this setting and many developing countries, considering the costs. Perhaps, a more realistic approach could be properly equipping healthcare facilities with the necessary testing facilities, such that the patients at least get tested and managed properly at each clinic visits. Also, private pharmaceutical companies could be encouraged to further support this bid, especially in resource-poor settings.

However, it is worthy of note that participants in the intervention arm showed an improvement in their dietary self-management behaviour following the six-month text messaging, against the decline observed in the control arm. Even though this change did not reach significant level, it is of clinical relevance. Adherence to dietary recommendations is a significant challenge in the management of diabetes in this setting (Shishana et al., 2013), yet it is very crucial in improving treatment outcomes. This, when combined with other lifestyle modifications such as physical activity could improve the metabolic health of these patients in terms of reduction in weight and its associated clinical relevance (Miller et al., 2014:2; Reiner et al., 2013). Participants also verbalised the importance of the text messaging intervention in terms of awareness creation and provision of information regarding the recommended and required dietary modifications for proper diabetes management. Many were willing to make the changes and only verbalised concerns in terms of inadequate resource or lack of purchasing power to maintain healthy dietary practices. This study however, enlightened participants in the intervention arm on the possible measures of improving their dietary practices, even in the presence of limited means and resources. This could be the underlying factor for the slight improvement observed. Possibly, a longer duration of the study could further enhance the observed improvement.

4.3.2.4 Impact of text messaging on diabetes self-efficacy

Diabetes self-management and self-efficacy often operate synergistically, as self-efficacy and patient's level of confidence influences self-management (Beckerle, 2013:1). According to Bandura's old socio-cognitive theory, self-efficacy describes an individual's beliefs as well as the abilities to carry out the required changes to improve their health (Bandura, 1994). This show how much effort an individual devotes to overcoming the challenges encountered in their care. Beckerle (2013:2) argued that a

high level of self-efficacy might not necessarily translate to healthy lifestyle behaviour. As observed in this study, the participants in both arms of the study demonstrated an improvement in self-efficacy. However, there was no significant difference in the mean self-efficacy change between those who received the SMS and those who did not (p=0.609). This is similar to the findings of Dobson et al. (2018:7) but contradicts the findings of Goodarzi et al. (2012:6).

The observed increase is encouraging; however, this might not necessarily translate into expected positive changes, as stated by Beckerle (2013:2). Even when patients appreciate the need to engage in healthier lifestyle behaviours and activities, there could still be other constraining factors which might hinder them from taking necessary steps. This was further highlighted by the response of one of the participants in the intervention arm's response that the SMS stressed her, and she felt the need to improve her dietary practices but was unable to do so because of lack of financial resources. Furthermore, some other participants highlighted their health condition and lack of time as impediments to engaging in physical activities. Given this, individualised interventions are required, which will significantly put into consideration the socio-demographic and clinical characteristics of the patients.

4.3.2.5 Impact of text messaging on diabetes distress

Diabetes mellitus is the most psychologically demanding of the various chronic health conditions, and psychological challenges have been recognised as one of the leading predictors of mortality among diabetic individuals (Bajwa, Sarowa & Bajwa, 2015:1). For some years, attention has shifted from medical to psychological factors as underlying factors for poor glycaemic control (Serrano-Gill & Jacob, 2010). Diabetes distress, an affective malady, is an emerging psychological challenge among diabetic

patients, unlike the popular depression (Fisher et al., 2012; Nicolucci et al., 2013). Diabetes distress is usually associated with poor treatment outcomes and self-management behaviour (Driscoll & Young-Hyman, 2014; Nam et al., 2011).

The average level of diabetes distress in all the participants was below three. Thus, going by Fisher et al. (2008)'s definition of a clinically significant level of distress as a score of three or more, it can be assumed that the distress level among the study participants is not critical. Participants in both arms of the study showed a further reduction in their distress level, with no significant difference between both groups (p=0.669). Majority of the intervention study making use of text messaging rarely looked into its effect on diabetes distress. This, therefore, leaves no room for comparison. It is somewhat encouraging that there was a further reduction in the level of distress among the study participants over six months, irrespective of whether they received SMS or not.

It is well documented that the lower the level of diabetes distress, the better the clinical outcomes, the better the diabetes empowerment, the better the health-related quality of life, and the higher the chances of complying with treatment regimens (Joensen, Tapagar & Williang, 2013). One can assume that this could have also been the case among the participants in this present study. The low level of distress and the observed further reduction might have contributed to the observed slight improvement in the empowerment, health-related quality of life and glycaemic status.

4.3.2.6 Impact of text messaging on secondary clinical outcomes

This study further investigated the impact of the SMS intervention on secondary clinical outcomes such as weight, body mass index, the systolic and the diastolic blood

pressures. Diabetes is often associated with other clinical variables such as weight, body mass index and blood pressure. There is a linear, positive association between these factors and glycaemic status (Heianza et al., 2014; Lv et al., 2018:5). It is, therefore, expedient to assess the impact of the SMS intervention on these clinical variables.

The participants in the intervention arm recorded a decrease of 0.83kg after six months of intervention while those in the control arm showed a reduction of 0.43kg after six months. There was no significant difference in the mean difference between both groups (p=0.654). This is in line with various reviews on the impact of SMS on weight reduction where text messaging usually results in no significant improvement in weight status (Arambepola et al., 2016; Siopis, Chay & Allman-Farinelli, 2015). Consistent with the findings from other studies, there was no significant difference regarding the impact of SMS on body mass index (Lim et al., 2011; Noh et al., 2010; Tamban et al., 2013; Waki et al., 2014; Yoo et al., 2009).

The two major contributors to weight loss, namely healthy dietary practices and exercise, were rarely practised or practised at a low level among the participants in this study. The highlighted reasons were lack of financial resources, lack of time and poor health condition. Therefore, the observed non-improvement in weight and body mass index is not surprising. This could also translate to the non-significant improvement in the glycaemic status. As much as text messaging could inform the patients on the required and expected healthy behaviours, little could be achieved in bringing desirable change without the patient's needed resources.

Likewise, there was no significant improvement in the participants' blood pressure levels, both the systolic and diastolic. Several studies have shown similar findings (Cui et al., 2013:10; Liang et al., 2010; Marcialino, Maia & Alkmin, 2013; Orsama et al., 2013; Quinn et al., 2011; Rossi et al., 2013; Rossi et al., 2010). On the contrary, few other studies showed a significant improvement in blood pressure following mHealth interventions (Bell et al., 2012; Noh et al., 2010; Yoo et al., 2009). The insignificant change in blood pressure could stem from the insignificant change in blood sugar level recorded and vice versa since a positive association often exist between the two factors. Similar reasons could be purported for this as with the insignificant improvement in glycaemic status, and these include the persistent unhealthy lifestyle behaviours in terms of dietary practices and physical activity. Poor socio-economic level might have also contributed to this (Assari et al., 2017:5; Houle et al., 2016:1; Rahman et al., 2015:8; Sutherland et al., 2018:1).

Furthermore, the impact of the SMS intervention on appointment compliance was assessed. Even though the intervention arm showed more decline in the number of appointment missed following the six months intervention, the mean difference (0.04, SD= -0.12 to 0.22) was not significantly different. It has been already established that adherence to appointment and treatment therapy is key in achieving good treatment outcomes. In terms of compliance with appointments for clinical evaluation and medication pick-up, the participants in this present study seemed to perform fair enough, with the majority only missing one in every six appointments, although this still leaves room for further improvement. After six months, both groups had further improvement in their appointment compliance. This might, however, not improve their health significantly as adherence in other areas of health such as medication; dietary practices and activity levels did not improve. Generally, the use of SMS prompts as

appointment reminders are usually acceptable and effective among patients (Chung et al., 2015; Gatwood et al., 2016; Youseff et al., 2014). This was also evidenced in the responses of the study participants when highlighting the ways through which the SMS helped as a source of reminder.

4.3.2.7 Impact of text messaging on other behavioural outcomes

Generally, there was a low level of tobacco and alcohol use among the study participants. However, there was no significant improvement in alcohol and tobacco use, although the very small sample might have significantly reduced the statistical power. Even though the level of alcohol use among the study participants seemed low, considering the health status of the patients, more efforts by health practitioners to encourage the patients to aim at zero tolerance to alcohol use as one of the safety health measures are required (GBD 2016 Alcohol collaborators, 2018). A review conducted on the impact of SMS on alcohol use and smoking among non-diabetic individuals emphasised the importance of face-to-face interactions, in addition to text messaging in fostering improvement in these behavioural outcomes (Mussener, Thomas, Linderoth, Leijon & Bendtsen, 2018:7). The absence of this concept in this study might have been responsible for the insignificant improvement following the SMS intervention. Another plausible explanation is that patient who engaged in these behaviours might not have even paid attention to the content of the SMS, especially if they engaged in these behaviours at a hazardous rate.

4.3.3 Acceptability of text messaging

The acceptability of the mHealth intervention was further explored among the patients. As shown in the participants' responses, all the participants stated that the SMS

intervention was helpful. Some of the listed benefits of the SMS were improvement in knowledge, motivation and its function as a reminder.

Generally, there appears to be a high rate of acceptability of text messaging among diabetic patients. Several studies have supported this notion (Abebe et al., 2013; Arora et al., 2014; Burner et al., 2014; Capozza et al., 2015; Shetty et al., 2011). Generally, the acceptability of the intervention by diabetic patients has been associated with its ease of use (Orsama et al., 2013; Waki et al., 2014; Yoo et al., 2009). Conversely, an mHealth intervention which used a non-user-friendly web-based interface showed a low rate of acceptability (Noh et al., 2010).

4.3.4 Feasibility of text messaging

Out of the 108 participants who took part in the SMS intervention, 91% completed the study. Each of the study participants received daily SMS throughout the six months period, averaging 180 SMS per participant. Some of the participants might have lost their contact details, while others might have relocated or been transferred to another level of healthcare. Though the message was unidirectional, some participants still responded to some of the questions and sent some concerns through to the investigator. For instance, the message “Have you taken your pills today?” triggered responses from the participants with many responding, “Yes”. Feasibility has often been defined in previous studies as the ability to complete the study intervention and many of the previously published articles demonstrated the feasibility of text messaging as a tool to improve diabetes care, even among youths (Dick et al., 2011:1; Haddad et al., 2014:1; Herbert, Mehta, Monaghan, Cogen & Streisand, 2014:1).

In all, the SMS intervention could be regarded as an acceptable intervention and a feasible and acceptable adjunct to standard care for diabetic patients. However, its efficacy concerning improving health outcomes needs careful consideration, especially in resource-poor settings, among those in the lower socio-economic group and among those attending primary healthcare clinics where the quality of care might not be optimal. Although it has been widely shown to have a potential for bringing about improvement, it still requires further actions and considerations.

CHAPTER FIVE

SUMMARY, CONCLUSIONS AND RECOMMENDATIONS

This final chapter presents the summary of the study, conclusions, study limitations and strengths, contribution to the existing body of knowledge and recommendations.

5.1 SUMMARY

Diabetes mellitus is a disease of significant public health concern and a leading cause of death and disability worldwide (WHO, 2016a). Several countries, both developed and developing, are undergoing an exponential increase in the disease burden (IDF, 2014:2; Seuring, Archangelidi & Suhrcke, 2015:1). Against previous knowledge of it being a disease of affluence, developing nations, including South Africa, are now confronted with a rapid increase in the burden of diabetes (Shen et al., 2016).

South Africa is faced with a surge in diabetes burden and its associated increase in morbidity and premature mortality (IDF, 2015). South Africa is ranked second among countries with the highest prevalence of diabetes in Africa (IDF, 2017; Guarigata et al., 2013:3). Worse still, despite the documented effectiveness of medication therapy and lifestyle modifications in attaining glycaemic control, the high prevalence of diabetes in the country is further complicated by poor level of control (Adeniyi et al., 2016, Daramola et al., 2012; Igbojiaku et al., 2013; Kadima & Tumbo, 2013; Shilubane, 2010). Plausibly, the high rate of sub-optimal control is attributed to the poor level of knowledge, poor healthcare services, and the low level of adherence to medication and recommended lifestyle modifications (Adisa & Fakeye, 2014; Bagonza et al., 2015; Booysen & Schlemmer, 2015; Kagee, 2004; Cramer, 2004). Consequently, there is a resultant predisposition to complications development leading to a poor

quality of life, disability, premature mortality and excessive burden on the individuals; thus placing a significant strain on the already overburdened healthcare system.

mHealth is an emerging and a cost-effective measure, shown to be effective in improving patients' self-management behaviours, adherence to therapeutic regimen, compliance with appointments and treatment outcomes. However, the effectiveness of mHealth among individuals with diabetes has rarely been documented in South Africa, and more specifically, in an economically poor region with a high burden of diabetes like the Eastern Cape. Hence, the need for an interventional study to determine the efficacy of mHealth technology, besides the usual care in promoting adherence to anti-diabetic therapy, glycaemic control and other treatment outcomes among individuals living with diabetes in South Africa. This study therefore aimed to determine the efficacy, the feasibility and the acceptability of the mHealth technology (SMS) in promoting adherence to anti-diabetic regimen and glycaemic control among diabetic patients in selected districts of the Eastern Cape Province of South Africa.

The specific objectives of the study were to:

I. assess the efficacy of mobile phone SMS in promoting glycaemic control among individuals living with diabetes in the selected districts in the Eastern Cape Province;
II. determine the efficacy of mobile phone SMS in improving diabetes knowledge among individuals living with diabetes in the selected districts in the Eastern Cape Province;
III. assess the efficacy of mobile phone SMS in promoting adherence to medication, physical activity regimen and dietary recommendations among

individuals living with diabetes in the selected districts in the Eastern Cape Province;

IV. determine the efficacy of mobile phone SMS in improving the health-related quality of life among individuals living with diabetes in the selected districts in the Eastern Cape province;

V. determine the efficacy of mobile phone SMS in improving self-management behaviour, self-efficacy and diabetes distress among individuals living with diabetes in the selected districts of Eastern Cape Province;

VI. assess the efficacy of the use of mobile phone SMS in improving secondary clinical outcomes (blood pressure, body mass index) among individuals living with diabetes in the selected districts in the Eastern Cape Province;

VII. assess the efficacy of the use of mobile phone SMS in improving behavioural characteristics (smoking and alcohol use) of individuals living with diabetes in the selected districts in the Eastern Cape Province;

VIII. determine the efficacy of the use of mobile phone SMS as a clinic appointment reminder among individuals living with diabetes in the selected districts in the Eastern Cape Province;

IX. determine the acceptability and feasibility of the mobile phone SMS intervention by individuals living with diabetes in the Eastern Cape Province; and to

X. determine the acceptability and feasibility of the mobile phone SMS intervention by individuals living with diabetes in the Eastern Cape Province.

The research questions framed for the study were:

I. Would the use of mobile phone SMS be effective in promoting glycaemic control among individuals with diabetes in the selected districts in the Eastern Cape Province?

II. Would the use of mobile phone SMS be effective in improving diabetes knowledge among individuals with diabetes in the selected districts in Eastern Cape Province?

III. Would the use of mobile phone SMS be effective in promoting adherence to medication, physical activity and recommended diet among individuals with diabetes in the selected districts in the Eastern Cape Province?

IV. Would the use of mobile phone SMS be effective in improving the health-related quality of life among individuals with diabetes in the selected districts in the Eastern Cape Province?

V. Would the use of mobile phone SMS be effective in improving self-management behaviour, self-efficacy and diabetes distress among individuals with diabetes in the selected districts of the Eastern Cape Province?

VI. Would the use of mobile phone SMS be effective in improving secondary clinical outcomes (blood pressure and body mass index) among individuals with diabetes in the selected districts in the Eastern Cape Province?

VII. Would the use of mobile phone SMS be effective in improving behavioural outcomes (smoking and alcohol use) among individuals with diabetes in selected districts in the Eastern Cape Province?

VIII. How effective is the mobile phone SMS as an appointment reminder among individuals with diabetes in the selected districts in the Eastern Cape Province?

IX. Is the SMS intervention acceptable to individuals living with diabetes in the selected districts of the Eastern Cape Province?

X. Will the SMS intervention be feasible among individuals living with diabetes in the selected districts of the Eastern Cape Province?

The study's primary hypothesis was:

Mobile phone SMS intervention in addition to the standard diabetes care, will significantly reduce blood glucose level among diabetic patients attending diabetes clinics in the selected districts of the Eastern Cape Province compared to standard care alone.

The secondary hypotheses were;

I. Participants in the intervention arm will demonstrate significantly improved adherence to medication, physical activity and recommended diets compared to those in the control arm.

II. Participants in the intervention arm will demonstrate significantly improved knowledge compared to those in the control arm.

III. Mobile phone SMS, in addition to standard care, will increase clinic attendance relative to the usual standard diabetes care.

IV. Participants in the intervention arm will have a better quality of life compared to participants in the control group.

V. Participants in the intervention arm will demonstrate significantly improved secondary clinical outcomes (blood pressure, weight, body mass index) than those in the control group.

VI. Participants in the intervention arm will demonstrate significantly improved behavioural outcomes (reduced smoking and alcohol use) compared to those in the control group.

This was a quantitative, experimental study which adopted a multi-centre, two-arm, parallel, randomised controlled trial design. The study was designed to compare a six-month mobile phone-based SMS intervention in addition to the standard diabetes care to standard diabetes care alone as tools for promoting adherence and health outcomes among diabetic patients receiving treatment in selected diabetes clinics in the EC province. The two randomly selected districts in the Eastern Cape Province were Buffalo City Metropolitan Municipality and Amathole District, from which six districts were randomly selected. Sample size calculation was based on the number of participants required to bring about an extra 0.5% decrease in blood glucose and sufficient to produce a power of over 90% at a standard deviation of 1 and alpha error level of 5%. In anticipation of 20% attrition rate (Islam et al., 2014), 108 participants were required in each arm of the study. After screening for eligibility, 36 participants were selected from each of the six randomly selected clinics in the two districts using computer-generated-random numbers, adjusting for age and mean duration of diabetes. The participants were randomly allocated to the intervention and control group at a ratio of 1:1. In order to avoid bias, the study statistician involved in randomisation was blinded to every identifying information, likewise, the primary outcome measure; blood sugar, which was an objective measurement, was also blinded to treatment allocation.

Three, well-trained research assistants helped in data collection. Data were collected at baseline, and six months after the intervention. The data collection instrument was

self-developed, using previously validated measurement scales. The participants' demographic information was obtained using the widely validated WHO STEPwise questionnaire (Virgin Island Ministry of Health and Social Development, 2010; Fereshtey et al., 2007; WHO, 2015f). The primary outcome measure was an objective measure of the morning random blood glucose level, using the ACCU CHEK glucose monitoring apparatus (Roche, Switzerland.

Secondary outcomes were measured as follow:

I. Knowledge of diabetes, which was obtained with the validated Michigan Diabetes Knowledge Test Questionnaire-2 (Fitzgerard et al., 2016).
II. Medication adherence assessed with the 8-item Morisky Medication Adherence Scale (Morisky, Ang, Krousel-Wood & Ward, 2009).
III. Health-related quality of life assessed with the EQ-5D quality of life questionnaire (Devlin & Brooks, 2017).
IV. Diabetes self-management behaviour assessed using the Diabetes Self-management questionnaire (Schmitt et al., 2013; Schmitt et al., 2016).
V. Diabetes self-efficacy assessed with Michigan Diabetes Empowerment scale Anderson et al., 2003.
VI. Co-morbid outcomes (hypertension and obesity) obtained through blood pressure measurement and anthropometric measurements (body weight, height, and waist and hip circumference) which followed standard protocols.
VII. Behavioural characteristics (smoking, alcohol use and physical activity) using the WHO STEPwise approach.
VIII. Acceptability of the SMS intervention using the participants' feedback obtained through some self-designed questions

IX. Feasibility of the study was assessed by the recruitment and the retention rates

The study intervention procedure entails both the intervention and the control groups to proceed with their usual care including all medical visits, tests and diabetes support programmes. Also, the intervention group received daily short message services (SMS) at an agreed time of the day tailored according to their needs, care plan and goals for six months.

The contents of the SMS used for the study were developed by a team involving the principal investigator, supervisor, family physician, endocrinologist and a nurse. The team followed the SEMDSA guideline for the management of diabetes, the health education materials from the National Diabetes Education Programme and some sample SMS from the previously documented pilot studies which were documented to be efficient. Also, the health care needs of the participants were not neglected.

Statistical analysis followed the intention-to-treat analysis. Descriptive statistics summarise the demographic and baseline characteristics. Continuous variables were summarised as numbers of observed values, means, standard deviation, minimum and maximum. Categorical variables were described as frequency and percentages. Chi-square and Fischer's exact test were used to assess the difference between groups for categorical baseline variables. For continuous variables, analysis of variance was used to assess the difference in the baseline characteristics of the study participants between the intervention and control group. The effect of the intervention on the primary outcome between the two groups and at the two periods was assessed using the mixed-effect model analysis. Adjustment was made for type of diabetes, and the baseline outcomes.

Regression statistics was used to assess for the effect of the intervention on secondary outcome measures between the groups and two periods; linear regression was used for continuous variables while binary logistic regression was used for categorical variables. The assumption underlying the analysis of missing variables was that the data were missed completely at random. Missing data were inputted for both the primary and secondary variables using the mean of the variables assessed. Sensitivity analyses were performed on assumptions that missing data were not missed at random. All statistical tests were two-sided at 5% significance level. A p-value less than 0.05 was considered statistically significant. The Statistical Package for Social Sciences (SPSS) version 23 was used for data analysis (SPSS Inc., Chicago, IL, USA).

5.1.1 Major Findings

The major findings of the study were:

I. There was a low level of knowledge of diabetes among the study participants, with an average score of 7.59 (SD ± 2.05), ranging from 5 to 17 out of a total score of 20.

II. Majority of the participants in both the intervention arm and the control arm had a moderate level of medication adherence, with an average of 6.90 and 6.87, respectively.

III. There was a significantly low level of adherence to dietary recommendations among the study participants in both the intervention arm (mean value of 1.52 out of 8) and the control arm (mean value of 1.69 out of 8).

IV. Inability to afford a healthy diet was the most cited reason for not adhering to the recommended dietary regimen among the study participants, 68.8% and 79.6% for the intervention and control groups, respectively.

V. Adherence to physical activity regimen was very low among all the participants, 1.48 for those in the intervention arm and 1.46 for those in the control arm.

VI. Over half of the study participants identified lack of time as the reason for not adhering to the physical activity pattern, 59.70% and 61.20% for the intervention and control group, respectively.

VII. The prevalence of alcohol use among the study participants was 12.00% for those in the intervention arm and 13.00% for those in the control arm.

VIII. The prevalence of tobacco use among the study participants was 1.90% for those in the intervention arm and 5.60% for those in the control arm.

IX. There was a low level of sedentary behaviour among the study participants, the average hours of sitting per day was 3.15 (SD ± 1.88) for the intervention group and 3.59 (SD ± 4.34) for the control group.

X. The mean quality of life score for all the participants in all the various aspects of health was 7.08 (SD ± 2.40), with actual scores ranging from 5 to 17.

XI. On a scale of 100, the average self-rated health-related quality of life of the study participants was 70.09 (SD±16.06) percent, with values ranging from 30% to 100% for both groups.

XII. On a scale of 10, the average diabetes management score for all the participants was 5.75 (SD ± 1.69), with scores ranging from 1.88 to 10.00.

XIII. On average, there was a high level of self-efficacy among the study participants at baseline; the mean self-efficacy of the participants was 3.82 (SD ± 0.85).

XIV. The level of diabetes distress among the study participants was generally below the level considered to be a clinically significant level of distress, with an average of 2.27 (SD ± 0.85).

XV. There was a high level of compliance with appointment among the study participants.

XVI. The average systolic blood pressure of the participants in the intervention arm and in the control arm was 144.28 (SD ± 21.15) mmHg and 146.26 (SD ± 23.84) mmHg, respectively.

XVII. There was a high prevalence of obesity among the study participants, depicted by an average body mass index of 32.21 (SD ± 5.63) kgm^{-2} for those in the intervention arm and 32.14 (SD ± 7.16) kgm^{-2} for those in the control arm.

XVIII. The average morning random blood sugar was 14.29 (SD ± 4.39) mmol/L for those in the intervention group and 14.39 (SD ±3.41) mmol/L for those in the control group.

XIX. Screenings for diabetes complications such as renal disorder, cardiovascular disorder, feet complications, and eyes complications were infrequently done for diabetic patients in this study setting.

XX. There was no significant difference in the primary outcomes, mean change in blood sugar level, between the intervention and control arm (p= 0.634), that is, the SMS intervention did not have a significant effect on their blood glucose level

XXI. There was no significant difference in change in diabetes knowledge of the participants in the intervention and control groups, post-intervention (p= 0.567), that is, the SMS intervention did not have a significant effect on the diabetes knowledge of the patients.

XXII. There was no significant difference in change in adherence to medication (p= 0.757), physical activity (p=0.978) and dietary recommendation (0.992) between participants in the intervention and control groups, post-intervention. That is, the SMS intervention did not have a significant effect on the adherence to anti-diabetic regimen among the study participants.

XXIII. There was no significant difference in the change in health-related quality of life (p=0.394) between participants in the intervention and the control group, post-intervention, that is, the SMS intervention did not have a significant effect on participants' health-related quality of life.

XXIV. There was no significant difference in the change in self-management behaviour (p= 0.821) between participants in the intervention and the control group, post-intervention, that is, the SMS intervention did not have a significant effect on the participants' self-management.

XXV. There was no significant difference in the change in self-efficacy (p=0.609) between participants in the intervention and control groups, post-intervention, that is, the SMS intervention did not have a significant effect on the participants' self-efficacy.

XXVI. There was no significant difference in the change in diabetes distress (p=0.669) between participants in the intervention and the control group, post-intervention. That is, the SMS intervention did not have a significant effect on the participants' diabetes distress.

XXVII. There was no significant difference in the change in appointment compliance (p=0.564) between participants in the intervention and control groups, post-intervention, that is, the SMS intervention did not have a significant effect on participants' compliance with appointment.

XXVIII. There was no significant difference in the change in secondary clinical outcomes; systolic blood pressure (p=0.610), diastolic blood pressure (p=0.535), weight (p=0.654) and BMI (p=0.439), between participants in the intervention and control groups, post-intervention. That is, the SMS intervention did not have a significant effect on the participants' secondary clinical outcomes.

XXIX. There was no significant difference in the change in behavioural characteristics, smoking (p=0.326) and alcohol use (p=0.999), between participants in the intervention and control groups, post-intervention. That is, the SMS intervention did not have a significant effect on the participants' behavioural characteristics.

XXX. There was a high level of acceptability of the SMS intervention among the study participants who took part in the intervention. All of the participants who completed the study declared it was helpful, and 95.9% declared their readiness to continue to receive the SMS even after the intervention.

XXXI. The SMS intervention is a feasible adjunct to clinical care for diabetic patients in low-resource settings of the Amathole and BCMM districts of the Eastern Cape, South Africa. The completion rate was 91%.

5.2 CONTRIBUTION TO EXISTING BODY OF KNOWLEDGE

There is a continual increase in the burden of diabetes mellitus worldwide, including South Africa, and constant efforts are being made to improve the management of the disease, improve the quality of life of the patients and reduce the associated burden. Despite the various intervention measures for promoting the health of individuals with diabetes, the use of mobile health technology as a cost-effective measure is increasingly advocated. Majority of studies conducted on the effectiveness of this measure as a means of promoting health among diabetic patients were carried out in

high-income countries, with relatively few conducted in developing countries. Also, these studies have documented varying results. In South Africa, there is hardly any study on the use of mobile health technology, specifically text messaging as a measure of promoting health among diabetic patients. This study thus adds to the body of knowledge concerning the implementation of the cost-effective mHealth technology among diabetic individuals in a resource-limited setting, considering the public health and economic importance of this health condition.

Previous studies on the use of text messaging among diabetic patients have demonstrated varying results, ranging from a significant improvement in diabetes treatment outcomes to non-significant outcomes. This current study, however, adds to the body of knowledge, showing that mobile health technology, specifically text messaging is highly acceptable by diabetic patients in this setting, and is a feasible adjunct measure to healthcare, even in the most remote settings. This study shows a low level of efficacy of text messaging as a measure of improving the health and behavioural outcomes of diabetic patients in this setting. This current study shows that for the widely documented text messaging intervention to be effective, particularly among patients in low socioeconomic level, several other factors should be considered.

In summary, this study shows that even though text messaging is a potential tool for improving healthcare, the use of text messaging alone might not be enough to improve diabetes treatment outcomes in the presence of several other constraining factors such as low socio-economic status and sub-optimal quality of healthcare services.

5.3 LIMITATIONS

Several limitations of this study should be considered when interpreting the findings of the study. The main limitation was that the use of random blood glucose rather than the HbA1c as a measure of glycaemic status is not optimal. However, HbA1c is an expensive measure and is often unavailable or seldom done in resource-limited settings and primary healthcare level such as this study setting. As a result, using HbA1c as a gold-standard for glycaemic status might not be a feasible measure in this setting. Although there was an attempt to bridge this gap by assessing the average of the previous three to six blood glucose readings, not all the patients had their blood glucose measured at every clinic visit. Likewise, the sample size calculation was based on the initially proposed measure of glycaemic control which was a change in HbA1c, although almost a similar result was obtained using fasting blood glucose. Also, most of the secondary measures were self-reported, and the use of such method of data collection is subjected to risk of bias. Besides, only a few of the clinics in the selected districts and only two of the eight districts in the province were covered; thus, the findings cannot be generalised to the entire province or districts. Recruitment of the study participants was very challenging because of the lapses in healthcare records. This explains the relatively small sample size which might have contributed to the insignificant changes associated with the study intervention. Also, the small number of participants who smoke and use alcohol in this study might have significantly reduced the statistical power to test the effect of the intervention on alcohol use and smoking. Finally, there was approximately 19% loss to follow-up, which might have introduced bias. However, sensitivity analyses were performed, and it affirmed the assumption that the study participants were missed completely at random, and the result did not differ when tested based on various other assumptions.

5.4 STRENGTHS

Notwithstanding the limitations, this study revealed a high level of acceptability and feasibility of the SMS intervention and a low level of efficacy among the participants in the study. The true experimental design employed was a significant strength. The use of a multi-centre approach added further credence to the study. Also, the use of objective measure for primary data and the use of validated tools are additional strengths. Finally, the finding of this study serves as a reference point for other related studies in the province, and even in the South African context.

5.5 CONCLUSION

Similar to previous reports, the use of SMS is a highly acceptable and feasible measure and serves as an adjunct to standard clinical care in the promotion of health among diabetic patients in this study setting. Although there was a little improvement, the efficacy of the unidirectional text messaging in promoting health outcomes among low-income earning patients in this study setting is still doubtful.

Also, this study indicates that adherence to anti-diabetic regimen; particularly dietary recommendations and physical activity pattern is the likely missing links in the management of diabetes in this study setting. Finally, this study reveals a generally poor quality of diabetes care and adherence to recommended management guideline at the primary healthcare level in this setting. Majority of the diabetic patients in this study setting rarely did the necessary screening for complications as recommended in the diabetes treatment guidelines.

5.6 RECOMMENDATIONS

Based on the findings of this study, the following recommendations are made;

I. The quality of diabetes care should be improved by ensuring prompt screening of patients for complications in this setting.

II. Primary healthcare givers in this setting should adhere to the recommended treatment guideline for diabetes.

III. Lifestyle and behavioural modifications, especially diet and physical activity pattern, should be promoted in this setting.

IV. Healthcare providers should educate patients on healthy lifestyle practices while putting their cultural beliefs, health and socio-economic context into consideration.

V. The low level of knowledge among the study participants suggests that healthcare providers should prioritise continual health education as a key component of diabetes care in this setting.

VI. An obvious challenge at this level of healthcare is the absence of clinical records for patients, except in just one of the facilities. Therefore, a proper record keeping at all health facilities to facilitate easy monitoring of the patients is advocated.

VII. There is an urgent need to explore the views of the healthcare providers on why the standard measure of glycaemic status, HbA1c is not often utilised, and to further create awareness on the need for this investigation as indicated in the country's guideline for management.

VIII. Future studies should consider using a bi-directional form of text messaging that includes communication with the patient's physician in the intervention in order to foster further improvement in participants' health outcomes.

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DATA COLLECTION TOOL

SECTION A : Demographic Information			
Demographic Information			
Question		**Response**	**Code**
1	Sex	Male 1 Female 2	C1
2	What is your date of birth?	⌊_⌊_⌋ ⌊_⌊_⌋ ⌊_⌊_⌊_⌊_⌋ dd mm year	C2
3	What is the **highest level of education** you have completed?	No formal schooling 1 Grade 1-7 2 Grade 8-12 3 Tertiary 4 Post-graduate degree 5	C5
4	What is your racial group?	Black 1 Coloured 2 White 3	C6
5	What is your **marital status**?	Never married 1 Married 2 Divorced 3 Widowed 4 Cohabiting 5	C7
6.	Which of the following best describes your **main work** status over the past 12 months?	Government employee 1 Non-government employee 2 Self-employed 3 Student 4 Retired 5 Unemployed 6	C8
7	When did you commence diabetes treatment?	_____	C9
8	Type of Diabetes?	Type 1 1 Type 2 2	
9.	What type of treatment are you receiving for your diabetes?	Oral pills 1 Insulin 2	
10	If you are on oral pills, mention the name of the drugs you are currently using	_____	

SECTION B Behavioural Measurements				
Tobacco Use				
1	Have you ever smoked any tobacco product?	Yes 1 No 2	*If No, go to T6*	T1

2	Do you currently smoke any **tobacco products**, such as cigarettes, cigars or pipes?	Yes 1 No 2 *If No, go to T6*	T1
3	Do you currently smoke tobacco products **daily**?	Yes 1 No 2 *If No, go to T6*	T2
4	On average, **how many** of the following do you smoke each day?	Manufactured cigarettes ⌊__⌋⌊__⌋	T5a
		Hand-rolled cigarettes ⌊__⌋⌊__⌋	T5b
		Pipes full of tobacco ⌊__⌋⌊__⌋	T5c
		Snuff ⌊__⌋⌊__⌋	T5d
5	During the past 7 days, on how many days did someone **in your home** smoke when you were present?	Number of days [ ]	T13
6	During the past 7 days, on how many days did someone smoke in closed areas **in your workplace** (in the building, in a work area or a specific office) when you were present?	Number of days [ ]	T14
Alcohol Consumption			
7	Have you **ever** consumed an alcoholic drink	Yes 1 No 2 *If No, go to D1*	
8	Have you consumed an alcoholic drink within the **past 30days**?	Yes 1 No 2 *If No, go to D1*	A1b
9	During the past 30days, **how frequently** have you had at least one alcoholic drink?	Daily 1 5-6 days per week 2 1-4 days per week 3 1-3 days per month 4 Less than once a month 5	A2
10	During the past 30 days, how many times did you have for **men**: **five or more** for **women**: **four or more** standard alcoholic drinks in a single drinking occasion?	Number of times ⌊__⌋⌊__⌋	A7

Dietary Practices			
11	Have you ever been taught about the recommended diets for diabetes?	Yes 1 No 2	
12	If yes, do you comply with the recommendations?	Yes 1 No 2	
13	Looking at this diabetes plate, do you feel you eat more than the recommended amount?	Yes 1 No 2	
14	If you do not comply, why?		

CORE: Physical Activity			
Question		Response	Code
15	Do you participate in moderate physical activities?	Yes 1 No 2	P1
16	Do you think you are active enough?	Yes 1 No 2	P2
17	Do you comply with all the recommended physical activity pattern?	Yes 1 No 2	P3
18	If not, why?		P4

Sedentary behaviour			
The following question is about sitting or reclining at work, at home, getting to and from places, or with friends including time spent sitting at a desk, sitting with friends, traveling in car, bus, train, reading, playing cards or watching television, but do not include time spent sleeping.			
20	How much time do you usually spend sitting or reclining on a typical day?	⌊_⌊_⌊ : ⌊_⌊ Hours : minutes	P16(a-b)

SECTION C: HISTORY TAKING

History of Raised Blood Pressure			
1	Have you ever been told by a doctor or other health worker that you have raised blood pressure or hypertension?	Yes 1 No 2 *If No, go to H6*	H2a
2	Are you currently receiving any of the following treatments/advice for high blood pressure prescribed		
	Drugs (medication) that you have taken in the past two weeks	Yes 1 No 2	H3a
History of Diabetes			
3	Are you currently receiving any of the following treatments/advice for diabetes prescribed by a doctor or other health worker?		
	Insulin	Yes 1 No 2	H8a
	Drugs (medication) that you have taken in the past two weeks	Yes 1 No 2	H8b
4.	What are the drugs you are currently using for your diabetes?		
5.	Does any member of your family have diabetes?	Yes 1 No 2	
6.	If yes, who?		

SECTION D: KNOWLEDGE OF DIABETES USING THE MICHIGAN DIABETES KNOWLEDGE TEST

Here are 20 statements about diabetes, some are true statements and some are false. Please read each statement and then indicate whether you think it is true or false by putting a circle round either TRUE or FALSE. If you do not know the answer please tick DON'T KNOW.

Question		True	False	Don't know
1	The diabetes diet is a healthy diet for most people			
2	Glycosylated haemoglobin (HbA1c) is a test that measures your average blood glucose level in the past week.			
3	A portion of chicken has more carbohydrate in it than a portion of potatoes			
4	Orange juice has more fat in it than low fat milk.			
5	Urine testing and blood testing are both equally as good for testing the level of blood glucose.			
6	Unsweetened fruit juice raises blood glucose levels.			
7	A can of diet soft drink can be used for treating low blood glucose levels.			
8	Using olive oil in cooking can help lower the cholesterol in your blood.			
9	Exercising regularly can help reduce high blood pressure.			
10	For a person in good control, exercising has no effect on blood sugar levels.			
11	Infection is likely to cause an increase in blood sugar levels.			
12	Wearing shoes a size bigger than usual helps prevent foot ulcers.			
13	Eating foods lower in fat decreases your risk for heart disease.			
14	Numbness and tingling may be symptoms of nerve disease.			
15	Lung problems are usually associated with having diabetes.			
16	When you are sick with the flu you should test for glucose more often.			
17	Having regular check-ups with your doctor can help spot the early signs of diabetes complications.			
18	Attending your diabetes appointments will stop you getting diabetes complications.			
For those receiving insulin only				
19	High blood glucose levels may be caused by too much insulin.			
20	If you take your morning insulin but skip breakfast your blood glucose level will usually decrease.			

SECTION E: MEDICATION ADHERENCE USING MORISKY MEDICATION ADHERENCE SCALE

S/N	QUESTION	YES	NO
1	Do you sometimes forget to take your diabetes pills?		
2	Over the past 2 weeks, were there any day you didn't take your medication for reasons other than forgetting?		
3	Have you ever stopped taking your medications or decreased the dose without first warning your doctor because you felt worse taking them?		
4	When you travel or leave the house, do you sometimes forget to take your medications?		

5	Did you take your diabetes medication yesterday?					
6	When you feel your blood sugar is controlled, do you sometimes stop taking your medications?					
7	Have you ever felt distressed for strictly following your high blood glucose treatment?					
		Never	Once in a while	Sometimes	Usually	All the time
8	How often do you have difficulty to remember taking all your blood glucose medications?					

SECTION E2

ADHERENCE TO DIETARY RECOMMENDATION

S/N	QUESTION	YES	NO
1	Do you sometimes forget to follow your recommended dietary regimen?		
2	Over the past 2 weeks, were there any day you didn't follow your recommended dietary regimen for reasons other than forgetting?		
3	Have you ever stopped following your recommended dietary regimen without first warning your doctor/nurse because you don't enjoy it?		
4	When you travel, do you sometimes forget to follow your recommended diet plan?		
5	Did you follow the recommended diet plan yesterday?		
6	When you feel your blood sugar is controlled, do you sometimes stop following your dietary regimen?		
7	Have you ever felt distressed for strictly following recommended dietary regimen?		

SECTION E3

ADHERENCE TO PHYSICAL ACTIVITY PATTERN

S/N	QUESTION	YES	NO
1	Do you sometimes forget to follow your recommended physical activity pattern?		
2	Over the past 2 weeks, were there any day you didn't follow your recommended physical activity pattern for reasons other than forgetting?		
3	Have you ever stopped following your recommended physical activity pattern without first warning your doctor/nurse because you don't enjoy it?		
4	When you travel or leave the house, do you sometimes forget to follow your recommended physical activit plan?		
5	Did you do exercise yesterday?		
6	When you feel your blood sugar is controlled, do you sometimes stop doing exercise?		

7	Have you ever felt distressed for strictly following recommended physical activity pattern?		

SECTION F: QUALITY OF LIFE (EQ-5D QUESTIONS)
Kindly tick one of the options provided under each question to describe your health TODAY

1. MOBILITY
I have no problems in walking about ☐
I have slight problems in walking about ☐
I have moderate problems in walking about ☐
I have severe problems in walking about ☐
I am unable to walk about ☐

2. SELF-CARE
I have no problems washing or dressing myself ☐
I have slight problems washing or dressing myself ☐
I have moderate problems washing or dressing myself ☐
I have severe problems washing or dressing myself ☐
I am unable to wash or dress myself ☐

3. USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*
I have no problems doing my usual activities ☐
I have slight problems doing my usual activities ☐
I have moderate problems doing my usual activities ☐
I have severe problems doing my usual activities ☐
I am unable to do my usual activities ☐

4. PAIN / DISCOMFORT
I have no pain or discomfort ☐
I have slight pain or discomfort ☐
I have moderate pain or discomfort ☐
I have severe pain or discomfort ☐
I have extreme pain or discomfort ☐

5. ANXIETY / DEPRESSION
I am not anxious or depressed ☐
I am slightly anxious or depressed ☐
I am moderately anxious or depressed ☐
I am severely anxious or depressed ☐
I am extremely anxious or depressed ☐

6. We would like to know how good or bad your health is TODAY. On a scale of 1 to 100, 100 means the best health you can imagine, 0 means the worst health you can imagine. Please write the number indicating how you feel about your health today

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	Very poor	Poor	Neither good nor poor	Good	Very Good
7. In the last four weeks, how would you rate your quality of life?					
	Very Dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
8. Over the past 4 weeks, how satisfied are you with your health?					

SECTION G: DIABETES SELF-MANAGEMENT

The following statements describe self-care activities related to your diabetes. Thinking about your self-care over the last 8 weeks, specify the extent to which each statement applies to you.

SN	VARIABLE	Applies to me very much [3]	Applies to me to a considerable degree	Applies to me to some degree	Does not apply to me
1.	I check my blood sugar levels with care and attention				
	Blood sugar measurement is not required as a part of my treatment ☐				
2.	The food I choose to eat makes it easy to achieve optimal blood sugar levels				

3.	I keep all doctors' appointments recommended for my diabetes treatment				
4.	I take my diabetes medication (insulins, tablets) as prescribed				
	Diabetes medication /insulin is not required as a part of my treatment ☐				
5.	Occasionally, I eat lots of sweets or other foods rich in carbohydrates				
6.	I record my blood sugar levels regularly				
	Blood sugar measurement is not required as a part of my treatment ☐				
7.	I tend to avoid diabetes-related doctors'appointments				
8.	I do regular physical activity to achieve optimal blood sugar levels				
9.	I strictly follow the dietary recommendations given by my doctor or diabetes specialist				
10.	I do not check my blood sugar levels frequenctly enough as would be required for achieving good blood glucose control				
	Diabetes medication /insulin is not required as a part of my treatment ☐				
11.	I avoid physical activity, although it would improe my diabetes				
12.	I tend to forget to take or skip my diabetes medication (e.g insulin, pills)				
	Diabetes medication /insulin is not required as a part of my treatment ☐				
13.	Sometimes I have real 'food binges' (not trigerred by hypoglycaemia)				
14.	Regarding my diabetes care, I should see my medical practitioner(s) more often				
15.	I tend to skip planned physical activity				
16.	My diabetes self-care is poor				

SECTION H: DIABETES EMPOWERMENT SCALE

The 8 items below constitute the DES-SF. The scale is scored by averaging the scores of all completed items (Strongly Disagree =1, Strongly Agree = 5)

Check the box that gives the best answer for you.

1.	In general, I believe that I know what part(s) of taking	☐1	☐2	☐3	☐4	☐5

care of my diabetes that I am **dissatisfied** with.	Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree
2. In general, I believe that I am able to turn my diabetes goals into a workable plan.	☐1 Strongly Disagree	☐2 Somewhat Disagree	☐3 Neutral	☐4 Somewhat Agree	☐5 Strongly Agree
3. In general, I believe that I can try out different ways of overcoming barriers to my diabetes goals.	☐1 Strongly Disagree	☐2 Somewhat Disagree	☐3 Neutral	☐4 Somewhat Agree	☐5 Strongly Agree
4. In general, I believe that I can find ways to feel better about **having** diabetes.	☐1 Strongly Disagree	☐2 Somewhat Disagree	☐3 Neutral	☐4 Somewhat Agree	☐5 Strongly Agree
5. In general, I believe that I know the **positive** ways I cope with diabetes-related stress.	☐1 Strongly Disagree	☐2 Somewhat Disagree	☐3 Neutral	☐4 Somewhat Agree	☐5 Strongly Agree
6. In general, I believe that I can ask for support for having and caring for my diabetes when I need it.	☐1 Strongly Disagree	☐2 Somewhat Disagree	☐3 Neutral	☐4 Somewhat Agree	☐5 Strongly Agree
7. In general, I believe that I know what helps me stay motivated to care for my diabetes.	☐1 Strongly Disagree	☐2 Somewhat Disagree	☐3 Neutral	☐4 Somewhat Agree	☐5 Strongly Agree
8. In general, I believe that I know enough about myself as a person to make diabetes care choices that are right for me.	☐1 Strongly Disagree	☐2 Somewhat Disagree	☐3 Neutral	☐4 Somewhat Agree	☐5 Strongly Agree

SECTION I: HEALTHCARE UTILISATION

SN	VARIABLE	RESPONSE
1.	How many times did you visit the clinic in the last 6 months?	

2.	How many times did you visit private doctor in the last 6 months?	
3.	How many times did you visit an emergency room in the last 6 months?	
4.	How many times did you stay overnight in the hospital in the last 6 months	
HEALTHCARE ACCESS		
5.	Where do you normally go when sick?	a. Hospital b. Clinic c. Private practice d. Traditional healer/prophet
6	How do you get there?	a. Walk b. Take public transport c. Own car
7.	How long does it take (km or hour)	
8.	Do you have access to diabetes medications?	Yes [ ] No [ ]
9.	Do you experience any difficulty going to the clinic when you have an appointment?	Yes [ ] No [ ]

SECTION J: DIABETES DISTRESS

Listed below are 2 potential problem areas that people with diabetes may experience. Consider the degree to which each of the 2 items may have distressed or bothered you DURING THE PAST MONTH and circle the appropriate number. If you feel that a particular item is not a bother or a problem for you, you would circle "1." If it is very bothersome to you, you might circle "6."

S/N	VARIABLE	Not a problem		Moderate problem		Serious problem	
1.	Feeling overwhelmed by the demands of living with diabetes	1	2	3	4	5	6
2.	Feeling that I am often failing with my diabetes regimen	1	2	3	4	5	6
	Over the past 2 weeks, how often have you been bothered by any of the following problems?	**Not At All (0)**		**Several Days (1)**	**More Than One-Half Of The Days (2)**	**Nearly Everyday (3)**	
3	Little interest or pleasure in doing things						
4.	Feeling down, depressed, or hopeless						

SECTION K: REASONS FOR NON-ADHERENCE WITH TREATMENT

1. How often do you take your medications?

1. Regularly as prescribed? -------- 2. In response to the signs of the disease?--------- 3. I do forget to take my mediations----------

2. What are the reasons for non-compliance? (Tick as appropriate, you may tick more than one option.

a. Unavailability of drugs [ ] b. Drugs are so expensive [ ]

c. Side effects of drugs [ ] d. Not properly taught about the benefits of using the drugs by health workers [ ]

3. How often do you adhere to your recommended drug regimen?

a. Always [ ] b. Sometimes[ ] Not at all [ ]

4. What are your reasons for non-compliance with dietary regimen?

a. Diet is not palatable b. Diet is expensive

c. Diet does not improve the condition

5. How often do you comply with physical activity regimen?

a. Always [ ] b. Sometimes[ ] Not at all [ ]

6. What are the reasons for non-compliance with physical activity regimen?

a. Lack of time [ ] b. Lack of equipment for exercising c. Lack of motivation [ ]

d. It does not improve my condition [ ] e. Lack of insight and initiative [ ]

7. Do you have family member(s) who supports you? a. Yes [ ] b. No [ ]

8. Are they involved in your care? a. Yes [ ] b. No [ ]

9. How involved are they? a. Deeply involved [ ] b. Fairly involved [ ]

c. Not involved

10. How is the attitude of health professionals to you? a. Good [ ] b. Satisfactory [ ] c. Poor [ ]

11. Does their attitude or the way they address you influence your compliance with any instruction given to you? a. Yes [ ] b. No [ ].

SECTION L: PERCEPTION ABOUT THE USE OF MHEALTH

1. Do you feel the use of mobile phone technology can assist you in any way regarding your diabetes treatment?

a. Yes [ ] b. No [ ]

2. Do you feel it is a waste of time?

a. Yes [ ] b. No [ ]

3. Are you happy with receiving SMSs daily regarding your diabetes care?

a. Yes [ ] b. No [ ]

4. Briefly tell us how you feel about it.

.....
.....
.....
.....
.....

SECTION M: DIABETES CARE

1a. Have you checked your blood sugar in the last 12 months?----------

b. If yes, how often? ----------

c. When last did you get your blood glucose checked? ----------

2a. Have you checked your blood pressure in the last 12 months?----------

b. If yes, how often? ----------

c. When last did you get your blood pressure checked? ----------

3a. Have you checked your blood lipid in the last 12 months?----------

b. If yes, how often? ----------

d. When last did you get your blood lipid checked? ----------

4a Have you undergone screening for eye complications in the last 12 months?----------

b. If yes, how often? ----------

c. When last did you screen for eyes complications? ----------

5a. Have you undergone screening for feet complications in the last 12 months?----------

b. If yes, how often? ----------

c. When last did you screen for feet complications? ----------

6a. Have you undergone screening for kidney complications in the last 12 months?----------

b. If yes, how often? ----------

c. When last did you screen for kidney complications? ----------

7a. Have you undergone screening for cardiovascular complications in the last 12 months?----------

b. If yes, how often? ----------

c. When last did you screen for cardiovascular complications? ----------

SECTION N: ANTHROPOMETRIC, PHYSICAL AND BIO-CHEMICAL MEASUREMNTS

	1ST ATTEMPT	2ND ATTEMPT	3rd ATTEMPT
Weight(Cm)			
Height(m)			
Waist circumference(Cm)			
Hip circumference(Cm)			
Blood pressure (mmHg)			
HbA1c (%)			
Lipid			

SECTION O: POST-INTERVENTION DATA COLLECTION

ACCEPTABILITY OF SMS INTERVENTION

SN	QUESTION	
1	DID YOU RECEIVE THE DAILY SMS?	Yes No
2	IF YES, DO YOU THINK IT WAS HELPFUL?	
3	IN WHAT WAY WAS IT HELPFUL? EXPLAIN	
4	DID IT STRESS YOU IN ANY WAY?	Yes No
5	IF YES, HOW DID IT STRESS YOU?	
6	WERE YOU COMFORTABLE WITH THE TIMING OF THE SMS?	Yes No
7	IF NOT, WHY?	
8	WOULD YOU RECOMMENDTHIS PROGRAMME TO A FRIEND?	Yes No
9	IF WE DECIDE TO CONTINUE, WOULD YOU LIKE TO CONTINUE?	Yes No
10	WHAT WOULD YOU LIKE US TO IMPROVE UPON REGARDING THE SMS?	

University of Fort Hare
Together in Excellence

ETHICAL CLEARANCE CERTIFICATE
REC-270710-028-RA Level 01

Certificate Reference Number:	GOO171OWA01
Project title:	**Efficacy, acceptability of health technology in promoting anti-diabetic therapy and glycaemic control among diabetic patients in Eastern Cape Province, South Africa.**
Nature of Project	PhD in Nursing Science
Principal Researcher:	Eyitayo Omolara Owolabi
Supervisor:	Prof D.T Goon
Co-supervisor:	N/A

On behalf of the University of Fort Hare's Research Ethics Committee (UREC) I hereby give ethical approval in respect of the undertakings contained in the above-mentioned project and research instrument(s). Should any other instruments be used, these require separate authorization. The Researcher may therefore commence with the research as from the date of this certificate, using the reference number indicated above.

Please note that the UREC must be informed immediately of

- Any material change in the conditions or undertakings mentioned in the document
- Any material breaches of ethical undertakings or events that impact upon the ethical conduct of the research

The Principal Researcher must report to the UREC in the prescribed format, where applicable, annually, and at the end of the project, in respect of ethical compliance.

Special conditions: Research that includes children as per the official regulations of the act must take the following into account:

Note: The UREC is aware of the provisions of s71 of the National Health Act 61 of 2003 and that matters pertaining to obtaining the Minister's consent are under discussion and remain unresolved. Nonetheless, as was decided at a meeting between the National Health Research Ethics Committee and stakeholders on 6 June 2013, university ethics committees may continue to grant ethical clearance for research involving children without the Minister's consent, provided that the prescripts of the previous rules have been met. This certificate is granted in terms of this agreement.

The UREC retains the right to

- Withdraw or amend this Ethical Clearance Certificate if
  - Any unethical principal or practices are revealed or suspected
  - Relevant information has been withheld or misrepresented
  - Regulatory changes of whatsoever nature so require
  - The conditions contained in the Certificate have not been adhered to

- Request access to any information or data at any time during the course or after completion of the project.

- In addition to the need to comply with the highest level of ethical conduct principle investigators must report back annually as an evaluation and monitoring mechanism on the progress being made by the research. Such a report must be sent to the Dean of Research's office

The Ethics Committee wished you well in your research.

Yours sincerely

Professor Lindelwa Majova-Songca
Acting Dean of Research

13 November 2017

Eastern Cape Department of Health

Enquiries:	Madoda Xokwe	Tel No:	040 608 0710
Date:	01 December 2017	Fax No:	043 642 1409
e-mail address:	madoda.xokwe@echealth.gov.za		

Dear Ms. E. Owolabi

Re: Efficacy, acceptability and feasibility of mHealth technology in promoting adherence to anti-diabetic therapy and glycaemic control among diabetic patients in Eastern Cape, South Africa (EC_201711_020)

The Department of Health would like to inform you that your application for conducting a research on the abovementioned topic has been approved based on the following conditions:

1. During your study, you will follow the submitted protocol with ethical approval and can only deviate from it after having a written approval from the Department of Health in writing.
2. You are advised to ensure, observe and respect the rights and culture of your research participants and maintain confidentiality of their identities and shall remove or not collect any information which can be used to link the participants.
3. The Department of Health expects you to provide a progress on your study every 3 months (from date you received this letter) in writing.
4. At the end of your study, you will be expected to send a full written report with your findings and implementable recommendations to the Epidemiological Research & Surveillance Management. You may be invited to the department to come and present your research findings with your implementable recommendations.
5. Your results on the Eastern Cape will not be presented anywhere unless you have shared them with the Department of Health as indicated above.

Your compliance in this regard will be highly appreciated.

SECRETARIAT: EASTERN CAPE HEALTH RESEARCH COMMITTEE

Province of the
EASTERN CAPE
HEALTH

BUFFALO CITY METRO HEALTH DISTRICT
OFFICE OF THE DISTRICT MANAGER
18 Shefield Road • Westbank •East London •5200, Eastern Cape
Private Bag X 9015 •Main Post Office, East London • 5200 • Eastern Cape
Tel.: +27 (0)43 708 1797 • Fax: +27 (0)43 708 1836/ 086 245 5023 • Website: www.ecdoh.gov.za
Enquiries: Ms Z Mntuyedwa

INTERNAL MEMORANDUM

To:	Acting Sub-District Manager Bhisho/ KWT Clinic Supervisors East London Clinic Supervisors Mdantsane Clinic Supervisors All CHC Facility Manager
From:	Acting District Manager
Subject:	Permission to conduct Research Study: Ms Eyitayo Omolara Owolabi
Date:	11 December 2017

Purpose

The purpose of this memorandum is to inform relevant Buffalo City Health District staff and patients of permission granted on research study to be conducted by Ms Eyitayo Owolabi towards a PHD in Nursing Science Degree with the University of Fort Hare.

Background and Exposition of Facts

Ms Owolabi is currently studying towards her PHD in Nursing Science Degree with the University Of For Hare. The topic of her research study is called **Efficacy, Acceptability And Feasibility Of Mhealth Technology In Promoting Adherence To Anti-Diabetic Therapy And Glycaemic Control Among Diabetic Patients In Eastern Cape, South Africa.**

She has requested for permission to do research in the Buffalo City Metro Health District health facilities. Ms Owolabi has submitted all the required documents for a research study in the Eastern Cape Department of Health facilities and as such permission has been granted to her by the Research unit to conduct the study in terms of her research protocol and methodology.

PERMISSION TO CONDUCT RESEARCH STUDY: Ms Owolabi

Approval by the district

1. Kindly note that this memorandum serves as an approval at district level for Ms Owolabi to conduct her research study in terms of the approved research protocol, ethical clearance and permission letter from the research unit subject to producing all necessary supporting documentation on request to prospective participants in the research study and management of the district;

2. All posters advertising the research must first be tabled with Acting Sub-District Manager and hospital CEOs to ensure compliance with departmental policies;

3. Patient details and addresses will only be provided to the researcher on those who have consented to participate in the research subject to the terms and condition of the letter of approval from the Research Unit of the Eastern Cape Department of Health.

APPROVED

MR DM LUSASA
ACTING DISTRICT MANAGER
BUFFALO CITY METROHEALTH DISTRICT

12/12/2017
DATE

Province of the
EASTERN CAPE
HEALTH

Room 111 Floor • Old Medical Centre Building • 19 St James Road • Southernwood • East London
Private Bag X 9015 • Bhisho • 5605 • REPUBLIC OF SOUTH AFRICA
Tel.: +27 (0)43 707 6766 • Fax: +27 (0)43 707 6843 • Website: www.ecdoh.gov.za

Ms. E. Owolabi 19/01/2018

RE: REQUEST FOR APPROVAL TO CONDUCT A RESEARCH STUDY AT AMATHOLE HEALTH DISTRICT

RE: Efficiency, acceptable and feasibility of Health Technology in promoting adherence to anti-diabetic therapy and glycaemic control among diabetic patients in Eastern Cape, South Africa (EC_201711_020)

In view, of the above subject request, the Office of the District Manager at Amathole Health District acknowledges your request and is gladly granting you permission to conduct your research.

Please be advised that:

1. During your study, you will follow the submitted protocol with ethical approval and can only deviate from it after having a written approval from the ECDoH in writing.
2. That the results of the subjects matter must be presented to the District Manager and the Team.
3. Your research must not, by any means violate people's rights and cultures.
4. You must maintain confidentiality of their identities and shall not collect any information which can be used to link the participants.
5. Your research must not contravene with the policies of the Department of Health.
6. Must not in anyway be harmful to the reputation of the Department nor dent its image.

We wish you a very successful result with your adventure.

Yours in service delivery.

Mrs. S. Gede

DM: Amathole District

Together, moving the health system forward

31/01/2018

Date:

17 October 2018

To Whom It May Concern:

RE: Efficacy, Acceptability and Feasibility of mHealth Technology in promoting adherence with anti-diabetic regimen among diabetic patients in Eastern Cape, South Africa

As project manager for the Pan African Clinical Trial Registry (www.pactr.org) database, it is my pleasure to inform you that your application to our registry has been accepted. Your unique identification number for the registry is **PACTR201810599931422**.

Please be advised that your trial is registered under an initiative within our system that allow us to capture data of trials that are already in progress or completed. As such, your trial registration may not adhere to the mandates set forth by the International Committee of Medical Journal Editors for registration requirements, and it is your duty to be transparent to any journal that may ask about the retrospective status of your registration.

Please note you are responsible for updating your trial, or for informing us of changes to your trial. Additionally, please provide us with copies of your ethical clearance letters as we must have these on file (via email or post or by uploading online) at your earliest convenience if you have not already done so.

Please do not hesitate to contact us at +27 21 938 0835 or email epienaar@mrc.ac.za should you have any questions.

Yours faithfully,

Elizabeth D Pienaar
www.pactr.orgProject Manager
+27 021 938 0835

University of Fort Hare
Together in Excellence

Ethics Research Confidentiality and Consent Form

EFFICACY, ACCEPTABILITY AND FEASIBILITY OF mHEALTH TECHNOLOGY IN PROMOTING ADHERENCE TO ANTI-DIABETIC THERAPY AND GLYCAEMIC CONTROL AMONG DIABETIC PATIENTS IN EASTERN CAPE, SOUTH AFRICA.

PRINCIPAL INVESTIGATOR: Miss EO OWOLABI (Mcur, BNSc, RN, RM)
SUPERVISOR: Prof DT GOON (Prof, Department of Nursing Science, University of Fort Hare, East London).

Dear Research participant,
You are invited to participate in a research study that forms part of my formal Doctoral degree programme. This information leaflet will help you to decide whether you will like to participate or not. Before you agree to take part, you should fully understand what is involved. You should not agree to take part unless you are completely satisfied with all aspects of the study.

WHAT IS THE STUDY ALL ABOUT?
Diabetes mellitus (DM) is an important public health concern, and forms part of the four priority non-communicable diseases (CVD, cancer, and chronic respiratory diseases) targeted by world leaders for special attention (WHO, 2016a:5). The burden associated with diabetes is enormous, thus the 2016 World Health Day was dedicated to diabetes with the slogan, “Beat Diabetes” (WHO, 2016b). Despite the effectiveness of drug therapy in diabetes management, high rate of poor adherence persists among diabetic patients, both globally and nationally (Adisa & Fakeye, 2014; Bagonza et al., 2015; Cramer, 2004; Mann et al., 2009). A surge in the prevalence of diabetes has been documented in South Africa with an increasing disease burden and mortality associated with it (IDF, 2015). South Africa has the second highest prevalence of diabetes in Africa (Guarigata et al., 2013:3). Also, glycaemic control among diabetic patients in South Africa appears to be a challenging task for healthcare professionals (Shilubane, 2010). This is likely to be a result of the documented poor adherence to medication among diabetic patients attending the primary healthcare facilities (Booysen & Schlemmer, 2015; Kagee, 2004); as intensive medication therapy and compliance with the prescribed medication regimen is a key factor for glycaemic control. Consequently, there is a resultant predisposition to complications development leading to poor quality of life, disability, premature mortality and excessive burden on the individuals; thus placing significant strain on the already overburdened healthcare system.

mHealth is an emerging and a cost-effective measure proven to be effective in improving patient's self-management behaviours, drug regimen adherence and appointment compliance. However, the effectiveness of mHealth among diabetic patients has rarely been documented in South Africa, and more specifically, in an economically poor region of the Eastern Cape Province. Hence, the focus of this study is to determine the efficacy of mHealth technology, aside the usual care in promoting glycaemic control and adherence to anti-diabetic therapy among individuals with diabetes in Eastern Cape Province.

WHAT WILL YOU BE REQUIRED TO DO IN THIS STUDY?

If you decide to take part in this study, you will be required to do the following:

- Sign this informed consent;
- Complete a questionnaire which comprises of demographic information (Age, Gender, Education, racial group, marital status and your main work and duration of diabetes), behavioral lifestyle (Tobacco use, smoking, alcohol consumption and diet) and physical activity participation, knowledge of diabetes, medication adherence and quality of life.
- Complete the questionnaire in a designated conducive place to be provided by the health facility. It should not take more than 30 minutes to complete it;
- Sit for ten minutes in a room to be provided by the health facilities where the blood pressure will be measured three times;
- Have your height, weight, waist and hip circumferences measured;
- Have your glucose level checked using a point-of-care device which analyses a drop of blood obtained from finger pricking.
- If you are selected to be part of the intervention group, you will receive a SMS health educating you about diabetes on a daily basis for 6 months.
- You will make yourself available for assessment three months and six months after this study is commenced

RANDOMISATION OF PARTICIPANTS TO GROUPS

Please note that this is an interventional study assessing the effect of SMS in promoting adherence among diabetic individuals. We are going to randomly select you into either the control or the intervention group. Please note that candidates are only allotted into groups based on the computer generated numbers, we do not have any personal reason for selecting the group which you belong.

ARE THERE CONDITIONS THAT MAY EXCLUDE YOU FROM THE STUDY?

You will not be eligible to participate in this study if you have psychiatric disorders, pregnant, debilitated, handicapped in any form such that obtaining anthropometric measurements will be difficult or with any cognitive impairment or any form of impairment that will hinder the use of cell phones or do not have a cellphone or not able to read SMS and do not have any close relative that is willing to assist in reading the SMS.

WHAT ARE THE RISKS INVOLVED IN THE STUDY or CAN ANY OF THE STUDY PROCEDURES RESULT IN PERSONAL DISCOMFORT OR INCONVENIENCE?

Questionnaires: The study and procedure involves no foreseeable physical discomfort or inconvenience to you or your family. Due to the personal nature of the questions, you may experience some emotional discomforts.
Blood Pressure: The procedure will not be painful as it is not invasive and will not involve any discomfort.
Anthropometric measurements: The procedure will not be painful as it is not invasive and will not involve any discomfort.
Finger Pricking: You might experience a slight sharp pain when your finger is being pricked for the glucose test.

WHAT ARE THE POTENTIAL BENEFITS OF PARTICIPATING IN THIS STUDY?

The benefits of participating in this study are;

- You will make a contribution towards broadening of academic knowledge and understanding towards the efficacy, acceptability and feasibility of the mHealth technology in promoting adherence to anti-diabetic therapy among diabetics in Eastern Cape, South Africa.
- You will receive personal information concerning your blood glucose level.
- It can direct efforts and reform in the prevention and management of uncontrolled diabetes.
- There is a possibility of having an improved knowledge on diabetes and self-management behaviour during and after the study.

WILL YOU RECEIVE ANY FINANCIAL COMPENSATION OR INCENTIVE FOR PARTICIPATING IN THE STUDY?

Please, note that you **will not** be paid for participating in the study.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT IN THIS STUDY?

Your participation in this study is entirely voluntary. You have the right to withdraw at any stage without any penalty or future disadvantage whatsoever. You don't even have to provide the reason/s for your decision. You may also be asked to withdraw from the study if you do not adhere to the study protocol.

HOW WILL CONFIDENTIALITY AND ANONYMITY BE ENSURED IN THE STUDY?

Confidentiality of data will be maintained−in other words your identity will only be known to the researcher. I will remove/mask all identifying data on transcriptions and final report documents (e.g. thesis and journal articles). Thus, your identity will not be revealed during or after the study, even when the study is published or used in any format.

IS THE RESEARCHER QUALIFIED TO CARRY OUT THE STUDY?

The researcher is a qualified, registered nurse and midwife and also holds a masters degree in nursing. She has previously completed similar research studies. Also, she has

received special training in nursing science from the university of Fort Hare, South Africa.

HAS THE STUDY RECEIVED ETHICAL APPROVAL?

Yes. The University of Fort Hare Research Ethics Committee (UREC) have approved the formal study proposal. All parts of the study will be conducted according to internationally accepted ethical principles.

WHO CAN YOU CONTACT FOR ADDITIONAL INFORMATION REGARDING THE STUDY?

The principal investigator, Miss EO Owolabi, can be contacted during office hours at Tel (043) 704-7368, or on her cellular phone at 0730719622. The supervisor, Prof DT GOON, can be contacted during office hours at Tel (043) 704-7368. Should you have any questions regarding the ethical aspects of the study, you can contact the Acting Dean of Research, University of Fort Hare, Prof WA Akpan, during office hours at Tel 0437047512.

DECLARATION: CONFLICT OF INTEREST

There is no any conflict of interest that may influence the study procedures, data collection, data analysis and publication of results.

A FINAL WORD

Your co-operation and participation in the study will be greatly appreciated. Please sign the underneath informed consent if you agree to partake in the study.

CONSENT

I hereby agree to participate in research regarding …Efficacy, acceptability and Feasibility of mHealth technology in promoting adherence to anti-diabetic therapy among diabetic patients in Eastern Cape South Africa.. I understand that I am participating freely and without being forced in any way to do so. I also understand that I can stop this interview at any point should I not want to continue and that this decision will not in any way affect me negatively.

I have received the telephone number of a person to contact should I need to speak about any issues which may arise in this interview.

I understand that this consent form will not be linked to the questionnaire, and that my answers will remain confidential.

I understand that if at all possible, feedback will be given to my community on the results of the completed research.

……..
Signature of participant **Date**:……..

I hereby agree to the tape recording of my participation in the study

……..
Signature of participant **Date**:……..

SMS CONTENTS

CORE MESSAGES

1. Control of your glucose level require you to eat good food, do exercise, and use your pills. Your nurse, dietician and doctor can assist you.

   Ukulawuleka kweswekile yakho kudinga ukuba utye ukutya okunesondlo, uzilolonge kwaye usebenzise ipilisi zakho ngendlela.
   UGqirha noMongikazi nabo baluncedo kuwe.

   Ngokuthi iswekile yakho ibesendaweni yayo entle yitya ukutya okunesondlo, wenze imisebenzi yomzimba, uqhubekeka ngokutya okuya egazini. UGqirha noMongikazi nabo baluncedo kuwe.

2. Taking care of yourself and diabetes can help you to feel good today and in the future

   Ngokuthi uzihoye wena neswekile yakho, ingakunceda uzive ungcono ngamalanga onke.

3. Do you know when your sugar is close to normal, you are likely to have more energy, be less tired and thirsty, urinate less often, have fewer skin and bladder infections? The answer is YES!!!

   Uyayazi iswekile yakho isondele ekubeni ibengcono? Ungangumntu onomdla wokusebenza, unganxanwa oko okanye udinwe okoko, ungabingumntu ochama oko, amathuba akho ohlaselwa yingxaki yesikhumbo somzimba kunye nengxaki nesinye sakho.
   Impendulo ngu Ewe!!!

4. Do you know when your sugar is close to normal, you have less chances of developing heart problems/stroke, eye problem and kidney problem? The answer is YES!!!

   Uyayaz xa iswekile yakho isendaweni yayo? Ubuyazi namathuba ohlaselwa zizifozentliziyo/stroke angangqongophala? Ingxaki yamehlo kunye nezintso?
   Impendulo ngu Ewe.

5. You are the most important member of your healthcare team because you are the one who manage your diabetes day by day

Ungoyena mntu ojongene nempilo yakho kuba nguwe ozokujongana neswekile yakho ntsuku zonke.

6. It is important for you to know your blood sugar level overtime. You do not want your blood sugar level to get too high.

   Kubalulekile utshekishe iswekile yakho qho. Akufunekanga iswekile yakho ibephezulu okanye inyuke.

7. High levels of blood sugar can harm your heart, kidney, feet, eyes and blood vessels

   Ukwenyuka kweswekile ingakwenzela ubenesifo sentliziyo, izintso, inyawo ezikuphatha kabuhlugu, amehlo,negazi elingacocekanga.

8. Tell your nurse you would like to know your HbA1c level, a test that helps you to know your average blood sugar over the past three months. It is different from the one you do at each clinic visit.

   Xelela umongikazi ukuba ufuna ukwazi iswekile yakho ingakanani emzimbeni, ungqomfwe umnwe kujongwe ingakanani emzimbeni emvakwenyangana ezintathu. Ihlukile le udlangoyenziwe eclinic.

9. If your blood pressure gets too high, it makes your heart work harder and can cause heart attack, stroke, damage your kidneys and eyes.

   Ukuba ipressure yakho iphezulu kakhulu, yenza intliziyo yakho isebenze kanzima ingakunikezala iingxaki zentliziyo, izistroke, okanye ukonakala kwezintso namehlo.

10. Ask your nurse what your blood pressure goal is and work towards that by taking your blood pressure pills as prescribed, doing exercise and eating good diet.

    Buza kumongikazi wakho umfufuzo kujongwe awunyukelwanga yihigh-high, usebenzisana nokutya ipilisi zakho zehigh-high njengoba uxelelwe, nokwenza umsebenzi usebenzisa umzimba nokutya ngendlela.

11. Ask your nurse what your blood cholesterol is and work towards that by taking your prescribed pills as you were told and eating good diet.

Buza umongikazi igazi lakho linjani, uqhubekeke ngokutya ngendlela iipilisi zakho ngendlela oxelelwe ngalo uqhubeke ngokutya ngendlela ukutya okunesondlo.

12. Excessive weight does not allow your blood sugar to be controlled. Do exercise such as walking or gardening almost daily and eat good diet always to keep your weight under check, even if you feel better.

    Ukubanomzimba omkhulu ayikuchazeli ukuba iswekile yakho isendaweni yayo. Qhubeka uwusebenzisa umzimba wakho ngosebenza,njengo hamba umgama omde okanye usebenze igadi yonke imihla okanye ithuba uthe walifumana nakhona ungcedisana nendlela yokutya uqhubekeke nokujonga umzimba wakho.

13. Take your pills as prescribed by your nurse/doctor daily even when you feel good.

    Thatha ipilisi zakho uzitye ngendlela ekuthiwa zitye ngayo ngumongikazi okanye ugqirha qho ngosuku nokuba uziva ungcono.

14. Take your diabetes pills always as prescribed even when you feel good.

    Thatha iipilisi zakho njengoba uxelelwe nokuba sosemandleni.

15. Keep track of your blood sugar, check and record in a book and always talk about it with your healthcare provider.

    Qhubekeka ujonga iswekile yakho, mayibhalwe encwadini uqhubeke nokuthetha nabancedisi bomongikazi.

16. Check your blood pressure and keep a record of it.

    Qhubeka uyijonga iswekile yakho uyibhalelwe phantsi encwadini.

17. Blood testing is the best test for measuring blood sugar. Testing your sugar in the urine is not the same as testing your sugar in the blood.

    Ukuhlolela iswekile egaini kubalulekile ngaphezu koyihlolela emcamweni.

18. Attending your diabetes appointment does not stop you from having complications but it can help you know in time when you do and can help you to quickly treat or manage it.

ukuya rhoqo kwicheck up yakho yeswekile ayinqandi ukuba ungavelelwa zingxaki kodwa yenza uhlale ulumkile kwangexesha nageyiphi into enothi yenzeke.

SMOKING AND ALCOHOL CESSATION MESSAGE

1. Hi [name]. Good management of your diabetes and your future health includes not smoking. Talk to your nurse about how they can help.

   Molo [igama]. Ingqubo elungileyo yokuhoyana neswekile yakho kunye nobomi bakho ayihambelani nokutshaya. Thetha nomongikazi wakho ngalemeko ngokuba bazakunceda.

2. HI [name]. Avoid taking alcohol in order to better control your glucose level and future health.

   Molo. Musa ukuqhubekeka notywala ukuze impilo yakho ibesendaweni entle kunye nobomi bakho.

3. For better control of your blood sugar, you need to stop smoking. Ask your nurse for help to quit.

   Yeka utshaya. Buza uncedo kuyekwa njani.

4. Alcohol is an empty form of energy without any nutritional value. Excessive amounts of alcohol will lead to weight gain.

   Utywala siselo esingalunganga sikunikeze amandla kungekho zakha mzimba. Ngokuthi usele umzimba wakho ubamkhulu uvuleke. Umntu angasela iglass enye ngosuku(Omama). Ko Tata (iglass ezimbini ngosuku). Isiphuzo ngasinye yi=125ml wine, 340 ml lite beer, 1 tot= 25ml spirit.

HEALTHY EATING MESSAGES

1. Eating healthy diet is an important aspect of your diabetes management. It will help in controlling your blood glucose level.

   Ngokutya ngendlela kubalulekile kwisekile yakho. Izakunceda ekubeni iswekile yakho ibesendaweni yayo entle.

2. Make a diabetes meal plan with help from your nurse.

   Bhala phantsi izinto okumele uzitya ngokuthu uncediswe ngumongikazi wakho.

3. Eat foods with more fibre such as whole grain cereals, brown bread, crackers, brown rice or whole-wheat pasta.

Yitya ukutya okuneFibre izinto ezifana nengqolowa ipapa, isonka esenziwe ngengqolowa.irice ebrown kunye nepsta eyenziwe ngengqolowa.

4. Choose foods such as fruits, vegetables, whole grains, bread, cereals, low-fat or skimmed milk and cheese.

   Khetha ukutya neziqhamo,imifuno, isonka, ipapa, izinto ezingatyebanga, kusetyenziswe ibisi olungatyebanga necheese.

5. Drink water instead of juice, regular soda, twizza or coke.

   Sela amanzi kunokusela ijuice okanye isoda, twizza okanye icoke.

6. When eating your meal, fill half of your plate with vegetables and fruits, one quarter with lean portion such as beans or chicken or turkey without the skin, one quarter with whole grain such as brown rice and whole wheat pasta.

   Xa usitya ukutya wakho, into mayibeninzi mayibeyimufuno utye neziqhamo, ikota enye yongeza ekondlekeni iibeans nenkukhu okanye itheki uzisuse isikhumba, ikota enye yebrown rice okanye ipasta yengqolowa.

7. Fats are energy-dense and consuming high levels of fat can lead to weight gain or being overweight.

   Ukutyeba kuqaba ungabinamandla nakhona kunyusa amazing aphezulu okutyeba.

8. Use healthy cooking methods: grill, bake, steam, poach, microwave, pressure cook or boil. You can also use cooking spray or a non-stick pan.

   Sebenzisa indlela elungileyo okutya, ukuyiqhotsa, ekubhakeni, ekuyibiliseni,ekufudumezeni, indllela yokutya kubile. Ungasisebenzisa ispray sokupheka.

9. Avoid using too much margarine, butter, mayo or salad dressing.

   Zama ukuyeka usebenzisa into eqatywayo like irama, mayonnaise ne salad dressing

10. Eat vegetables that are half your plates or size you can hold in your two hands. Choose from any of these common vegetables: Broccoli, Cucumber, Green beans, Leafy salad greens (including Romaine lettuce), Lettuce, Collards, Turnip greens, Green herbs e.g. Parsley, beetroot, Carrots, Pumpkin, Red peppers, tomato, cabbage, Cauliflower, Eggplant (brinjal), Mushrooms and Onions.

    Itya ivege ehlaza kakhulu like lettuce, green beans, broccoli, cauliflower njalo-njalo

11. Cook your vegetables in a healthy way and try to add only a little butter, sugar, cream, cheese sauce or oil.

    Pheka imifuno yakho ngendlela elungileyo uzame ugalela nentwana yerama,iswekile kancinci,icream,icheese sauce okanye uthi chatha intwana yamafutha.

12. Fill a quarter of your plate or a size of your closed fist with whole-grain starchy foods like Brown/Wild rice, Couscous/Quinoa, Legumes/Soya/Hummus, Mealie meal (pap, phutu, porridge), Oats/oat brand, Pearled barley, Pearled/bulgur wheat, Sorghum, whole grain crackers/bread/cereal, Whole grain/seeded breed or Whole wheat pasta, butternut and potatoes.

    Ikota yeplate yakho makubekhona istarch ezinjenge Brown/Wild rice, uMili-mili(papa), iOats/oats beand, ibhathanathi kunye netapile.

13. Avoid white bread or rolls, samp, white rice as they are lower in fibre and can increase your blood glucose.

    Sukusebenzisa isonka esimhlophe okanye irolls, umgqusho, irice emhlophe ngokuba zinesinikamdla osezantsi nakhona zinyusa iswekile.

14. Eat you mealie meal or porridge cold or allow it to cool down to lower the effect on blood sugar.

    Yitya imili-mili okanye uwusebenzise epapeni.yilinde iphole izingenyusi iswekile yakho

15. Fill a quarter of your plate or size of the palm of your hand with protein such as White fish e.g. hake, Salmon, pilchards, sardines, snoek, mackerel and herring, Lean poultry chicken and turkey (remove the skin), Red meat - beef, lamb, pork with visible fat removed (eat limited amounts), dried beans, lentils, chickpeas, Eggs, Tofu, Cottage cheese. Hard cheese can be included in small amounts. Opt for lower fat options e.g. mozzarella cheese.

    Itya izinto ezinje nge whitefish umzekelo hake, salmon, pilchard, sardines, snoek, mackerel and herring, lean poutry chicken and turkey, ususe iskin, ungazitya nazo izinto ezifana ne red meat kodwa usise iskin nakuzo uxobule namanqatha or skin and uzame ukuzitya kancinci zona, idriend beans namaqada ungawatya kodwa in small portions.

    Enye ikota esityeni sakho makubekhonaifish emhlophe umzekelo iHake, iSalmon,ipilchards, isardines,usnoek,imackerel kunye nerring, ibanenkukhu uyisuse ufele,inyamana ebomvu,inyamama yehagu nayo isusiwe inqatha, ibeans zome, amaqanda,chickpeas, Tofu, Cottage cheese. Icheese etyebileyo ungayisebenzisa kodwa ingabininzi umzekelo imozzarella cheese.

16. Foods such as chocolates, biscuits etc. that are labelled “Suitable for diabetics” OR “Sugar Free” OR “No sugar Added” are not recommended. Remember, sugar-free does not mean carbohydrate and calorie free.

Ukutya okufana nezinto ezisweet njenge chocolates,biscuits nezinye zibhaliwe ukuba akukho swekile efakiweyo. Kumbula ezi zithi akukho swekile zincedesana unganyukelwa yiswekile.

17. Eating too much salt in your diet can cause high blood pressure (hypertension) which can cause damage to the kidneys, heart, brain and eyes.

    Xa utya kakhulu ityuwa ingakwenza ubenehigh-high leyo imosha izintso zakho.

18. Sugar substitutes may be used instead of sugar to sweeten foods and drinks. Sugar substitutes contain very few kilojoules and will therefore not affect your blood glucose levels. Example is the sweetex given at the clinic.

    Iswkile ezi zizipilisi ezincinci ungazisebenzisa ekutyeni okanye kwisiphuzo sakho. Intwana yeswekile yezapilisi ziyanceda nakhona aziyichaphazeli iswekile yakho.Umzekelo iSweetex ezi nizinikezwa eclinic.

19. Water is the best drink and it is recommended. Add fruit slices (e.g. strawberries), cucumber slices, lemon juice or mint leaves to your water to vary the taste. Avoid any sugary drinks (e.g. sugar-containing fizzy drinks, cordials, iced tea).

    Amanzi abalulekile uwasele. Neziqhamo kunyanzelekile uyitye njenge (strawberries), icucumber uyisike, ilamoni juice, okanye amagqabi emint uwagalele emanzini akho ukuze ibenencasa. Sukusebenzisa iziphuzo ezineswekile(umzekelo iifizzy drinks, cordials okanye iezibandayo eziqinileyo.

20. Avoid fruit juice.

    Sukuyisela ujuice

21. Avoid hot drinks that contain sugar e.g. hot chocolate, Horlicks and Milo.

    Sukusebenzisa iziphuzo ezishushu ezineswekile, njenge hotchocolate, horlicks, nemilo.

22. You may include tea and coffee in your diet. Avoid adding sugar to your hot drinks.

    Ungayiphunga itea necoffee kwidiet yakho, kodwa ungayifaki iswekile

23. Fruits are very high in vitamins, minerals and fibre just like vegetables. Fruit do contain carbohydrates so keep that in mind with your meal plan. 1 portion of fruit = size of a tennis ball (e.g. small apple, orange or pear), 2 golf balls (e.g. 2 plums), small banana, handful of grapes, ½ cup of cut-up fruit, 30g dried fruit (± 2 pieces),

    Ifruit nevege ibalulekile ngoba ine vitamins, minerals and fibre enintsi zam ukutya ifruit enintsi uyixubaxube.

± 125ml 100% fruit juice (with no added sugar). Try to include a variety of different fruits.

24. If you must take yoghurt, ensure it is a plain yoghurt. Avoid sweetened yoghurts.

    Xa uzotya iyoghurt, itya le ibhalwe plain yoghurt.

25. The diet you choose to eat as a diabetic patient is not just good for you only, other people without diabetes can also be encouraged to eat it. The diabetes diet is a healthy diet for most people.

    Indlela ukhetha ngayo ukutya kwakho njengomntu oneswekile iyakho good kuew qha, nabanye abantu abangenaswekile bangakhuthazela ngoba kubalukile nakuwo wonke umntu.

26. A portion of chicken does not have more fat than low-fat milk. Choose food items that are lower in fat.

    I ntwana yenyama yenkukhu unamafuthu amakhulu ngaphezu kobisi iwe low fat.

27. A portion of chicken does not have as much fat as a low fat milk. Even though the milk is said to be low fat, there is still some contents of fat in there. Reduce the intake of food items with fat.

    Intwana yenyama yenkhulu ayinamafuths amaninzi nje nge low fat milk, nangona kuthwa ubisi lu low fat ulugqibelelanga ngoko ke nciphisa izinto ezinamafutha.

28. Rather than fry, you can cook your meat in water, stew or put in the oven.

    Pheka ngamanzi odwa. Njengaxa upheka isityu okanye I suphu okanye pheka kwi oven okanye emlilweni.

29. You are allowed to braai meet with fat like pork, chiken or fish, just remove the fat before braaing.

    Inyama engatyenanga enje ngeyenkhukhu, ihagu okanye ifishi.

30. Water is the best drink. Drink at least 8 glasses of water everyday.

    Ukuba uyasela, sela amanzi ikomityi ezisibhozo ngosuku. Akululgele emzimbeni wakho.

STRESS AND MOOD MANAGEMENT MESSAGE

1. Hello [name]. Too much stress increase your blood sugar. Make sure you have fun and do something you enjoy today. This will help you reduce stress and improve how you feel.

Molo. Ukuba nestress esikhulu, kungusa iswekile yakho yonwaba wenze into ekanwabise, leyonto izakwehlisa istress neswekile.

2. Try deep breathing, gardening, taking a walk, listening to your favorite music or doing your hobby today in order to reduce stress.

   Zama Ukuba nezibilini ezise zatsi, thatha uhamba umgamana onde, umamele unculo owuthandayo, ukuze ungabinaso istress.

3. Are you feeling down? If yes, ask for help from a friend, family member, clergy, counsellor or your nurse today.

   Uziva unomoya uphantsi? Ukuba ewe, cela uncedo kumhlobo wakho okanye komnye umntu kusapho, okanye kubancedi bocinizelelo iwengqondo okanye kononkikazi.

REMINDERS

1. Have you taken your pills/insulin today?

   Uzithathile ipilisi okanye insulin namhlanje?

2. Hi [name]. Today is your appointment visit. Do not miss it.

   Molo. Namhlanje lusuku iwakho lokuya eclinic ungalibali.

3. Attending your appointments regularly gives your nurse the opportunity to monitor your condition properly, quickly detect any abnormality and counsel as appropriate. Do not miss your appointments.

   Ukungaziphosi iappointments zakho uye qho kuzo kwenza inurse zikuxilonge kakuhle bakwazi ubona yonke into eyenza kuwe ngexesha, suziphosa iaapoinments zakho.

4. Do you still have your diabetes pills? Or are you running out of it? If you don't have or you are running out of it, go to your clinic for more pills.

   Unazo na ipilisi zeswekile? Uba awunazo iya eclinic uyofumana zona

5. Do you still remember you next appointment date? Do not miss it.

   Idate yakho elandelayo usayikhumbula na? ungayilibali

FOOT CARE MESSAGE

1. Looking after your feet will help you prevent foot problems in the future. Check your feet daily and contact your nurse, doctor or foot doctor if there are any changes.

Ukujonga inyawo zakho rhoqo kuceda ukungabinazifo zenyawo. Dibana noGqirha, uNurse okanye uGqirha wenyawo xakukho umehluko kwinyawo zakho.

2. Check your feet everyday for cuts, blisters, red spots or swelling.

   Jonga inyawo zakho yonke imihla ukwenzela ukwazi uqhabela ukusikeka, imibhala ebomvu okanye ukudumba.

3. Visit your clinic immediately you observe a sore that doesn't go away.
   Iya eclinic ngokukhawulweza kuzoxilongwa ukudumba okungapheliyo.

4. Do not wear too fitted or tight shoes.

   Suzinxiba izahlangu ezincinci okanye ezikubambayo kakhulu, qhiniseka ukuba inyawo zakho zisoloko zinespace esi free.

EXERCISE

1. Set a goal to become more active most days of the week. Start slow by taking 10 minutes' walk, three times a day.

   Bhala phantsi icinto ozakuzenza ngosuku , qala kancinci umane uhamba hamba kathathu ngemini.

2. Stay at or get a healthy weight using your meal plan and doing more exercise.

   Hlala kumzimba wakho omhle nusebenzisana nokutya okutyayo.

3. Increase your physical activity pattern. Start slow by taking 10 minutes' walk, three times a day.

   Yandisa kakhulu nakwi exercises zomzimba. Qala kancinci umane uhamba hamba kathathu ngemini.

4. Exercising regularly can help reduce your blood pressure.

   Ukuzilonga umzimba ngokwenza iexercise rhoqo kunceda ukwehlisa ihigh blood pressure.

OTHERS/GENERAL

1. Brush your teeth daily and floss to keep your mouth, teeth and gums healthy.

   Hlamba amazinyo akho rhoqo yonke imihla ukwenzela umlomo wakho uzobasempilweni.

2. Talk to your nurse/doctor if you have any questions about your diabetes.

Theta nomongikazi, ukuba unembuzo yeswekile yakho komongikazi.

3. Report any changes you observe in your health to your doctor or nurse.

   Chaza ingxaki nemphile yakho ekuphete kakubi.

4. At each visit, be sure to check your blood sugar, blood pressure, weight and foot and review how well you are doing with your diabetes plan.

   Qho undwendwela iclinic, jonga iswekile nepressure ujonge umzimba wakho, uhlolo iwanyawo, iswekile yakho ibesendaweni entle.

5. When your sugar drops too low and you feel symptoms like shaking, trembling, blurry eyes, weakness, dizziness, pale skin, sweating, rapid pulse, hunger, nausea, irritability and feeling confused. Immediately eat or drink something that is high in sugar such as 125ml of regular Coke (not Coke Light) OR a 125ml glass of fruit juice OR 1 Tablespoon jam or honey OR 3 teaspoons sugar in water. This will push your sugar level up quickly (within 10 – 15 minutes).

   Xa iswekile yakho iszantsi kakhulu, umzimba uyashukuma qmehlo ankungu, ukukanomzimba aphantsi, ubedizzy, ubene sikhumba somzimba esicekeceke, ukubile, ukadikwa, ukuziva ulahlakelwa ngumqondo khawalleza utye okanye usele into eneswekile njenge coke ne juice yesiqhamo 125 izakwenguko iswekile yakho.

SMS GROUPS

1 = MORNING, XHOSA
2 = MORNING, ENGLISH
3= AFTERNOON, XHOSA
4 = ANYTIME, XHOSA
5= ANYTIME, ENGLISH
6 = EVENING, XHOSA

THESIS OUTPUTS

PUBLISHED

1. The use of text messaging for improving adherence to anti-diabetic regimen and glycaemic control in low-resource settings of South Africa: A study protocol for a randomised controlled Trial. **Contemporary Clinical Trials Communication**, 2019, 15:100418.

REVISED

1. Efficacy, acceptability and Feasibility of daily text messaging in promoting glycaemic control in a rural South Africa setting: Results of a randomised trial in low-resource settings of South Africa, **Plos One**, 2019.

UNDER REVIEW

1. Impact of unidirectional text messaging on adherence among patients with diabetes in a low-resource setting of South Africa: A randomised controlled trial. Medicine, 2019.

2. Efficacy of distance education via unidirectional text messaging on diabetes knowledge among rural primary healthcare patients in South Africa: A randomised controlled Trial. Journal of Diabetes Research, 2019.

3. Impact of a unidirectional daily text messaging on diabetes self-management and empowerment in rural primary healthcare settings in South Africa: A Randomised controlled Trial. Journal of Diabetes, 2019.

ACCEPTED ABSTRACTS FOR CONFERENCE PRESENTATIONS

1. Owolabi, E.O., Goon, D.T. & Ajayi, A.I. High level of acceptability and feasibility with low level of efficacy of daily text-messaging on glycaemic status and self-management: Result of a randomised trial among low-income earning black South Africans. **World Congress on Insulin Resistance, diabetes and cardiovascular diseases, Los Angeles, California**, **USA, 5th -7th December, 2019**.

2. Owolabi, E.O., Goon, D.T. & Ajayi, A.I. Adherence to dietary regimen and recommended physical activity: A missing link in the management of diabetes in low-resource settings of Eastern Cape South Africa. **World Congress on Insulin Resistance, diabetes and cardiovascular diseases, Los Angeles, California, USA, 5th - 7th December, 2019.**

3. Owolabi, E.O., Goon, D.T. & Ajayi, A.I. Efficacy, acceptability and feasibility of daily text-messaging on glycaemic status and self-management: Result of a randomised trial among low-income earning black South Africans. **Public Health Association of South Africa Conference, Cape Town, South Africa, 16th - 18th, September, 2019.**

4**.** Efficacy of distance education via unidirectional text-messaging on diabetes knowledge among rural primary healthcare diabetic patients in South Africa: a randomised controlled trial. **SAMRC Research Symposium, East London ICC, South Africa, 28th - 29th August, 2019.**

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31st May, 2019

To Whom It May Concern

CERTIFICATE OF EDITING

This document certifies that the thesis listed below was edited for proper English language, grammar, punctuation, spelling, and overall style by Oluwatobi Aikomo, an expert in English language, editing and proofreading. Neither the research content nor the author's intentions were altered in any way during the editing process.

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