AN INTERVENTION STUDY ON MEDICATION ADHERENCE AND CLINICAL OUTCOME AMONG TYPE 2 DIABETIC PATIENTS IN A TERTIARY HEALTH FACILITY IN NIGER STATE NIGERIA

BY

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DEPARTMENT OF CLINICAL PHARMACY AND PHARMACY PRACTICE, FACULTY OF PHARMACEUTICAL SCIENCES AHMADU BELLO UNIVERSITY, ZARIA

NOVEMBER 2017

DECLARATION

I declare that the work in this dissertation entitled ‘an intervention study on medication adherence and clinical outcome among type 2 diabetic patients in a Tertiary Health Facility in Niger State Nigeria’ has been carried out by me in the department of Clinical Pharmacy and Pharmacy Practice. The information derived from the literature has been duly acknowledged in the text and a list of references provided. No part of this dissertation was previously presented for another degree or diploma at this or any other institution.

_____	_____	_____
Name of Student	**Signature**	**Date**

CERTIFICATION

This dissertation entitled "**AN INTERVENTION STUDY ON MEDICATION ADHERENCE AND CLINICAL OUTCOME AMONG TYPE 2 DIABETIC PATIENTS IN A TERTIARY HEALTH FACILITY IN NIGER STATE NIGERIA"** by Mohammed Ndagi USMAN, meets the regulation governing the award of Masters of science, Clinical Pharmacy and Pharmacy Practice of the Ahmadu Bello University, Zaria and is approved for its contribution to knowledge and literary presentation.

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ABSTRACT

Diabetes is one of the leading causes of morbidity and mortality in adults globally. Type 2 diabetes is a disease associated with a huge burden of medication non-adherence due to complex regimens leading to complications that further increase morbidity and mortality among this population. The aim of this study was to assess medication adherence and the impact of mobile phone short message service (SMS) reminders on clinical outcome among type 2 diabetic patients in IBB Specialist Hospital Minna, Niger State Nigeria. A prospective intervention study with a control arm comparing standard of care with standard of care plus SMS reminders was conducted. The sample consisted of 423 patients with type 2 diabetes that were randomly sampled and assigned to two groups; an intervention group (n=213) and the control group (n=210). Morisky 8-Medication Adherence Scale (MMAS) was used to assess the medication adherence of patients. The SMS reminders were sent by the principal investigator thrice weekly for three months; the control group did not receive any SMS reminders. For three successive months FBS levels were recorded for both the intervention and control groups and compared to baseline. The collected data was categorized, coded and analyzed using Statistical Package for Social Sciences (SPSS) version 20 (SPSS Inc, Chicago, Illinois, USA). Chi-square test was used to ascertain associations between adherence to diabetic medication and patient related, medication related and disease related factors. Paired t-test was used to compare baseline and post intervention FBS levels. A P-value of less than 0.05 was considered statistically significant for this study. The result of the study showed that only about 15% of patients had good adherence to medication, the others range between the poor (10.7%) and non-adherent (74.3%) categories. The intervention group had significant reduction in FBS levels ($P < 0.05$) with a mean reduction of 1.3mmol/l compared to the control group in which there was no reduction in

FBS ($P > 0.05$). It was concluded that medication adherence among type 2 diabetic patients in this study setting was suboptimal and intervention using mobile phone short message service (SMS) reminders slightly improves clinical outcome (FBS).

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LIST OF ABBREVIATIONS

ACR	Albumin Creatinine Ratio
APPS	Applications
BG	Blood Glucose
BMI	Body Mass Index
C	Control
CVD	Cardiovascular Disease
DM	Diabetes Mellitus
ENT	Ear Nose and Throat
FBS	Fasting Blood Sugar
GDM	Gestational Diabetes Mellitus
HbA1c	Glycated Heamoglobin
HHNS	Hyperosmolar Hyperglycemic Non-ketotic Syndrome
I	Intervention
IDF	International Diabetic Africa
IBBSH	Ibrahim Badamasi Babangida Specialist Hospital
MRDM	Malnutrition Related Diabetes Mellitus
MI	Myocardial Infarction
MODY	Maturity Onset Diabetes of the Young
MMAS	Morisky Medication Adherence Scale
OGTT	Oral Glucose Tolerance Test
OAs	Oral Anti-diabetic Agents
PVD	Peripheral Vascular Disease

PR	Principal Researcher
REC	Research and Ethics Committee
SMS	Short Message Service
SPSS	Statistical Package for Social Sciences
T2DM	Type 2 Diabetes Mellitus
UK	United Kingdom
USA	United States of America
UKPDS	United Kingdom Prospective Diabetes Study
WHO	World Health Organization

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CHAPTER ONE

1.0 INTRODUCTION

Diabetes mellitus (DM) is a chronic metabolic disorder characterized by chronic hyperglycemia, caused by an absolute or relative insulin deficiency or defective action or both resulting in disorder of carbohydrates, protein and fat metabolism (Alam *et al*., 2014; Ogbonna *et al*., 2005). It is associated with long-term damage, dysfunction and failure of various organs especially the eyes, kidneys, nerves, heart and blood vessels (WHO., 2010). The global burden of diabetes mellitus is enormous and glaring. The impact on health is substantial, yet this disease is assuming an epidemic proportion worldwide, with its global prevalence estimated at about 366 million today, and about 552 million by 2030 (WHO., 2010; Ekpenyong *et al.,* 2012), meaning that the number of people with diabetes is increasing daily and in every country with the highest increase (80%) recorded in low and middle income countries (Alam *et al*., 2014). Currently, China has the highest estimated number of people with diabetes (90.0 million) with the projection to about 129.7 million by 2030 (Ekpenyong *et al.,* 2012). It is predicted that the global prevalence of diabetes will increase by 65% over the next 20 year (Shrestha *et al*., 2013). DM is also an important problem in Africa. In Sub-Saharan Africa, like the rest of the world, diabetes prevalence coupled with both communicable and non-communicable diseases is on the rise (Rwegerera., 2014). According to International Diabetes Federation (IDF), it was estimated that as at 2010, about 12.1 million people were living with diabetes in Africa, and the number is projected to increase to 23.9 million by 2030 (Rwegerera., 2014). In Nigeria, about 1.7million people were affected in 2010, and the figure is expected to rise to 4.8million by 2030 (Nwaokoro *et al.*, 2014). DM causes about 5% of all deaths globally each year (Ekpenyong *et al*., 2012),

which represents 6 deaths attributable to diabetes or related conditions every minute, with 80% of diabetes deaths occurring in low- and middle-income countries (Ekpenyong *et al*., 2012).

Deaths related to diabetes in Nigeria in 2013 were estimated to be 105,091 cases. About two million of the cases of diabetes in Nigeria are undiagnosed (Oputa and Chinyere., 2013). The mainstay of diabetes management is aimed to obtain a good glycemic control and reduce the chronic complications of diabetes and the comorbid diseases such as cardiovascular, cerebrovascular diseases, which are preventable and manageable with proper punctual medication, good regular follow ups and investigations (Brahmbhatt *et al*., 2014).

Adherence is defined as "the extent to which a person's behavior and/or life style changes corresponds with agreed recommendations from a health care provider (Abdulaziz *et al*., 2014; Ogbonna *et al*., 2015). Patient's adherence to prescribed medicine regimen is essential to achieving targeted health outcomes. Medications are one of the most effective methods of prevention, treatment and management of diseases when used correctly (Ogbonna *et al*., 2015). Adherence is an interactive collaborative relationship between the patient and the clinicians/care givers and suggests that patients are involved in treatment planning and implementation unlike compliance which is unilateral and authoritarian and places the patient in a passive role (Ogbonna *et al*., 2015).

1.1 Statement of Research Problem

Understanding how to recognize medication non-adherence to prescribed medication and factors that affect adherence is important in the success of interventions designed to address diabetes which is now a public health problem (Ogbonna *et al*., 2015). Many patients experience

difficulties in adhering to long-term treatment, although patients reasons for not being adherent are diverse, one of the most commonly reported barriers is forgetfulness (Vervloet *et al*., 2012).

Patients often forget or delay their consumption of medication or neglect the instructions of healthcare providers (Huang *et al*., 2013). Non-adherence rates for diabetic therapies are high with estimates ranging from 36% to 93% (Sheikh *et al*.,2014), and averaging only 50% in developing countries such as Nigeria. Failure to attain the desired therapeutic goal might be related to inadequate adherence. Instead of changing the prescription, increasing the drug dosage, or adding a new drug, adherence assessment to the treatment should be considered first in most patients (Sharma *et al., 2014).* Such low medication adherence by various patient groups with chronic diseases has compelled the worldwide medical community to increasingly focus on applying technology to remedy this situation (Huang *et al.,* 2013). Poor adherence compromises the effectiveness of medication treatment and results in suboptimal illness control. This can lead to increased use of healthcare services, reduction in patients quality of life (Vervloet *et al*., 2012). Studies linking glycemic control, hypoglycemic medications, and complications of diabetes have shown that good glycemic control is important in preventing micro vascular complications of this condition (Parsons *et al*., 2014).

1.2 Justification of the Research

For some decades now, patients' adherence to therapeutic regimen has been recognized as a key to the successful delivery of healthcare. Drug treatment relies heavily on the adherence of the patient for self-administration, as patients adherence in ambulatory care is an important link between medical process and treatment outcome (Abdulazeez *et al.,* 2014).

DM is a challenging disease to manage successfully, although the treatment regimen is mostly complex, patients with good diabetes self-care behaviors can attain excellent glycemic control (Alam *et al*., 2006). However, many patients do not achieve good glycemic control and continue to suffer health problems as a result. Diabetes health care providers know that if only their patients adhered to their treatment recommendations, they could do well and avoid diabetes-related complications. The fact that so many patients do not can be very frustrating (Alam *et al*., 2006). As a group, patients with diabetes are especially prone to substantial regimen adherence problems (Alam.,2006). In general, research has shown that the diabetes regimen is multidimensional, and adherence to one regimen component may be unrelated to adherence in other regimen areas. For example, research has shown better adherence for medication use than for lifestyle change (Alam., 2006). DM is a serious condition for an individual and on a global scale. There is rapidly increasing prevalence and as such, patients' adherence to diabetic medication is a great cause for concern (Abdulazeez *et al.*, 2014). In Nigeria, there are sparse and inadequate information on the prevalence of diabetes mellitus. However, available data suggest that the disease is emerging as a major and most challenging health problem in this region (Ekpenyong *et al.*, 2012). This study is the first of its kind in Niger State. Therefore, there is no data that exist currently on medication adherence and use of short message service (SMS) reminders among type 2 DM patients in Niger State. Mobile phone text messaging has rapidly become a socially popular form of communication. It is personal, highly transportable, and widely used, particularly in the Western countries *(*Abbas.*et al*., 2015). However, text messaging coupled with specific management strategies has yet to be utilized effectively in developing countries with high prevalence of diabetes (Abbas *et al.,* 2015).Mobile phone SMS have been shown to be an effective tool for providing diabetes health education, clinic and appointment

reminders, medication reminders and for building awareness about the disease. However, no data on the effects of such an approach on patient outcomes in resource-limited settings are available to date (Islam *et al*., 2014). Numerous interventions aimed at improving adherence have been conducted, but these were mostly complex and not very effective (Haynes *et al.*,2008). An example of a simple intervention is reminding patients of their medication intake. Reminders can especially provide a solution for patients who are unintentionally non-adherent, ie, patients who are willing to take their medication but forget it or are inaccurate with their timing. Forgetfulness is commonly reported as a barrier to adherence in various patient populations (Marcia *et al*., 2012).

1.3 Aim and Objectives

The aim of the study was to assess the medication adherence and evaluate the effect of mobile phone short message service (SMS) reminder on clinical outcome (FBS) among type 2 diabetic patients in a tertiary health facility.

The specific objectives of the study include the following;

I. To assess anti-diabetic drug utilization among type 2 diabetic patients in the facility.
II. To assess medication adherence and to identify potential predictors of adherence.
III. To examine the patients clinical outcome after the intervention.

1.4 Statement of Research Questions

I. What is the level of medication adherence among type 2 diabetic patients?
II. What is the impact of mobile phone short message services (SMS) reminder on clinical outcome (FBS) among these patients?

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Brief Overview

Type 2 DM is a chronic disease characterized by coexisting insulin deficiency and insulin resistance, with the resultant hyperglycemia leading to micro and macro vascular complications (Stratton., 2000; Mohammad and Ahmadi., 2015). Complications include altered metabolism of lipids, carbohydrates, protein and an increased risk of vascular diseases. The diagnosis is based on a single raised glucose reading with symptoms of polyuria, polydipsia, unexplained weight loss and polyphagia (Cameron and Fergus., 2016; Redmon *et al.*, 2014). Other symptoms include recurrent infections, eye symptoms, poor obstetric history, foot sepsis/gangrene, erectile dysfunction etc. It is important to emphasize that blood glucose may be elevated without having the classic symptoms of diabetes mellitus (Redmon *et al.*, 2014). A fasting plasma glucose of ≥7.0mmol/l (≥126mg/dl) or a casual (Random) plasma glucose of ≥11.1 mmol/l (≥ 200mg/dl) or a 2- Hour plasma glucose of ≥11.1mmol/l (≥200mg/dl) during a standard 75 gm oral glucose tolerance test (OGTT) is diagnostic (Cameron and Fergus., 2006).

Type 2 DM is much more common and accounts for around 90% of all diabetes cases worldwide (Alam *et al.*, 2014). It occurs most frequently in adults but is being observed increasingly in adolescents as well. Because of the progressive nature of the disease, an evolving treatment strategy is therefore necessary to maintain both fasting and postprandial glycemic control (Alam *et al*., 2014). Insulin therapies are required when dietary restrictions and lifestyle modifications combined with oral hypoglycemic agents (OHAs) fails to provide acceptable metabolic control (Ibrahim, 2010). United Kingdom Prospective Diabetes Study (UKPDS)

advocates for increasing requirement of multiple therapies in patients with type 2 DM to achieve blood glucose (BG) target control (Alam *et al*., 2014).

2.2 Classification/Types of Diabetes Mellitus

The classification of diabetes includes four clinical classes:

Type 1 Diabetes Mellitus: It is characterized by beta cell destruction caused by an autoimmune process, usually leading to absolute insulin deficiency (Hackett and Jacques., 2009). The onset is usually acute, developing over a period of a few days to weeks. Over 95 percent of persons with type 1 DM develop the disease before the age of 25, with an equal incidence in both sexes and an increased prevalence in the white population (Ekpenyong *et al.*, 2012). Most cases have the "immune-mediated form" of type 1 DM, with islet cell antibodies and often have other autoimmune disorders such as Hashimoto's thyroiditis, Addison's disease, vitiligo or pernicious anemia (Redmon *et al*., 2014; Camreon and Fergus., 2016). A few patients, usually those of African or Asian origin, have no antibodies but have a similar clinical presentation; consequently, they are included in this classification and their disease is called the "idiopathic form" of type 1 DM (Cameron and Fergus., 2006).

Type 2 diabetes mellitus: It is characterized by insulin resistance in peripheral tissues and an insulin secretory defect of the beta cell (Hackett and Jacques., 2009). This is the most common form of DM and is highly associated with a family history of diabetes, older age, obesity and lack of exercise. It is more common in women, especially women with a history of gestational diabetes, and in blacks, Hispanics and Native Americans (Mohammad and Ahmadi., 2015). Insulin resistance and hyperinsulinemia eventually lead to impaired glucose tolerance. Defective

beta cells become exhausted, further fueling the cycle of glucose intolerance and hyperglycemia (Kelly., 2000). The etiology of type 2 DM is multifactorial and genetically based, but it also has strong behavioral components. In Nigeria it constitutes about 96% of diabetic patients (Alexander., 2012).

Other Specific Types of Diabetes: These include diabetes due to various known etiologies. This group includes persons with genetic defects of beta-cell function (This type of diabetes was formerly called MODY or maturity-onset diabetes in young) or with defects of insulin action (Hackett and Jacques., 2009). Persons with diseases of the exocrine pancreas, such as pancreatitis or cystic fibrosis; persons with dysfunction associated with other endocrinopathies (e.g., acromegaly); and persons with pancreatic dysfunction caused by drugs, chemicals or infections, and drug or chemical-induced (such as in the treatment of AIDS or after organ transplantation). Malnutrition Related Diabetes Mellitus (MRDM) which is specific to the tropics and developing world (Nigeria inclusive) is a member of this class (Cameron and Fergus., 2016).

Gestational DM : GDM is defined as any degree of glucose intolerance that was first recognized during pregnancy, regardless of whether the condition may have predated the pregnancy or persisted after the pregnancy (Rittenhouse *et al*., 2009; Cameron and Fergus., 2016).

2.3 Type 2 Diabetes Mellitus

Type 2 diabetes mellitus is a chronic disorder that results from the combination of insulin resistance and insulin secretory defect. It is the commonest form of DM and constitutes >95% of the diabetic population in Nigeria (Adisa *et al*., 2009; Ogbonna *et al*., 2015). Although type 2 DM typically affects individuals older than 40 years, it has been diagnosed in children and

adolescents and this emerging scenario is the result of the epidemic of obesity and inactivity in children. The diagnosis of DM is readily entertained when a patient presents with classic symptoms of polyuria, polydipsia, polyphagia, and blurring of vision; however, as many as 50% of patients with type 2 DM are asymptomatic (Mohammad and Ahmadi., 2015), and their disease remains undiagnosed for many years (Redmon *et al*., 2014). The epidemic of type 2 DM has become a major concern because it affects all age groups. The incidence of diabetes was estimated to have risen by 55% between 1995 and 2010 (Ekpenyong *et al*., 2012). The global figure is set to rise from 220 million in 2010 to 300 million in 2025, further demonstrating the large impact of type 2 DM on the growing population (Nwaokoro *et al*., 2014). It is not surprising that type 2 DM is, at present, one of the most prevalent chronic diseases. Interestingly, it is strongly associated with obesity and a sedentary lifestyle, thus, lifestyle modification is an important step in addressing this issue. However, controlling blood glucose through lifestyle modification alone is a challenging feat; therefore, a more rapid method of controlling blood glucose is required. The use of medication is thus vital in the management of type 2 DM. However, the effectiveness of the treatment is largely dependent on the level of adherence toward prescribed medication (Shaimol *et al*., 2014).

Type 2 DM is typically a chronic disease associated with a ten-year-shorter life expectancy (Mohammad and Ahmadi., 2015). This is partly due to a number of complications with which it is associated, including: two to four times the risk of cardiovascular disease, including ischemic heart disease and stroke; a 20-fold increase in lower limb amputations, and increased rates of hospitalizations (Mohammad and Ahmadi., 2015). In the developed world, and increasingly elsewhere, type 2 DM is the largest cause of non-traumatic blindness and kidney failure (Ripsin *et al*., 2009; Mohammed and Ahmadi., 2015). It has also been associated with an increased risk

of cognitive dysfunction and dementia through disease processes such as Alzheimer's disease and vascular dementia (Ripsin *et al*., 2009; Faraz *et al*., 2015). Other complications include Acanthosis Nigricans, sexual dysfunction, and frequent infections. Short-term complications of type 2 DM are hypoglycemia (very low blood glucose), diabetic ketoacidosis (DKA) and hyperosmolar hyperglycemic non-ketotic syndrome (HHNS), which is very high blood glucose (Fowler and Micheal., 2008). Long-term complications of type 2 DM are diabetic retinopathy, kidney disease (nephropathy), diabetic neuropathy, and macro vascular problems (Fowler and Micheal., 2008). Long-term complication develops over many years and they all relate to how blood glucose levels can affect blood vessels. Over time high blood glucose can damage the body's blood vessels, both tiny and large. Damage to tiny blood vessels causes micro vascular complications; damage to large vessels causes macro vascular complications (Mohammad and Ahmadi., 2015; Faraz *et al*., 2015).

2.4 Classical Signs and Symptoms of Type 2 Diabetes Mellitus

The signs and symptoms of type 2 DM are the same as type 1 DM but differs in their onset, with type 2 DM having slower or gradual onset. These symptoms include; Polyuria, polydipsia, excessive weight loss despite increase in appetite, fatigue, generalized pruritus, vaginitis symptoms due to candida infection (most complaint by women having type 2 DM), retinopathy, foot ulcer as a result of combination of neuropathy, peripheral vascular diseases and infection, occasionally, diabetic ketoacidosis.

2.5 Screening and Testing for Diabetes Mellitus

Several literatures recommend screening patients who are at increased risk for diabetes (Redmon *et al*., 2014; Cameron and Fergus., 2016). Risk factors for type 2 DM include; age of 45 years or older, overweight or obesity (BMI ≥ 25), First-degree relative with diabetes, Polycystic ovarian syndrome (in women), Certain racial/ethnic backgrounds, including African American, American Indians/Alaska Natives, Asian American, Hispanic/Latino, and Native Hawaiian/Pacific Islander (WHO., 2004). It is reasonable to have a higher clinical index of suspicion in adults with multiple risk factors and to use clinical judgment or shared decision making about whether to screen these individuals for type 2 DM. If the decision is to screen, consider a frequency of every 3 years using either fasting plasma glucose or HbA1c (WHO., 2004; Cameron and Fergus., 2016). Screening tests are followed by diagnostic tests in order to make the diagnosis. Combined screening strategies have sensitivity and specificity in the order of 75%, and 25% (Hackett and Jacques., 2009). People who screen negative should be re-tested after 3-5 years (WHO., 2004). These people should also be offered lifestyle advice to minimize their risk of developing diabetes. Although the usefulness of urine glucose as a screening test for undiagnosed diabetes is limited because of low sensitivity (21-64%), specificity is high (> 98%), so it may have a place in low-resource settings where other procedures are not available (Faraz *et al*., 2015). Following a positive screening test, diagnostic testing is required.

2.6 Treatment of Type 2 Diabetes Mellitus

Management of type 2 DM focuses on lifestyle interventions such as self-management education, nutrition, physical activity, smoking cessation, psychosocial care, lowering cardiovascular risk factors, and maintaining blood glucose levels in the normal range (Ripsin *et*

al., 2009; Ibrahim., 2010). Early initiation of pharmacologic therapy is associated with improved glycemic control and reduced long-term complications in type 2 DM (Ibrahim., 2010). Drug classes used for the treatment of type 2 DM include the following: Biguanides such as metformin, Sulfonylureas e.g, glibenclamide, glyburide, glipizide, glimepiride, Meglitinide derivatives (e.g, repaglinide, nateglinide), Alpha-glucosidase inhibitors e.g acarbose, meglitol, Thiazolidinediones (TZDs) (e.g, pioglitazone [Actos], rosiglitazone [Avandia]), Glucagon-like peptide–1 (GLP-1) agonists (i.e, exenatide, liraglutide, albiglutide, dulaglutide), Dipeptidyl peptidase IV (DPP-4) inhibitors (e.g, sitagliptin, saxagliptin, linagliptin), Selective sodium-glucose transporter-2 (SGLT-2) inhibitors. e.g; Canagliflozin, empagliflozin, dapagliflozin, Insulins, Amylinomimetics e.g Pramlintide acetate, Bile acid sequestrants e.g Colesevelam, Dopamine agonists e.g bromocriptin emesylate (Cycloset) (Ibrahim., 2010).

2.7 Complications of Type 2 Diabetes Mellitus

Since type 2 DM is not usually diagnosed early, most patients will have already developed complications by the time it is diagnosed (Fowler and Micheal., 2008; Ibrahim., 2010). However, diabetic complications can be limited and sometimes prevented, if the condition is managed well from an early stage. Hyperglycemia and hypertension are the two major factors that influence their development (Fowler and Micheal., 2008). The complications of diabetes are divided into those of macro and micro vascular nature. Macro vascular complications arise from damage to large blood vessels, whereas micro vascular complications result from damage to smaller vessels (Adibe *et al.,* 2009). The precise cause is not fully understood but hyperglycemia and atherosclerosis are major contributing factors (Hackett and Jacques., 2009; Mohammad and Ahmadi., 2015).

2.8 Macro vascular Complications

The risk of macro vascular complications, such as cardiovascular disease (CVD) and peripheral vascular disease (PVD), is two to four times higher for diabetic patients than for people without diabetes (Fowler and Micheal., 2008).

Cardiovascular disease; CVD is the most common cause of mortality among type 2 DM patients, causing an estimated 80% of all deaths (Fowler and Micheal., 2008). Diabetes increases a patient's risk for myocardial infarction (MI) to the same extent as does a history of MI itself. The presence of diabetic nephropathy (a micro vascular complication) increases the risk of CVD further. Silent MI (i.e, with the absence of classic symptoms) is more common in those with diabetes than those without, possibly because diabetic patients are more likely to have damage to cardiac nerves (namely, cardiac autonomic neuropathy). Cerebrovascular disease is also more common among people with diabetes than among those without. Furthermore, diabetic patients are at a greater risk of mortality and morbidity post-stroke (Cochran and Conn., 2010).

Hypertension; Hypertension affects 80% of people with type 2 DM which is double the rate seen for the general population (Akinlua *et al.*, 2015).

Peripheral vascular disease; PVD encompasses all diseases caused by occlusion of the major blood vessels outside the heart. It often affects the arteries of the legs and may give rise to painful ischemia, otherwise known as intermittent claudication. People with PVD are at an increased risk of developing CVD (Mweene *et al*., 2010).

2.9 Micro vascular Complications

Micro vascular complications occur as a result of atherosclerosis and damage of the finer blood vessels, thought to be due to the toxic effects of hyperglycemia (Ripsin *et al*., 2009). Damage to these smaller vessels often occurs due to the formation of micro emboli or vessels leaking, particularly in the eye and kidney (Faraz *et al*., 2015).

Retinopathy; Diabetic retinopathy is the leading cause of blindness in people under 60 years of age in industrialized countries (Fowler and Micheal., 2008). Over 60% of patients with type 2 DM develop diabetic retinopathy within 20 years of diagnosis. Retinopathy is difficult to diagnose since it is asymptomatic until it becomes advanced (Faraz *et al*., 2015). The UKPDS showed that tight glycemic control and tight blood pressure control reduces the risk of developing retinopathy for those with type 2 DM (Hackett and Jacques., 2009).

Nephropathy; Diabetic nephropathy is identified by detecting micro albuminuria (an albumin creatinine ratio [ACR] in the urine of ≥2.5mg/mmol for men or ≥3.5mg/mmol for women). If larger amounts of albumin are detected (ACR >30mg/mmol or urine albumin concentration >200mg/L) this constitutes proteinuria and signifies more severe renal damage. Proteinuria can progress to end-stage renal disease, which may require renal dialysis (Fowler and Micheal.,2008; Hackett and Jacques, 2009).

Peripheral Neuropathy; Peripheral neuropathy describes nerve dysfunction caused by the progressive loss of peripheral nerve fibers. There are many types of diabetic neuropathy, each causing different sensory, motor and autonomic symptoms. Distal sensory neuropathy, particularly evident in the feet, is the most common. It usually causes patients to lose the

sensation of vibration and can progress to complete loss of feeling (Giles et al., 2009). Painful diabetic neuropathy, which can be highly disabling, is another neuropathic complication. Autonomic neuropathy can affect any part of the sympathetic or parasympathetic nervous systems. Its most frequent manifestation is erectile dysfunction (also known as diabetic impotence) (Ibrahim, 2010). Others include gastroparesis which can delay gastrointestinal transit (thus causing erratic food absorption) and cause vomiting. Both of these effects create difficulty in controlling blood glucose for those treated with insulin. Autonomic neuropathy can also cause dry skin and lack of sweating, which can both contribute to development of diabetic foot problems (Fowler and Micheal., 2008).

Foot problems; Diabetic foot problems arise from a combination of macro and micro vascular complications. They are costly, often requiring lengthy hospital admission, and are associated with an increased risk of morbidity. Infected diabetic foot ulcers account for more diabetes-related hospital bed-days than any other complication and are the second most common reason for amputation (after trauma). Lower- limb amputation is 15 times more likely among diabetic patients than among the general population (Jemal *et al*., 2017).

2.1.0 Factors Associated with Medication Adherence

Medication non-adherence is a common clinical problem which is associated with sub-optimal clinical outcomes and increased health-care burden (Vervloet *et al*., 2012). Several chronic disorders including diabetes mellitus, hypertension, schizophrenia, and bipolar disorder are associated with medication non-adherence, which leads to poorer clinical outcomes and exacerbated complications of the disorder. The causes of non- adherence to medications can be manifold including those which are patient related and health-care system related (Sarkar et al.,

2015). Previously, numerous studies have explored potential risk factors of non-adherence to medicines across a variety of conditions (Bagonza *et al.,* 2015; Shaimol *et al*., 2014). Frequently cited risk factors include age, sex, ethnicity, income, education, and co- morbidity, though their relationship to adherence has been inconsistent due to variations in study designs and sample populations (Bagonza *et al.*, 2015). Medication related side effects are also associated with non-adherence. A study done in Uganda in an urban hospital indicated long time interval to a facility visit, patients not understanding the drug regimen and inability to afford the cost of the drugs as associated with non-adherence (Bagonza *et al.*, 2015). Use of a diet plan and being told how to control diet are also associated with adherence. Other proposed reasons for non-adherence to oral medication regimens include forgetfulness and spontaneous activities due to a lack of self-discipline, limited intelligence, or fearless attitude towards the consequences of diabetes (Shrestha *et al.*, 2013). Only 37.7% of the patients treated with OHAs have improved glycemic control. Once the prescription is written, however, the fate of drug therapy is with the patient. For such chronic medical conditions, a wide and persistent separation exists between evidence-based recommendations and the actual care patients receive. Reasons for this gap are not always clear, however, lack of persistence with adherence to prescribed treatments is a critical part of the gap (Shrestha *et al.*, 2013).

2.1.1 Importance of Short Message Service (SMS) in Medication Adherence

Access to mobile technology has grown rapidly in the last two decades and is increasingly being used in the health care sector for a variety of purpose (Sarkar *et al*., 2015). Mobile technology has seen many applications in the clinical setting including promoting medication adherence. Medication adherence can be increased using SMS, voice reminders and special applications

("apps") to remind patient to take medications (West *et al.*, 2012; Sarkar *et al*., 2015). Out of these, SMS reminders are probably the least intrusive to the patient privacy and can be delivered through simpler mobile phones, enabling potential access to a larger number of clients (Huang *et al*., 2013). Hence, SMS reminders offer a promising method of promoting medication adherence among patients, especially those who suffer from chronic conditions and are required to take medications for a long period of time (Sarkar., 2015). Treatment as usual or standard care was the most common control group in most of the studies (Sarabi *et al*., 2016; Van olman *et al.*, 2015). Efficacy of the SMS intervention had been evaluated in a variety of ways, though self-reported adherence was the most common method of representing the outcomes (West *et al.*, 2012). The efficacy of SMS reminders was largely positive, though a study did not find SMS reminders more effective than the control group (Sarkar *et al*., 2015).

CHAPTER THREE

3.0 MATERIALS AND METHOD

3.1 Materials

Materials used in the study include Morisky Adherence scale, mobile phones, charts, pens, patient's hospital folders, and laboratory test request forms. All study participants are patients attending the diabetes clinic.

3.2 Study Setting

The study was carried out at the Ibrahim Badamasi Babangida Specialist Hospital (IBBSH) Minna Niger State. The hospital is located at km 10 Paiko road, Chanchaga Minna. The Centre is a hundred (100) bedded tertiary (referral) hospital and has several departments including surgery, gynecology, orthopedic, endocrinology, nephrology, ENT, outpatient, pharmaceutical and nursing services.

3.3 Research Design

The study was a prospective intervention study with a control arm, comparing standard-of-care (medication therapy only) with standard-of-care plus a mobile phone-based SMS intervention carried out between August and December 2016. The endocrinology clinic attends directly to in and out patients and those who are being referred from other hospitals within and neighboring states.

3.3.1 Sampling

Simple random sampling method was employed to recruit patients. A pharmacist other than the principal researcher (PR) picked out cards (labeled I= intervention and C= control) sealed in an envelope. Each of the cards carry codes (e.g 001I, 002C, O12I) which are recorded on each patients questionnaire as soon as it was picked. The sample size was completed in two months (August to September 2016).

3.3.2 Sample size

423 participants were sampled in this study, with 30 opting out by either not giving their informed consent, referred out of the facility or giving incomplete information. This sample size was arrived at using Fisher's formula.

$$n = \frac{z^2 pq}{d^2}$$

Where,

N =Sample size,

Z = Critical value associated with significance level of 0.05, taken as 1.96 for a 95% confidence interval.

P = Estimated proportion of medication adherence by diabetic patients assumed to be=0.5

q = Estimated proportion of medication non-adherence amongst diabetes patients assumed to be=0.5 (1.0-p)

d = Acceptable degree of accuracy required taken as 0.05

$$n = \frac{1.96 \times 1.96 \times 0.5 \times 0.5}{0.0025}$$

N = 384. Adding 10% for non-response = 384 + 38 = 423

Sample size = 423.

A Pilot Testing was performed on some participants (approximately 10% of the intended sample size) before commencement of the study. These participants were excluded from the final study sample. This allowed testing the intervention for smooth application, identifying eligibility criteria and the feasibility of achieving sample size. The data collection tool was assessed for flow of questions and comprehensiveness. The intervention was also assessed for practicality relating to delivery, accuracy, timeliness, comprehension and satisfaction.

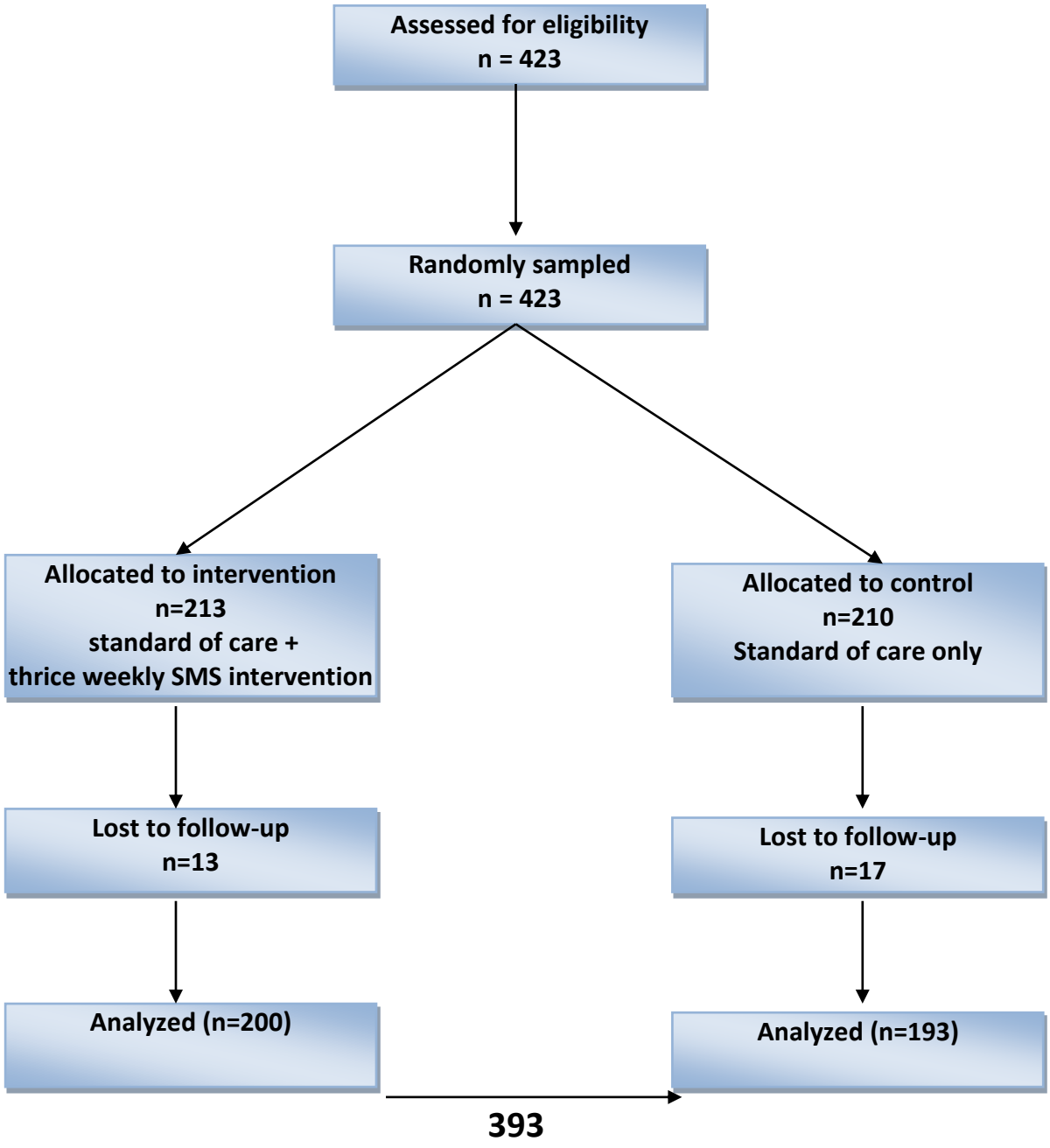


Figure I: Flow Chart and Recruitment Strategy

Reasons for lost to follow up include transfer to other health centers, relocation of participant, absenteeism from clinic appointments and inability to pay for cost of services. After participants signed and submitted informed consent forms attached to the Morisky questionnaire, they were randomly selection to receive the standard care (medication therapy) or mobile phone SMS interventions plus standard care (medication therapy). The endocrine clinics hold twice weekly Mondays and Thursdays, with about 30 to 35 type 2 DM patients in attendance. The study was able to recruit about 30 participants on every clinic day and few others on other days of the week. This was done continuously for two months (August to September 2016). Phone numbers were collected at the point of submitting the Morisky questionnaires, as well as their hospital numbers for follow up. Medication reminders were sent to participants for three months (October to December 2016) by using the SMS system; text messages were sent only to participants in the intervention group without participants choosing the time SMS were sent (Huang *et al*., 2013). The SMS content was developed to ensure that all the participants in the research can read the SMS messages by themselves or have someone in the family who can describe the messages to them if they do not understand. The first SMS depend on participants' medication and frequency of medication use which was obtained from submitted questionnaires.

For example, "A warm reminder; i would like to remind you to take your drugs, which includes metformin 500mg® and glimepiride 2mg®, I wish you a quick recovery."

The second and subsequent SMS contained only simple medication adherence reminders. The SMS was sent to participants at least three times a week, on Mondays, Wednesdays, and Fridays (Vervloet *et al*., 2012). The patients were encouraged to send messages/call the study team for any replies to the text messages. Study team maintained a study register to record all SMS responses and other mobile phone communications with participants.

A baseline fasting blood sugar (FBS) was recorded for all participants before the intervention. Subsequently, FBS levels were again recorded for both the intervention group that received SMS and the control group at first, second and third months respectively. The post intervention FBS readings were compared to the baseline.

3.4 Data Collection

Morisky Medication Adherence Scale (MMAS)

Assessment of medication adherence was based on the self-reported Morisky 8-item Medication Adherence Scale (MMAS) which was administered to both the intervention and control groups. Adherence level score was calculated and a score of 8 was considered good/high adherence while a score of 6 to 7 and 0 to <6 were considered fair/poor adherence and non-adherence respectively. A structured questionnaire was used to assess patient's socio-demographic details like age, sex, marital status, education level, occupation level, medication therapy such as duration of DM, type of medicines prescribed, and ability to pay for medication etc. and information on the patient's mobile phone use and habits.

Fasting Blood Sugar Level (FBS)

Fasting blood sugar readings were recorded on a designed FBS chart. Values recorded are baseline and post-test for the two groups.

3.5 Data Analysis

The collected data was categorized, coded and analyzed using Statistical Package for Social Sciences (SPSS) version 20 (SPSS Inc, Chicago, Illinois, USA). Chi-square test was used to ascertain associations between adherence to diabetic medication and patient related, medication

related and disease related factors. Paired t-test was used to compare baseline and post intervention FBS levels. A p-value of less than 0.05 was considered statistically significant for this study.

3.6 Inclusion Criteria

Participants recruited for the study were those;

1. Diagnosed with type 2 diabetes mellitus with or without comorbidity.
2. Who were currently using anti-diabetic medication.
3. Who had a personal mobile phone and could retrieve/read and send SMS.

3.7 Exclusion Criteria

Participants excluded from the study included;

1. Those that were pre-diabetic or have other forms of diabetes.
2. Those currently not using any anti-diabetic medication.
3. Those who did not have a personal mobile phone and could not retrieve/read and send SMS.

3.8 Ethical Consideration

The study was approved by the research and ethics committee (REC) of IBB Specialist Hospital Minna, (IBBSH/SUB/654/VOL.1/04) after proper review of the research proposal (Appendix 2).

CHAPTER FOUR

4.0 RESULTS

4.1 Socio-demographic Characteristics of Participants

Out of the 423 questionnaires that was administered (213 for intervention and 210 for control), only 393 were correctly filled and returned (200 for intervention and 193 for control) which was about 93% response rate. Majority of the participants were females 228 (58%) as compared to males 165 (42%) the mean age of participants was 54years ± 13years and most of them fell within the age category 50-59years 166 (42.2%). Also 189 (48.1%) of the participants were married, while only 26 (6.6%) were single. Most of the participants had tertiary education 139 (35.4%) compared to 115 (29.3%), 108 (27.5%), 31 (7.9%) for primary, secondary and no formal education. In terms of employment status, most of the participants were self- employed 124 (31.6%). Details are shown in table 1.

Table 4.1: Socio-Demographic Characteristics of Participants

Demographic Characteristics	Intervention n (%) 200	Control n (%) 193	Total n (%)
Gender			
Male	80(40)	85(44)	165(42)
Female	120(60)	108(56)	228(58)
Age			
20-29	4(2)	27(14)	31(7.9)
30-39	31(15.5)	27(14)	58(14.8)
40-49	32(16)	31(16)	63(16)
50-59	99(49.5)	67(34.7)	166(42.2)
60 Above	34(17)	41(21.3)	75(19.1)
Marital Status			
Single	-(-)	26(13.5)	26(6.6)
Married	103(51.5)	86(44.6)	189(48.1)
Widowed	33(16.5)	33(17.1)	66(16.8)
Separate	64(32)	48(24.9)	112(28.5)
Education Status			
Primary	59(29.5)	56(29)	115(29.3)
Secondary	49(24.5)	59(30.6)	108 (27.5)
Tertiary	92(46)	47(24.4)	139 (35.4)
No Education	-	31(16)	31 (7.9)
Employment Status			
Farming	-	20(10.4)	20(5.1)
Trading	69(34.5)	54(28)	123(31.3)
Self-employed	76(38)	48(24.9)	124(31.6)
Public sector	55(27.5)	33(17.1)	88(22.4)
Private sector	-	19(9.8)	19(4.8)
Unemployed	-	11(5.7)	11(2.8)
Retired	-	8(4.1)	8(2)

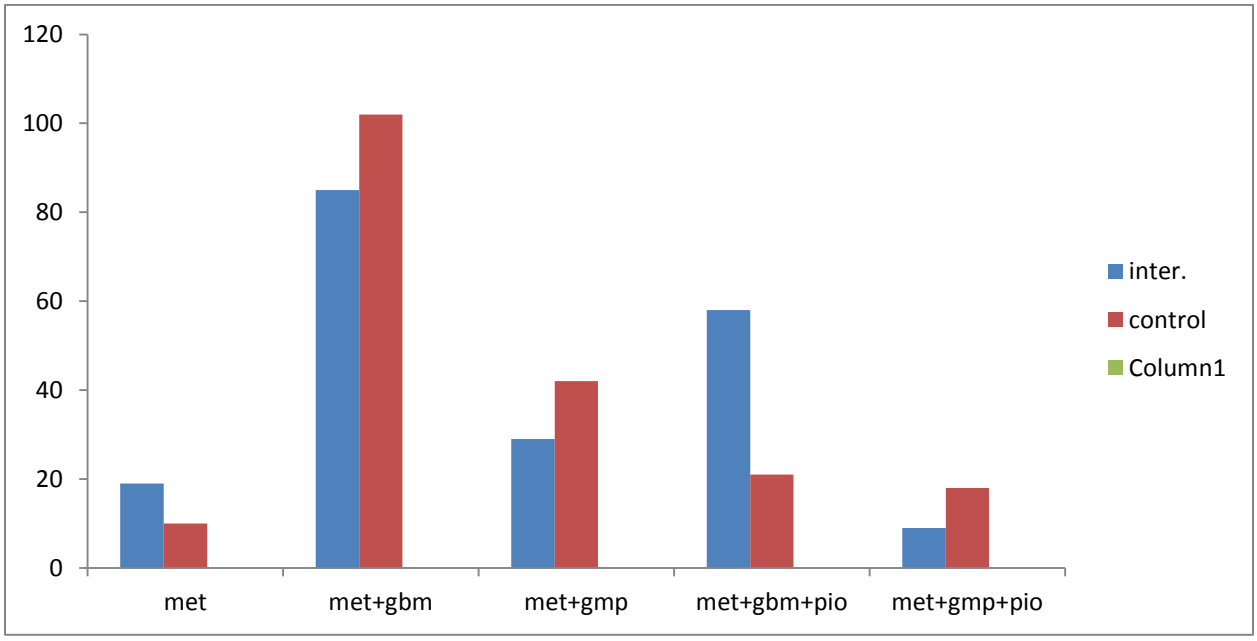
n=Frequency

4.2 Association of Adherence Between The Control and Intervention Groups

Most of the participants were non- adherent (74.1%) for control and (74.5%) for participants in the intervention group as compared to good adherence (15%) for the two groups. Also, 10.9% and 10.5% of the participants showed poor adherence in the control and intervention groups respectively. The results showed no statistical significance association between medication adherence among the control and intervention groups.

Table 4.2: Association of Adherence Between the Control and Intervention groups

ADHERENCE CATEGORY	CONTROL (%) 193 (100)	INTERVENTION (%) 200 (100)	TOTAL (%) 393 (100)	P-VALUE
Good Adherence (8)	29 (15.0)	30 (15.0)	59 (15.0)	0.631
Poor Adherence (6 to 7)	21 (10.9)	21 (10.5)	42 (10.7)	0.786
Non Adherence (0 to < 6)	143 (74.1)	149 (74.5)	292 (74.3)	0.817



MET-metformin, GBM-glibenclamide, GMP-glimeperide, PIO-pioglitazone
Figure II: Anti-diabetic Drug Utilization in IBBSH.

4.3 Anti-diabetic Drug Utilization

From figure 2 above, metformin plus glibenclamide combination was the most prescribed anti-diabetic regimen in both the control 102(52.9%) and intervention 85(42.5%) groups as compared to metformin alone 19(9.5%) in the intervention group and metformin-glimepiride-pioglitazone 18(9.3%) combination in the control group.

4.4 Factors Associated with Patient Adherence (Intervention)

Table 4.3 shows that there was statistical significant association between age and employment status and medication adherence ($p < 0.05$) in the intervention. Other factors such as gender, marital status and educational status were not associated with medication adherence ($p > 0.05$).

Table 4.3: Factors Associated with Patient Adherence (Intervention)

Variables	Frequency (%)				Mean	P
	GA 30(15.0)	PA 21(10.5)	NA 149(74.5)	Total 200(100)		
Gender						
Male	10(5.0)	9(4.5)	61(30.5)	80(40.0)	1.600	0.507
Female	20(10.0)	12(6.0)	88(44.0)	120(60.0)		
Age (yrs.)						
20-29	1(0.5)	0(0.0)	3(1.5)	4(2.0)	3.640	0.033*
30-39	3(1.5)	1(0.5)	27(13.5)	31(15.5)		
40-49	1(0.5)	1(0.5)	30(15.0)	32(16.0)		
50-59	19(9.5)	15(7.5)	65(32.5)	99(49.5)		
60 Above	6(3.0)	4(2.0)	24(12.0)	34(17.0)		
Marital Status						
Married	17(8.5)	9(4.5)	77(38.5)	103(51.5)	2.805	0.848
Widowed	4(2.0)	1(0.5)	28(14.0)	33(16.5)		
Separated	9(4.5)	11(5.5)	44(22.0)	64(32.0)		
Edu. Status						
Primary	4(2.0)	4(2.0)	51(25.5)	59(29.5)	2.165	0.061
Secondary	10(5.0)	7(3.5)	32(16.0)	49(24.5)		
Tertiary	16(8.0)	10(5.0)	66(33.0)	92(46.0)		
No Formal Edu.	0	0	0	0		
Emp. Status						
Farming	0(0)	0(0)	0(0.0)	0(0.0)	2.930	0.002*
Trading	8(4.0)	3(1.5)	58(29.0)	69(34.5)		
Self- Employed	10(5.0)	11(5.5)	55(27.5)	76(38.0)		
Public sector	12(6.0)	7(3.5)	36(18.0)	55(27.5)		

Table 4.4: Medication- and Disease- Related Factors Associated with Adherence (Intervention)

Variables	Frequency (%)				Mean	P
	GA 30(15.0)	PA 21(10.5)	NA 149(74.5)	Total 200(100)		
Dod (yrs.)						
1-5	2(1.0)	4(2.0)	11(5.5)	17(8.5)		
6-10	8(4.0)	5(2.5)	76(38.0)	89(44.5)		
11-15	9(4.5)	6(3.0)	47(23.5)	62(31.0)	2.7358	0.002*
16- 20	8(4.0)	3(1.5)	8(4.0)	19(9.5)		
21-25	3(1.5)	3(1.5)	7(3.5)	13(6.5)		
Type of Medication						
Met	8(4.0)	4(2.0)	7(3.5)	19(9.5)		
Met + Gbm	16(8.0)	7(3.5)	62(31.0)	85(42.5)		
Met + Gmp	3(1.5)	6(3.0)	20(10.0)	29(14.5)		
Met + Gbm + Pio	1(0.5)	1(0.5)	56(28.0)	58(29.0)	2.6632	0.028*
Met + Gmp + pio	2(1.0)	3(1.5)	4(2.0)	9(4.5)		
Comorbidity						
Hypertension	23(11.5)	17(8.5)	86(43.0)	126(63.0)		
Arthritis	7(3.5)	3(1.5)	22(11.0)	32(16.0)		
Asthma	0(0.0)	1(0.5)	8(4.0)	9(4.5)		
Dyslipidemia	0(0.0)	0(0.0)	9(4.5)	9(4.5)	2.4S870	0.001**
Hyperthyroidism	0(0.0)	0(0.0)	12(6.0)	12(6.0)		
Hypertension +Arthritis	0(0.0)	0(0.0)	6(3.0)	6(3.0)		
Hypertension + Dyslipidemia	0(0.0)	0(0.0)	6(3.0)	6(3.0)		
Ability to Pay(Cost)						
No	2(1.0)	4(2.0)	8(4.0)	14(7.0)	1.000	0.002**
Yes	28(14.0)	17(8.5)	141(70.5)	186(93.0)		
Side Effect						
Yes	17(8.5)	11(5.5)	59(29.5)	87(43.5)	1.000	0.063
No	13(6.5)	10(5.0)	89(44.5)	112(56.5)		

*GA-Good Adherence, PA-Poor Adherence, NA-Non Adherence, Chi Square * indicates significance. Met-metformin, Gbm-glibenclamide, Gmp-glimepiride, Pio-pioglitazone, Dod-Duration of Diabetes,*

4.5 Medication-and Disease-Related Factors Associated with Adherence (intervention)

From table 4.4, duration of diabetes, type of medication, co-morbidity and cost of medication were significantly associated with medication adherence ($p < 0.05$), while side effect of medication was not associated with medication adherence ($p > 0.05$).

Table 4.5: Factors Associated with Patients Adherence (Control Group)

Variables	GA 29(15.0)	PA 21(10.9)	NA 143(74.1)	Total 193(100)	Mean	P
Gender						
Male	12(6.2)	4(2.1)	69(35.3)	85(45.0)	1.56	0.986
Female	17(8.8)	17(8.8)	74(38.3)	108(55.0)		
Age (yrs.)						
20-29	2(1.0)	2(1.0)	23(11.9)	27(7.9)	3.35	0.033*
30-39	5(2.6)	2(1.0)	20(10.4)	27(14.8)		
40-49	5(2.6)	4(2.1)	22(11.4)	31(16)		
50-59	12(6.2)	8(4.1)	47(24.4)	67(42.2)		
60 Above	5(2.6)	5(2.6)	31(16.1)	41(19.1)		
Marital Status						
Single	3(1.6)	6(3.1)	17(8.8)	26(13.5)	2.5337	0.228
Married	14(7.3)	13(6.7)	59(30.7)	86(44.6)		
Widowed	6(3.1)	1(0.5)	29(15.0)	33(17.0)		
Separated	6(3.1)	5(2.3)	37(19.2)	48(24.9)		
Edu. Status						
Primary	7(3.6)	6(3.1)	43(22.3)	56(29.0)	2.2746	0.495
Secondary	5(2.6)	4(2.1)	50(25.9)	59(30.6)		
Tertiary	8(4.1)	5(2.3)	34(17.6)	47(24.4)		
No Formal Edu.	9(4.7)	6(3.1)	16(8.3)	31(16.0)		
Emp. Status						
Farming	5(2.6)	3(1.6)	12(6.2)	20(10.4)	3.2176	0.01*
Trading	7(3.6)	5(2.6)	42(21.8)	54(28.0)		
Self- Employed	4(2.1)	5(2.6)	39(19.7)	48(24.9)		
Public sector	4(2.1)	2(1.0)	27(14.0)	33(17.1)		
Private Sector	4(2.1)	2(1.0)	13(6.7)	19(9.8)		
Unemployed	3(1.6)	3(1.6)	5(2.6)	11(5.7)		
Retired	2(1.0)	1(0.5)	5(2.6)	8(4.1)		

*GA-Good Adherence, PA-Poor Adherence, NA-Non Adherence, Chi Square * indicate Significance*

4.6 Factors Associated with Patients Adherence (Control Group)

Table 4.5 shows that age and employment status, were significantly associated with medication adherence *($p < 0.05$).* Other factors such as gender, marital status and educational status were not associated with medication adherence *($p > 0.05$).*

Table 4.6: Medication- and Disease- Related Factors Association with Adherence (Control)

Variables	GA 29(15.0)	PA 21(10.9)	NA 143(74.1)	Total 193(100)	Mean	P
Dod (yrs.)						
1-5	3(1.6)	1(0.5)	4(2.1)	8(4.15)		
6-10	7(3.6)	8(4.1)	64(33.2)	79(40.9)		
11-15	12(6.2)	8(4.1)	55(28.5)	75(38.9)	2.610	0.002*
16- 20	5(2.6)	1(0.5)	12(6.2)	18(9.3)		
21-25	2(1.0)	3(1.6)	8(4.1)	13(6.7)		
Type of Medication						
Met	0(0.0)	0(.00)	10(5.2)	10(5.2)		
Met + Gbm	17(8.8)	15(7.8)	70(36.3)	102(52.9)		
Met + Gmp	8(4.1)	4(2.1)	30(15.5)	42(21.8)		
Met + Gbm + Pio	1(0.5)	2(1.0)	18(9.3)	21(10.9)	2.765	0.001**
Met + Gmp + pio	3(1.6)	0(0)	15(7.8)	18(9.3)		
Comorbidity						
Hypertension	13(6.7)	13(6.7)	71(36.8)	97(50.3)		
Arthritis	3(1.6)	3(1.6)	24(12.4)	30(15.5)		
Asthma	4(2.1)	0(0.0)	9(4.7)	13(6.7)	1.955	0.001**
Dyslipidemia	3(1.6)	0(0.0)	17(8.8)	20(10.4)		
Hyperthyroidism	1(0.5)	2(1.0)	5(2.6)	8(4.2)		
Hypertension +Arthritis	2(1.0)	1(0.5)	8(4.2)	11(5.7)		
Hypertension + Dyslipidemia	3(1.6)	2(1.04)	9(4.7)	14(7.3)		
Ability to Pay(Cost)						
No	12(6.2)	7(3.6)	27(14.0)	43(22.3)	0.621	0.025*
Yes	17(8.8)	18(9.3)	115(59.6)	150(77.7)		
Side Effect						
Yes	11(5.7)	13(6.7)	50(25.9)	73(37.8)	1.798	0.224
No	18(9.3)	12(6.2)	93(48.1)	120(62.2)		

Met-metformin, gbm-glibenclamide, gmp-glimepiride,pio-pioglitazone, Dod-Duration of Diabetes, GA-Good Adherence, PA-Poor Adherence, NA-Non Adherence,

4.7 Medication- and Disease- Related Factors Association with Adherence (Control Group)

From table 4.6, duration of diabetes, type of medication, co-morbidity and cost of medication were significantly associated medication adherence *($p < 0.05$)*, while side effect of medication was not associated with medication adherence level *($p > 0.05$).*

.

Table 4.7: Effect of SMS Reminders on Clinical Outcome (FBS)

Intervention Group

Variables (mmol/l)	Mean	Std. Deviation	Std. Error Mean	T	Df	Sig. (2tailed)
Baseline fbs	8.5	2.5	0.2	6.8	199	<0.05
Post-test fbs	7.2	1.3	0.1			

Paired t-test,

Control Group

Variable mmol/l	Mean (Control)	Df	Sig.(2tailed)
Baseline fbs	9.8	192	1.0000
Post-test fbs	9.8		

< 0.05 Significant,

4.8 Effect of SMS Reminders on Clinical Outcome (FBS)

The average number of submitted SMS messages was three messages per patient per week with the total number of approximately 7668 messages over three months for all participants. Table 8 shows that there was statistical significant association *(p < 0.05)* between SMS reminder and clinical outcome (FBS) in the intervention group, while there was no significant association *(p 1.000 > 0.05)* between SMS reminder and clinical outcome in the control group.

`Table 4.8: Socio-Demographic Characteristics of Patients Associated with Clinical Outcome (FBS)

Demographic Characteristics	Intervention n (%) 200	Mean FBS	P
Gender		1.600	0.345
Male	80(40)		
Female	120(60)		
Age			
20-29	4(2)		
30-39	31(15.5)	3.640	0.181
40-49	32(16)		
50-59	99(49.5)		
60 Above	34(17)		
Marital Status			
Single	-(-)		
Married	103(51.5)	2.805	0.439
Widowed	33(16.5)		
Separate	64(32)		
Education Status			
Primary	59(29.5)		
Secondary	49(24.5)	2.165	0.595
Tertiary	92(46)		
No Education	-		
Employment Status			
Farming	-		
Trading	69(34.5)		
Self-employed	76(38)	2.930	0.313
Public sector	55(27.5)		
Private sector	-		
Unemployed	-		
Retired	-		

4.9 Socio-demographic Characteristics of Patients Associated with Clinical Outcome (FBS) Post Intervention

Table 4.8 above showed that patient factors such as gender, age, marital status, educational status and employment status were not significantly associated with clinical outcome (FBS).

Table 4.9: Medication- and Disease-Related Factors Associated with Clinical Outcome (FBS)

Variables	Intervention (%) 200	Mean FBS	P
Dod (yrs.)			
1-5	17(8.5)		
6-10	89(44.5)		
11-15	62(31.0)	2.735	0.774
16- 20	19(9.5)		
21-25	13(6.5)		
Type of Medication			
Met	19(9.5)		
Met + Gbm	85(42.5)	2.663	0.251
Met + Gmp	29(14.5)		
Met + Gbm + Pio	58(29.0)		
Met + Gmp + pio	9(4.5)		
Comorbidity			
Hypertension	126(63.0)		
Arthritis	32(16.0)		
Asthma	9(4.5)		
Dyslipidemia	9(4.5)	2.488	0.284
Hyperthyroidism	12(6.0)		
Hypertension +Arthritis	6(3.0)		
Hypertension + Dyslipidemia	6(3.0)		
Ability to Pay(Cost)			
No	14(7.0)	1.000	0.096
Yes	186(93.0)		
Side Effect			
Yes	87(43.5)	1.000	0.411
No	112(56.5)		

Met-metfomin, gbm-glibenclamide, gmp-glimepiride,pio-pioglitazone, Dod-Duration of Diabetes

4.1.0 Medication- and Disease-Related Factors Associated with Clinical Outcome (FBS)

Table 4.9 also showed that patient medication and disease related factors such as duration of diabetes, type of medication, co-morbidity, cost of medication and side effects were not significantly associated with clinical outcome (FBS).

CHAPTER FIVE

5.0 DISCUSSION

This study is the first of its kind to assess medication adherence and the impact of mobile phone SMS reminder for glycemic control in patients with type 2 diabetes in the clinical setting. Poor medication adherence seems to be a significant barrier to attainment of positive clinical outcomes among type 2 diabetic patients in both developed and developing countries (Adisa *et al.,* 2009). Morisky Medication Adherence Scale (MMAS) was used to study patient medication adherence. The result of this current study showed that medication adherence among the group of patient was suboptimal. This is consistent with the result of Abdulazeez *et al*., (2014) in which only 26.36% of patients were adherent to medication regimen as compared to 73.64% that were non-adherent. The Fear of daily ingestion of drugs and undue scare of taking multiple drugs at a time especially for patients with co-morbid diseases like hypertension and arthritis may have constituted a hindrance to medication adherence among patients with type 2 diabetes in this study setting. As a result, patients may deliberately take drug holidays or skip doses of medication(s) without the knowledge of their physician. The implication would be that the physician may attribute the lack of response to drug therapy as therapeutic ineffectiveness rather than medication non-adherence and may take the decision of either increasing the dose of the current medications or add another drug. Also, this study showed that gender, marital status, and educational status were not significantly associated with medication adherence ($P > 0.05$) both in the control and intervention groups. This result is consistent with Bagonza *et al.,* (2015) who reported in their study that respondent's socio-demographic characteristics such as age, sex, education level and marital status were not associated with adherence to anti-diabetic medication. Other studies such as (Parsons *et al*., 2014; Ogbonna *et al.,* 2015) also reported the

same result, while studies such as Adisa *et al*., (2009) reported contrary to this finding. Duration of diabetes was significant in this study (*P < 0.05)* in both the control and intervention groups. The result is consistent with the results of Islam., (2015) and Bagonza *et al*., (2015). Patients who had diabetes between 6-10years showed better adherence to medication than other age groups. Patients with long duration of diabetes were likely to have had more interactions with their health care providers, could have understood their regimen better and would be self-motivated to take their medication. However, as the duration of diabetes increases, there is a gradual reduction in adherence rate probably due to the fact that patients may feel they are not getting any benefit from their medications or might feel asymptomatic or get fed up from their use (Shrestha *et al*., 2013).

Co-morbidity was significantly associated with medication adherence (*P < 0.05*) in both the control and intervention groups in the study setting. Patients with less co-morbidity showed better adherence than those with more conditions due to lesser pills to use with less complex regimens (Ogbonna *et al*., 2015). Co-morbid conditions can be a source of concern and frustration, simpler regimens with fewer side effects can improve adherence compared to complex regimens associated with some comorbidities such as hypertension and arthritis. The result of this study also showed that there was statistical significant association between the type of medication and medication adherence (*P < 0.05*). Patients on metformin-glibenclamide combination showed better adherence, but as the number of medication increased to three there was a gradual decrease in adherence. This is consistent with the result of Shaimol *et al., (*2014). A Study reported that more oral medication is rather a marker for a greater likelihood of poor control only by increasing the number of medicines and might not improve glycemic control Shrestha *et al*., (2013). However, Parsons *et al*., (2014) reported no statistical significant

association. High cost of medication can affect adherence among patients as observed in this study setting. The effect of cost of medication on adherence was significant ($P < 0.05$). This result is consistent with studies done by Ogbonna *et al*., (2015); Parsons *et al*., (2014) and Shaimol *et al.,* (2014). The high cost of medications in tertiary hospitals could be associated with higher cost of expert care obtainable at referral hospitals (Ezenduka *et al*., 2014). With reference to this study, patients paid for anti-diabetic drugs just as in countries like India, Malaysia and Korea, where patients pay for drugs and clinic consultations (Bagonza *et al.,* 2015). These associated financial costs may deter or delay patients from re-filling prescribed medication and this negatively impacts on their medication adherence. Even though side effects can affect medication adherence, the result of this study showed that there was no association between side effect and medication adherence ($P > 0.05$). The fears of hypoglycemia and weight gain are other factors that can adversely influence patients' ability to adhere to treatment, whereas hypoglycemia is less common among patients with Type 2 diabetes mellitus compared to type 1 (Abdulazeez *et al*., 2014).

In terms of the SMS reminders, participants who received the SMS support were more likely to have their blood glucose levels reduced compared to patients who received standard of care alone (Adisa *et al*., 2009). The overall effect of mobile phone SMS reminder was superior to standard of care alone in reducing mean FBS level among patients with type 2 diabetes in the study setting. Growing evidence suggests that utilizing mobile phones messages might improve diabetes and clinical outcomes (Abbas *et al*., 2015). Many patients experience difficulties in adhering to long-term treatment (Vervloet *et al*., 2012). Electronic reminders have been shown to improve clinical outcome among diabetic patients (Vervloet *et al*., 2012; Abbas *et al*., 2015). This is consistent with the result of this current study, as it was noted that there was overall

reduction in mean FBS level from 8.5mmol/l to 7.2mmol/l in the intervention group, while there was no difference in mean FBS level (baseline and posttest) in the control group. This might be as a result of SMS reminders received by the patients in the intervention group. The effectiveness of the intervention may be due to factors related to the process itself (for instance, the level of interaction and personalization of the SMS), patients familiarity with mobile phones and on the context of the SMS, frequency and duration of SMS sent as reported by van Olmen *et al.,* (2013). Other studies such as Vervloet *et al., (*2012)*;* Da tao *et al., (*2015) reported that SMS reminders caused significant but small improvement in glycemic control. Also, further analysis of the association between patients socio-demographic characteristics, medication- and disease-related factors and clinical outcome (FBS) showed no association between the variables. This could be attributed to the fact that changes in clinical outcome might be largely related to behavioural and attitudinal changes exhibited by the patients. Vervloet *et al., (*2012) reported that using SMS reminders are primarily based on the principles of behavioral learning theory. According to this theory, behavior depends on stimuli or cues, either internal (thoughts) or external (envronmental cues).

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATION

6.1 Conclusion

This research showed that anti-diabetic medication adherence among type 2 diabetic patients in the setting was suboptimal. Gender, marital status and educational status were not significantly associated with medication adherence while age, type of medication, co-morbidity and cost of medication were associated with good medication adherence. SMS intervention improved patients' clinical outcome (FBS). Patients in the intervention group showed a decrease in mean FBS level compared to the control group. Metformin–glibenclamide combination was the most prescribed oral anti-diabetic regimen among patients in the study setting.

6.2 Recommendation

Adherence problems are common in diabetes management. Identifying and overcoming medication adherence might be challenging, but worth the time and effort. Practitioners should always look for poor adherence and can enhance adherence by emphasizing the value of a patients' regimen, making it simple and customized to the patient's lifestyle. Multifaceted interventions that incorporate structural and counseling components that include appropriately skilled and motivated pharmacists appear useful to promote medication adherence. Also, given the positive effect of SMS reminders for improving clinical outcome, such an intervention can be scaled up to provide routine service to a larger number of individuals. Other relevant factors that determine medication adherence also need to be given a thorough consideration, and attempts should be made to ameliorate them. Synergistic effects of different adherence promotion measures with SMS reminders need to be considered for improving patient outcomes further.

Also, the findings of this study can be further reinforced and replicated with larger sample size and longer follow- up times.

6.3 Limitation of The Study

Self-reports might be subjective and may overestimate patients adherence status. Recall and memory biase can lead to ceiling effects in self-report scales where an unrealistic majority of participants indicate perfect adherence and also for some patients to deliberately indicate a poor level of adherence. The issue of access and usability of a mobile phone. Several patients and/or caregivers may have reported having a mobile phone when they actually don't or had difficulty in using it, leading to difficulty in using SMS reminder as an intervention in this subset of population. Another issue of concern is the optimum frequency of the SMS text messages. Medication regimen can be fairly complicated with patients needing to take pills several times a day. In that situation, whether the text messages should be sent multiple times a day, or once a day, or at a lesser frequency can be deliberated upon. Excess number of messages can be exhausting for the patient, and can lead to the SMS reminder being ignored as a reflex. On the other hand, less frequent messages can translate to patient 'forgetting' about the medications on the days SMS are not sent. Also, HbA1c would have been used as clinical outcome but because of accessibility and affordability, FBS was used.

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APPENDICES

Appendix 1: Map of Niger State



Appendix 2: Copy of Ethical Approval

GOVERNMENT OF NIGER STATE

IBRAHIM BADAMASI BABANGIDA SPECIALIST HOSPITAL

MINNA

Chief Medical Director
Dr. Umar Isah A.
(MBBS, FWACP, PGDMS)

Director Clinical Services
Dr. Ibrahim, Abdullahi
(MBBS, FWACS, MDRM, MPH, MPA)

KM 10, Paiko Road,
Chanchaga P.M.B. 169
Minna, Niger State, Nigeria.

Our Ref: IBBSH/SUB/654/VOL.I/04 Your Ref: _____ Date: 15/06/2016

HEALTH RESEARCH ETHICAL CLEARANCE CERTIFICATE

RE: AN INTERVENTIONAL STUDY ON MEDICATION ADHERENCE AND CLINICAL OUTCOME AMONG TYPE 2 DIABETES MELLITUS PATIENTS IN A TERTIARY HEALTH FACILITY IN NIGER STATE

Name of the principal Investigator:	-	Mohammed Ndagi Usman
Address of the Principal Investigator	-	Department of Clin. Pharmacy and Pharmacy Practice, Faculty of Pharm. Sciences A. B. U. Zaria, Kaduna State Nigeria
Date of receipt of valid application	-	09/06/2016
Date of ethical approval:	-	15/06/2016

This is to inform you that the research described in the submitted protocol, the consent forms, and other participant information materials have been reviewed and given full approval by the Ibrahim Badamasi Babangida Specialist Hospital Ethical Committee.

Please note: this approval dates from 15th June 2016 to 15th December, 2016. No participant recruited into this research may be considered outside this time range.

Should you require an extension of your research period this Ethical Committee expects that you submit your application as well as progress report for ethical clearance renewal 3 months prior to expiration of study dates. This is to enable you obtain renewal of your approval and avoid interruption of your research.

If there is delay in starting the research, please inform the IBBSH Ethical Committee so that starting dates can be adjusted accordingly.

No changes are permitted in the research without prior approval by IBBSH Ethical Committee except in circumstances outlined in national code for Health Research Ethics: *http//www.nhrec.net*.

IBBSH Ethical Committee reserves the right to conduct compliance assessment visits to your research site without prior notification.

Abdullahi

Dr Ibrahim, Abdullahi (MBBS, FWACS, MPH, MDRM, MPA)
IBBSH Ethical Committee Chairman

Tel: 07032415295, 07068798085, 08036273421 e-mail:ibbsh.ng@gmail.com

Appendix 3: Informed Consent Form

TITLE OF STUDY: AN INTERVENTIONAL STUDY ON CLINICAL OUTCOME AND MEDICATION ADHERENCE AMONG TYPE 2 DIABETES MELLITUS PATIENTS IN A TERTIARY HEALTH FACILITY IN NIGER STATE NIGERIA.

INFORMED CONSENT FORM

Dear Sir/Madam

My name is Pharmacist Mohammed NdagiUsman, I am a Postgraduate student at the Ahmadu Bello University, Zaria. I am conducting a study on the above topic.

The findings will show if there are any pitfalls in how patients medication adherence impact on fasting blood sugar levels and then show which areas need to be improved in order to benefit the patients. I therefore invite you to participate in the study.

It is a questionnaire based study and there are no damages to you participating and there are no costs involved for you. I also request permission to monitor your FBS and to look in to your medical files for follow up.

If you agree to be part of this study please complete below;

I …… Agree to be part of this study conducted by Pharmacist Mohammed Ndagi Usman. I acknowledge that the information obtained from my medical records and questionnaire will be solely for research/educational purposes. I also acknowledge that my identity will not be divulged. I agree that the procedures to be followed have been explained fully to me and the benefits of the study. I am free to withdraw consent and discontinue participation in the study at any time.

Signature……..
Date……..

Appendix 4: Adherence Assessment Questionnaire

AN INTERVENTION STUDY ON MEDICATION ADHERENCE AND CLINICAL OUTCOME AMONG TYPE 2 DIABETIC PATIENTS IN A TERTIARY HEALTH FACILITY IN NIGER STATE NIGERIA.

QUESTIONNAIRE

The aim of this research is to assess medication adherence and evaluate the impact of mobile phone short message services (SMS) on clinical outcome (FBS) among type 2 diabetes mellitus patients in a tertiary health facility. Please feel free to answer all the questions, all answers will be kept completely confidential.

Section A: Socio-demographic Information

1. Gender: Male ( ) Female ( )
2. Age: 18 - 20 ( ) 21- 29 ( ) 30 - 39 ( ) 40 - 49 ( ) 50 - 59 ( ) 60 and above ( )
3. Marital Status: Single ( ) Married ( ) Widowed ( ) Separated ( )
4. Educational status: Primary ( ) Secondary ( ) Tertiary ( ) No formal education ( )
5. What is your main source of income? Farming ( ) Petty trading ( )

   Self-employed ( ) Employed in public sector ( ) Employed in private sector ( )

   Unemployed ( ) Retired ( )

Section B: Medication Therapy

6. How long do you have Diabetes? 1 – 5yrs ( ) 6 – 10yrs ( ) 11 – 15yrs ( )

   16 – 20yrs ( ) 21 – 25yrs ( ) 25yrs and above
7. What anti-diabetic medications are you currently taking?

   Metformin (Glucophage) ( ) Glibenclamide (Daonil) ( )

   Glimepiride (Amaryl) ( ) Pioglitazone ( )

   Sitagliptin ( ) Insulin ( )

   Glipizide ( ) Acarbose ( )
8. If more than one (1), are they combined as a single medication? Yes ( ) No ( )
9. What other disease condition are you treating apart from Diabetes Mellitus

   Hypertension ( ) Arthritis ( ) Asthma ( )

Hyperthyroidism ( ) Hepatitis ( )

Chronic Obstructive Pulmonary Disease (COPD) ( )

10. a. Please can you indicate the cost of your diabetic drugs monthly?

b. Are you able to pay for the cost of your medication? Yes ( ) No ( )

Section C: Mobile Phone Information

11. Do you have a personal mobile phone? Yes ( ) No ( )

12. How often do you use your mobile phone? Always ( ) Sometimes ( )

Rarely ( ) Never ( ) Usually ( )

13. Can you or your care giver read and send SMS? Yes ( ) N0 ( )

Section D: Adherence to Anti-diabetic Medications (MMAS)

14. Do you sometimes forget to take your Anti-Diabetic medicine? Yes ( ) No ( )

15. Over the past two weeks, where there any days when you did not take your

Anti-diabetic medicine? Yes ( ) No ( )

16. Have you ever stopped taking your medications without telling your

Doctor, because you felt worst when you took it? Yes ( ) No ( )

17. When you travel or leave home, do you sometimes forget to bring alone your medications? Yes

( ) No ( )

18. Did you take your anti-diabetic medicine yesterday? Yes ( ) No ( )

19. When you feel your sugar level is under control, do you sometimes stop

taking your medicine? Yes ( ) No ( )

20. Taking medications every day is a real inconvenience for some people. Do

you ever feel hassled about sticking to your diabetes treatment plan? Yes ( ) No ( )

21. How often do you have difficulty remembering to take all your anti-diabetic?

Medication? Always ( ) Usually ( ) Sometimes ( ) Rarely ( ) Never ( )

Appendix 5 : Gender * Adherence Level Cross Tabulation Intervention Group

			ADHERENCE LEVEL			
			Non-adherence (0<6)	Fair/poor adherence(6<8)	Good adherence(8)	Total
GENDER	MALE	Count	61	9	10	80
		% within GENDER	76.2%	11.2%	12.5%	100.0%
		% within ADHERENCE LEVEL	40.9%	42.9%	33.3%	40.0%
		% of Total	30.5%	4.5%	5.0%	40.0%
	FEMALE	Count	88	12	20	120
		% within GENDER	73.3%	10.0%	16.7%	100.0%
		% within ADHERENCE LEVEL	59.1%	57.1%	66.7%	60.0%
		% of Total	44.0%	6.0%	10.0%	60.0%
Total		Count	149	21	30	200
		% within GENDER	74.5%	10.5%	15.0%	100.0%
		% within ADHERENCE LEVEL	100.0%	100.0%	100.0%	100.0%
		% of Total	74.5%	10.5%	15.0%	100.0%

Appendix 6 :Age Group * Adherence Level Cross Tabulation Intervention Group

			ADHERENCE LEVEL			
			Non-adherence (0<6)	Fair/poor adherence(6<8)	Good adherence(8)	Total
AGE	20-29	Count	3	0	1	4
		% within AGE	75.0%	.0%	25.0%	100.0%
		% within ADHERENCE LEVEL	2.0%	.0%	3.3%	2.0%
		% of Total	1.5%	.0%	.5%	2.0%
	30-39	Count	27	1	3	31
		% within AGE	87.1%	3.2%	9.7%	100.0%
		% within ADHERENCE LEVEL	18.1%	4.8%	10.0%	15.5%
		% of Total	13.5%	.5%	1.5%	15.5%
	40-49	Count	30	1	1	32
		% within AGE	93.8%	3.1%	3.1%	100.0%
		% within ADHERENCE LEVEL	20.1%	4.8%	3.3%	16.0%
		% of Total	15.0%	.5%	.5%	16.0%
	50-59	Count	65	15	19	99
		% within AGE	65.7%	15.2%	19.2%	100.0%
		% within ADHERENCE LEVEL	43.6%	71.4%	63.3%	49.5%
		% of Total	32.5%	7.5%	9.5%	49.5%
	60 ABOVE	Count	24	4	6	34
		% within AGE	70.6%	11.8%	17.6%	100.0%
		% within ADHERENCE LEVEL	16.1%	19.0%	20.0%	17.0%
		% of Total	12.0%	2.0%	3.0%	17.0%
Total		Count	149	21	30	200
		% within AGE	74.5%	10.5%	15.0%	100.0%

Appendix 7: Marital Status and Adherence Level Cross Tabulation

			ADHERENCE LEVEL			
			Non-adherence (0<6)	Fair/poor adherence(6<8)	Good adherence(8)	Total
MARITAL STATUS	MARRIED	Count	77	9	17	103
		% within MARITAL STATUS	74.8%	8.7%	16.5%	100.0%
		% within ADHERENCE LEVEL	51.7%	42.9%	56.7%	51.5%
		% of Total	38.5%	4.5%	8.5%	51.5%
	WIDOWED	Count	28	1	4	33
		% within MARITAL STATUS	84.8%	3.0%	12.1%	100.0%
		% within ADHERENCE LEVEL	18.8%	4.8%	13.3%	16.5%
		% of Total	14.0%	.5%	2.0%	16.5%
	SEPERATED	Count	44	11	9	64
		% within MARITAL STATUS	68.8%	17.2%	14.1%	100.0%
		% within ADHERENCE LEVEL	29.5%	52.4%	30.0%	32.0%
		% of Total	22.0%	5.5%	4.5%	32.0%
Total		Count	149	21	30	200
		% within MARITAL STATUS	74.5%	10.5%	15.0%	100.0%
		% within ADHERENCE LEVEL	100.0%	100.0%	100.0%	100.0%
		% of Total	74.5%	10.5%	15.0%	100.0%

Appendix 8 : Educational Status * Adherence Level Cross Tabulation Intervention Group

			ADHERENCE LEVEL			
			Non-adherence (0<6)	Fair/poor adherence(6<8)	Good adherence(8)	Total
EDUCATIONAL STATUS	PRIMARY	Count	51	4	4	59
		% within EDUCATIONAL STATUS	86.4%	6.8%	6.8%	100.0%
		% within ADHERENCE LEVEL	34.2%	19.0%	13.3%	29.5%
		% of Total	25.5%	2.0%	2.0%	29.5%
	SECONDARY	Count	32	7	10	49
		% within EDUCATIONAL STATUS	65.3%	14.3%	20.4%	100.0%
		% within ADHERENCE LEVEL	21.5%	33.3%	33.3%	24.5%
		% of Total	16.0%	3.5%	5.0%	24.5%
	TERTIARY	Count	66	10	16	92
		% within EDUCATIONAL STATUS	71.7%	10.9%	17.4%	100.0%
		% within ADHERENCE LEVEL	44.3%	47.6%	53.3%	46.0%
		% of Total	33.0%	5.0%	8.0%	46.0%
Total		Count	149	21	30	200
		% within EDUCATIONAL STATUS	74.5%	10.5%	15.0%	100.0%
		% within ADHERENCE LEVEL	100.0%	100.0%	100.0%	100.0%

Appendix 9 : Descriptive Statistics of Fasting Blood Sugar Level for Intervention Group

		BASELINE INTER	POST TEST FBS INTER
N	Valid	200	200
	Missing	184	184
Mean		8.4960	7.2125
Std. Deviation		2.51438	1.26666

Appendix 10 : Descriptive Statistics of Fasting Blood Sugar Level for Control Group

	BASELINE CONTROL	POST TEST FBS CONTROL
N Valid	193	193
Missing	0	0
Mean	9.7824	9.7824
Std. Deviation	10.78387	10.78387
Minimum	5.00	5.00
Maximum	112.00	112.00