EFFECTIVENESS OF A MOBILE PHONE BASED INTERVENTION IN IMPROVING MEDICATION ADHERENCE AMONG HYPERTENSIVE PATIENTS IN NYERI COUNTY, KENYA

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DECLARATION

This thesis is my original work and has not been presented for a degree at any other University or for any other award.

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DEDICATION

I dedicate this thesis to my dear family, including my wife Esther, my two children, Edwin and Eleanna, my parents, Bernard and Anastacia and all my brothers and sisters for their moral support and inspiration throughout the entire journey of my PhD course of study.

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DEFINITION OF OPERATIONAL TERMS

eHealth: Use of information and communication tools for purposes of health care delivery (Shaw *et al.*, 2017).

Health Literacy: The extent to which individuals have the capacity to acquire, internalize, and understand basic health information and services needed to make appropriate health decisions (Schönfeld *et al.*, 2021).

Hypertension: Condition characterized by persistently elevated systemic arterial blood pressure of systolic blood pressure> 140 and/or diastolic blood pressure of >90 (Kenya Ministry of Health, 2018).

Medication Adherence: The extent to which a patient takes prescribed medications as instructions given by a health care provider (Burnier & Vrijens, 2018).

mHealth: Delivery of health care through a mobile device (Cameron *et al.*, 2017).

ABBREVIATION AND ACRONYMS

CAK	**:**	Communication Authority of Kenya
CI	**:**	Confidence interval
CVD	**:**	Cardiovascular disease
CONSORT	**:**	Consolidated Standards of Reporting Trials
CRH	**:**	County Referral Hospital
HIV/AIDS	**:**	Human Immune Deficiency Virus/ Acquired Immunodeficiency Syndrome
ICF	**:**	Informed Consent Form
ITT	**:**	Intention to Treat
KNBS	**:**	Kenya National Bureau of Statistics
LMIC	**:**	Low and Middle Income Countries
MAQ	**:**	Medication Adherence Questionnaire
MOH	**:**	Ministry Of Health
MOPC	**:**	Medical Outpatient Clinic
NCDs	**:**	Non Communicable Diseases
OPD	**:**	Outpatient Department
PDC	**:**	Proportion of Days Covered
RCT	**:**	Randomized Controlled Trial
SMS	**:**	Short Message
TB	**:**	Tuberculosis
WHO	**:**	World Health Organization

ABSTRACT

Globally, non-adherence to prescribed medications is identified as a major barrier to blood pressure control among persons living with hypertension. Uncontrolled hypertension is a leading risk factor for heart disease, kidney disease, stroke and general poor health. In Kenya, over a quarter of the adult population is estimated to be living with hypertension, with only 12.5% of them having their blood pressure under control. This study sought to evaluate the effectiveness of a mobile phone based intervention in improving medication adherence among hypertensive patients on follow-up in Nyeri County. The study adopted an interventional design conducted in two phases. In phase I, a total of 339 hypertensive patients attending two tertiary care hospitals (Consolata Mathari Mission Hospital and Nyeri County Referral Hospital) were enrolled in a baseline cross sectional survey to assess the extent to which they were adhering to their prescribed medicines, and also to explore the factors associated with their medication taking behavior. In phase II, a two arm parallel randomized controlled trial comprising of 120 patients who had been found to be non-adherent to their prescribed medicines in phase I was undertaken to evaluate the effectiveness of a mobile phone based intervention in supporting medication adherence. Participants in the experimental arm received the study's mobile phone based intervention on top of the usual care offered in the outpatient clinic, while those in the control group were continued on the regular care only. The mobile phone intervention comprised of text messages and voice calls to deliver hypertension related health education to patients allocated to the experimental arm. The primary outcome variable of the study was medication adherence, which was assessed using a validated medication adherence questionnaire and calculation of the proportion of days a patient was covered with medication (PDC) during the follow-up duration. Nearly half (46.6%) of the 339 patients who participated in the baseline survey were non-adherent to their prescribed medications. After fitting a multivariate logistic regression model, the factors that were significantly associated with antihypertensive medication non-adherence included: having poor hypertension knowledge (adjusted odds ratio (AOR), 5.6, 95% CI, 3.3, 9.4); being on multiple medications (AOR, 2.8, 95% CI, 1.7, 4.7) and receiving two or more daily doses of medications (AOR, 2.3, 95% CI 1.3, 4.0). In the randomized controlled trial, it was established that the study's mobile phone based intervention led to a statistically significant medication adherence improvement effect over a 6 month period of follow up; patients who had received the mobile phone based intervention were 6.1 times more likely to be adherent than those who had been on usual care only (95% CI 2.6, 14.3). The intervention also resulted to a significant improvement in blood pressure control; at the end of follow up, patients who were in the experimental arm were 4.6 times more likely to have achieved the target blood pressure level compared to their counterparts in the usual care group (95% CI, 2.0, 10.3). The intervention also led to an improvement in patients' knowledge and perceptions about hypertension and the need for persistence with medication use. Overall, this study found that use of an educational mobile phone based intervention was effective in enhancing medication adherence among patients on hypertension treatment. Given the central role of medication adherence in hypertension management, the intervention may be considered as an additional component in the comprehensive care given to patients living with hypertension.

CHAPTER ONE: INTRODUCTION

1.1 Background to the Study

Hypertension, also known as high blood pressure, is a chronic condition characterized by sustained elevation of arterial blood pressure. An individual is considered to be having hypertension if they have a systolic blood pressure of 140 mmHg or more, or a diastolic blood pressure of 90 mmHg or more, or he/she is taking any antihypertensive medication (World Health Organization, 2021). If left untreated, hypertension can cause several end organ complications, including heart disease, stroke and chronic kidney disease (Suvila & Niiranen, 2022). Effective management of hypertension entails a combination of approaches, including use of antihypertensive medication alongside other non-pharmacological measures such as physical activity and consumption of foods rich in fruits and vegetable and low on salt and saturated fats. For antihypertensive medications to produce the desired therapeutic effects, it is critical that persons on treatment for the condition fully adhere to their prescribed dosage regimens.

Adherence is defined as the extent to which patients take medications as instructed by their health care providers (Burnier & Vrijens, 2018). For chronic conditions such as hypertension, long-term adherence to prescribed medications is essential to achieving desired therapeutic outcomes and prevention of complications. However, it is estimated that as many as 40-60% of patients with chronic conditions are non-adherent to their medications (Kleinsinger, 2018). Non-adherence to medications is associated with higher rates of morbidity and mortality, increased health care costs and poor health outcomes (Cutler *et al.*, 2018).

For patients with hypertension, non-adherence to medications is a risk factor for uncontrolled blood pressure, which subsequently increases the risk of cardiovascular diseases (coronary artery disease, stroke, and heart failure) and chronic kidney disease (Zhou *et al*., 2018). Non-adherence to medications is highly prevalent among patients with hypertension; on average, it is estimated that about 50% of persons newly diagnosed with hypertension stop taking their prescribed medicines within one year (Burnier & Egan, 2019).

In Kenya, existing data shows that 87.5% of patients with hypertension have uncontrolled blood pressure (Pengpid & Peltzer, 2020). This situation, if left unaddressed, is likely to result to an unprecedented upsurge in hypertension related complications that may potentially overwhelm the country's health care system. In fact, the burden imposed by hypertension is already evident from the country's Ministry of Health statistics, which indicate that 25% of hospital admissions are related to cardiovascular diseases and other hypertension-associated complications (Kenya Ministry of Health, 2018). Medication non-adherence has been identified as the single most important barrier to blood pressure control among hypertensive patients (Choudhry *et al*., 2022). Therefore, investigations aimed at evaluating possible interventions to address the problem in different health care settings are urgently required.

Though there is no nationally representative estimate on prevalence of antihypertensive medication non-adherence in Kenya, the few available studies indicate it ranges between 43% and 85.4% (Moss et al., 2021; Xiong et al., 2022). The contextual factors contributing to antihypertensive medication non-adherence in the country have also not

been well characterized. Studies in different care settings in the country are therefore needed to not only quantify the magnitude of antihypertensive medication non-adherence, but also to identify the associated factors in order to inform design of interventions to address the problem.

Inadequate knowledge of hypertension as a chronic asymptomatic condition has been shown in previous studies to be strongly associated with medication non-adherence among hypertensive patients in various care settings (Algabbani & Algabbani, 2020; Rahmawati & Bajorek, 2018). In developed countries, mobile phone based health interventions (mHealth) have been shown to be effective in educating hypertensive patients to take up self-management practices such as compliance to prescribed medications and self-monitoring (Li et al., 2020). However, evidence on whether mHealth may have similar effects in addressing antihypertensive medication non-adherence in developing countries such as Kenya is lacking.

1.2 Problem Statement

In Kenya, the most recent nationwide data shows that 28.6% of adults aged 18- 69 years are living with hypertension, and out of this, only 12.5% have their blood pressure controlled (Pengpid & Peltzer, 2020). In a previous population based survey conducted among eight counties in Kenya, Nyeri County was ranked top in hypertension burden, with a prevalence of 24.7% (Turpin *et al.*, 2018). The level of blood pressure control among hypertension patients in Nyeri County is also strikingly low; a previous cross sectional study by Mutua *et al* in 2014 reported that only 33.4% of hypertension pa-

tients on follow up in Nyeri County Referral Hospital had their blood pressure within the recommended limits (Mutua *et al.*, 2014).

Among several factors that have been associated with suboptimal blood pressure control, non- adherence to antihypertensive medication is considered the most important barrier to achieving the desired treatment targets (Choudhry *et al*., 2022). Non-adherence to antihypertensive medication can lead to poorer health outcomes, such as increased risk of heart attacks and strokes, which may result in hospitalization and higher healthcare costs (Gardezi *et al.*, 2023).

In Kenya, several mHealth interventions have been successfully applied to improving healthcare outcomes for infectious diseases, including HIV & AIDS, tuberculosis, and malaria (Njoroge *et al.*, 2017). However, there is currently a dearth of data regarding the effectiveness of these interventions for chronic NCDs, such as hypertension.

1.3 Justification of the Study

Suboptimal adherence to medications among persons living with hypertension leads to uncontrolled blood pressure, which subsequently increases the risk of development of cardiovascular diseases (coronary artery disease, stroke, and heart failure) and chronic kidney disease (Gardezi *et al.*, 2023; World Health Organization, 2021). In Kenya, it is estimated that 25% of hospital admissions are due to cardiovascular diseases (Ministry of Health (MoH), Kenya, 2018). Hence, it is crucial that interventions are designed and applied to support patients to adhere to their prescribed medications in order to not only improve their quality of life, but also avert the growing health care burden imposed by NCDs in the Kenyan health care system.

The primary goal of this study was to investigate the potential effectiveness of applying a mobile phone delivered intervention to support medication adherence among patients on follow-up for hypertension. It is expected that the findings generated from this study will be of value in informing design of effective medication adherence supportive interventions to optimize treatment outcomes among patients on follow-up for hypertension in Kenya. Indeed, and as it was recommended in the World Health Organization's landmark review on adherence to long-term therapies, enhancing the effectiveness of adherence supportive interventions may potentially have higher payoffs than making improvements on specific medical treatments (WHO, 2003).

1.4 Research Questions

This study sought to address the following questions:

1. What is the level of medication non-adherence among hypertensive patients on follow-up?
2. What are the factors associated with medication non-adherence among hypertensive patients on follow-up?
3. What is the effectiveness of applying a mobile phone based intervention in improving medication adherence?
4. To what extent can the proposed intervention improve blood pressure control?

1.5 Hypotheses

1. $H_{01.}$ There is no difference in the rate of medication adherence between the group that receives the study's mobile phone based intervention and those who are continued on usual care only (control group).

$H_{a1:}$ There is a difference in the rate of medication adherence between the group that receives the study's mobile phone based intervention and those who are continued on usual care only (control group).

2. $H_{02.}$ There is no difference in the rate of blood pressure control between the group that receives the study's mobile phone based intervention and those who are continued on usual care only (control group).

   $H_{a2:}$ There is a difference in the rate of blood pressure control between the group that receives the study's mobile phone based intervention and those who are continued on usual care only (control group).

1.6 Broad Objective

This study aimed at assessing the effectiveness of a mobile phone based intervention in improving medication adherence and blood pressure control among hypertensive patients on follow up in two tertiary referral hospitals in Nyeri County, central Kenya.

1.7 Specific Objectives

The specific objectives of this study were to:

1) Determine the prevalence of medication non-adherence among hypertensive patients on follow-up.
2) Identify factors associated with medication non-adherence among hypertensive patients on follow-up.
3) Test the effectiveness of applying a mobile phone based intervention in improving medication adherence among hypertensive patients on follow-up.

4) Determine the effect of the study's mobile phone based intervention on blood pressure control among hypertensive patients on follow-up.

1.8 Significance

In Kenya, a large proportion of people living with hypertension have uncontrolled blood pressure, therefore being at risk of developing cardiovascular diseases. Non-adherence to prescribed medications is a major barrier to attaining blood pressure control, and therefore interventions to address the problem are urgently needed in the Kenyan health care system. The data generated from this study is in support of the effectiveness of a mobile phone based intervention in improving medication adherence among patients on treatment for hypertension. The findings will not only inform design of mhealth based interventions that can be applied to support medication adherence among patients living with hypertension in Nyeri County, but also contribute to formulation of national policy guidelines for optimizing hypertension treatment outcomes across different health care settings in the Country.

1.9 Delimitation

Considering the fact that medication adherence is a complex process that may be influenced by multiple factors, some related the patient and others occurring at the health system level, this study specifically focused on investigating and addressing patient related barriers to medication adherence such as inadequate hypertension knowledge.

The medication adherence supportive intervention undertaken in the study only targeted hypertensive patients who were in possession of a mobile phone, and were familiar with use of *sms* text messages for communication. Given the widespread penetration of mo-

bile phones in the country, it was contemplated that the intervention would be scalable, should it be found effective. The trial was also undertaken in a care setting where health services including medicines were provided free under the Kenya Universal Health Coverage (UHC) programme, and therefore it was possible to assess the potential impact of the intervention in addressing non-cost patient related barriers to medication adherence.

1.10 Study Limitations

This study was undertaken in two purposively selected health care facilities in Nyeri County. This may therefore limit generalizability of the study findings to other populations, and as such, it may be of interest to have similar studies conducted elsewhere to test for replicability. However, the two health care facilities are referral hospitals serving a diverse population of Nyeri County residents, and therefore the study population may be considered to have a representation of various characteristics of the target population.

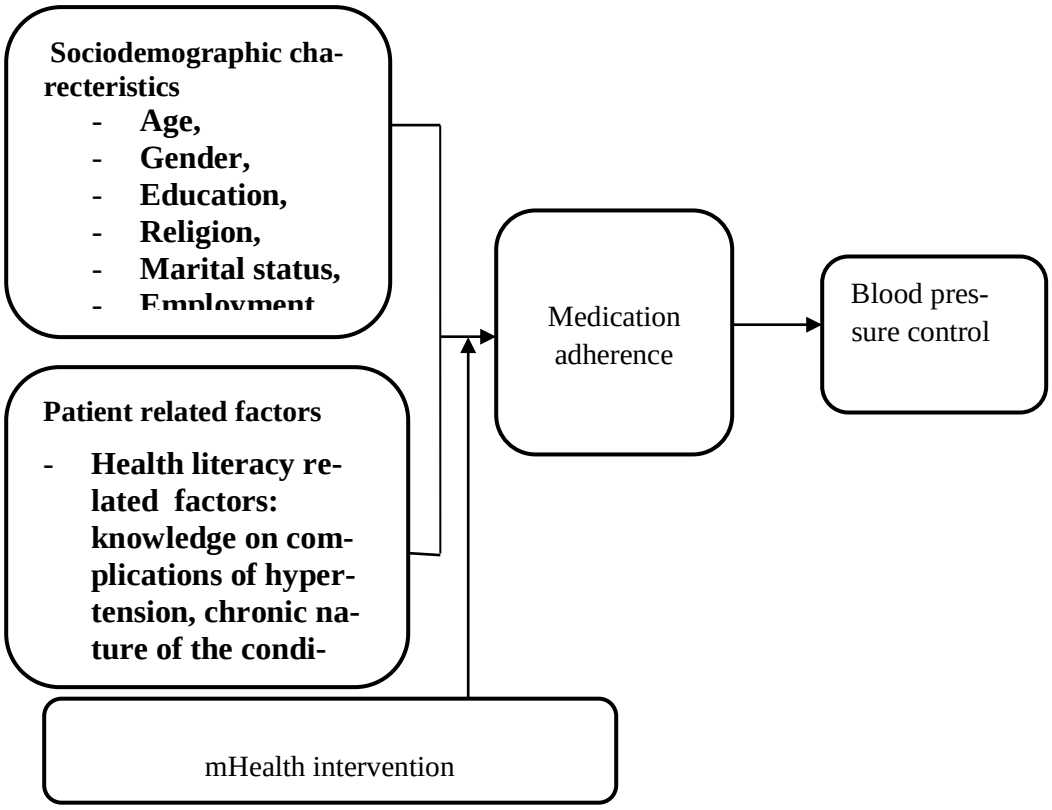
1.11 Conceptual Framework

The study's conceptual framework was derived from a review of the literature on the various patient related factors associated with medication adherence (Abu *et al.*, 2018; Najjuma *et al.*, 2020; Olowe & Ross, 2017). Reference was also made to the existing literature on the relationship between health literacy and health outcomes, where it has been found that inadequate understanding of a disease and insufficient knowledge about the existing treatment modalities act as significant barriers to medication adherence (Lee *et al*., 2017; Liu *et al.*, 2020). The primary dependent variable was adherence to antihy-

pertensive medication, with blood pressure control being picked as a secondary outcome variable. The independent variables were grouped into two categories: 1) socio-demographic characteristics (e.g. age, gender, education) and patient related factors (health literacy related factors, forgetfulness). A diagrammatic representation of the interrelationships between these variables is given in Figure 1.

Figure 1.1: Conceptual Framework

Independent variables Primary outcome variable Secondary outcome variable



Intervening variable

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

This chapter presents a review of the different aspects of the existing literature related to the topic under study. It gives an account of the public health burden of hypertension and its related complications, both at the global and regional levels. It also highlights the status of blood pressure control and the associated factors among hypertensive patients based on research conducted in different parts of the world. The existing research on antihypertensive medication adherence and the associated barriers, including a review of the interventions attempted to address the problem is also covered. In the final section, a summary of the key findings from the review is given, pointing out the identified gaps that this research sought to address.

2.2 Hypertension Basics

Systemic arterial hypertension, also referred to as hypertension, is a condition characterized by persistently elevated pressure in arteries (World Health Organization, 2021). Hypertension is diagnosed in an individual if blood pressure readings, measured on two separate days, are ≥140 (systolic) and/or ≥90 (diastolic) (World Health Organization, 2021). Hypertension is classified based on etiology into two classes; primary and secondary hypertension. Primary hypertension, which accounts for the majority of cases (90%) does not have any specific causes, but is linked to certain risk factors such as, physical inactivity, overweight or obesity, smoking, high salt diets, excessive consumption of alcohol and reduced consumption of fruits and vegetables. Secondary hypertension is usually diagnosed in an individual if there is an underlying condition that is

linked to high blood pressure such as endocrine disorders (for example hyperthyroidism, aldosteronism) and renal disease among other causes (World Health Organization, 2021).

Hypertension is largely an asymptomatic condition that progresses in many people without being noticed; in fact, it is estimated that more than half of people with hypertension are unaware of the condition (Oparil *et al.*, 2018). In the long term, uncontrolled hypertension causes damage in multiple organs, leading to development of complications such as heart disease, stroke, kidney disease, retinopathy and neurocognitive impairment (dementia) (Oparil *et al.*, 2018). In view of the associated health risks of hypertension, international guidelines currently recommend a clinical target of <140/90 mmHg for blood pressure management among patients living with the condition (Unger *et al.*, 2020). Hypertension treatment requires a comprehensive approach comprising of both non-pharmacological and pharmacological interventions. Non-pharmacological measures include adoption of healthy lifestyles such as eating food that is rich on vegetables and fruits and low on saturated fat and salt, maintenance of healthy body weight and being physically active (Unger *et al.*, 2020).

Pharmacological interventions (pharmacotherapy) include use of medications that have been proven to be effective and safe in long term management of hypertension. Depending on the level of blood pressure reading, hypertension may be controlled with a single drug, or in some cases, it may require a combination of drugs drawn from various classes (Unger *et al.*, 2020). In order for the desired therapeutic goals to be achieved, patients on treatment need to take their medications consistently without stopping, given

the lifelong nature of hypertension; however existing data indicate that over half of patients on treatment for hypertension do not adhere to their prescribed medications (Burnier & Egan, 2019). The central role of pharmacotherapy in treatment of hypertension is scientifically backed by an array of evidence showing that long term use of the different classes of antihypertensive drugs contributes to improved blood pressure control and the overall reduction in cardiovascular disease risk (Canoy *et al.*, 2022; Hughes *et al.*, 2022).

2.3 Hypertension Burden and Control Rates

Globally, hypertension is ranked as the leading risk factor for cardiovascular disease and all-cause mortality (Kyu *et al.*, 2018; Stanaway *et al.*, 2018). As of 2019, a total 1.22 billion people aged 30-79 years were estimated to be having hypertension worldwide, with a large majority of them (82%) living in low and middle income countries (Zhou *et al*., 2021). In sub-Saharan Africa, recent estimates indicate that 27.9% of persons aged ≥18 years have hypertension, and the condition has been identified as a key driver of the growing burden of cardiovascular diseases in the continent (Beaney *et al.*, 2020; Keates *et al.*, 2017).

Based on the most recent national survey conducted in Kenya in 2015, it is estimated that 28.6% of persons aged 18-69 years have hypertension (Pengpid & Peltzer, 2020). Existing data also indicates that hypertension related complications have been on the rise in the country, accounting for 25% of all hospital admissions (MoH, Kenya, 2018). Though available evidence indicates that adequate hypertension control results to decreased cardiovascular disease morbidity and mortality, attaining this clinical target in

many patients has remained a significant challenge. Globally, it is estimated that only one in five adults with hypertension have their blood pressure under control (Chow & Gupta, 2019; WHO, 2021). The burden of uncontrolled hypertension is highest in low and middle income countries, with only 8% of those diagnosed with the condition having their blood pressure below the recommended upper limit (Schutte *et al.*, 2021).

In sub-Saharan Africa, poorly controlled hypertension has been identified as a major risk factor for heart failure, stroke and kidney failure (Seedat *et al.*, 2018). In Kenya, available nationally representative data indicate that only 12.5% of patients on treatment for hypertension have their blood pressure controlled (Pengpid & Peltzer, 2020). Therefore, there has been a growing need for research to identify the barriers hampering adequate blood pressure control among hypertensive patients in the Country.

2.4 Barriers to hypertension control

Barriers to effective blood pressure are multifactorial, and can be grouped into three main domains: patient related barriers, health care provider related barriers and health system related barriers (Carey *et al.*, 2018). Studies conducted in diverse settings have identified multiple factors that hinder blood pressure control at the patient level, among them, non-adherence to medication and follow-up care, inadequate understanding and misconceptions about hypertension, and failure or inability to adopt healthy lifestyles (Abaynew & Hussien, 2021; Dhungana *et al.*, 2021; Heinert *et al.*, 2020).

Health care provider related barriers include clinical inertia to intensify treatment regimens, insufficient knowledge about evidence based hypertension treatment guidelines and failure to educate patients about the condition (Dhungana *et al.*, 2021; Sorato *et al.*,

2021). Among the barriers occurring at the health system level include unaffordability and unavailability of services and the necessary health care commodities for hypertension control (Dhungana *et al.*, 2021; Sorato *et al.*, 2021).

2.5 Adherence to antihypertensive medications

Medication adherence is defined as the process through which patients take their prescribed medications (Burnier & Vrijens, 2018). Adherence in the context of managing chronic illnesses has three important components: initiation, implementation and persistence with a prescribed treatment regimen (Burnier & Egan, 2019). Initiation refers to commencement of intake of prescribed medications after a patient has been newly diagnosed of an illness (Burnier & Vrijens, 2018). Implementation of a treatment regimen refers to the extent to which patients take their prescribed medications at the specified doses and frequencies. Persistence is the continued use of prescribed medications for long-term management of a medical condition. In hypertension treatment, existing research shows that outcomes for all the above mentioned aspects of adherence are suboptimal (Burnier & Egan, 2019).

Regarding initiation, it is estimated that over 20% of patients who have been newly prescribed antihypertensive medications fail to take the first dose (Burnier & Egan, 2019). It has also been documented that skipping of doses either through forgetting or intentionally is a common phenomenon among some patients on treatment for hypertension (Gebreyohannes *et al.*, 2019; Náfrádi *et al.*, 2016; Souliotis *et al.*, 2022). In terms of persistence, it has been reported that <50% of newly diagnosed patients remain on pharmacotherapy within the first one year of initiation of treatment (Burnier & Egan, 2019).

Poor adherence to antihypertensive medication is globally recognized as the most important barrier to effective blood pressure control (Choudhry *et al*., 2022). There is also evidence that non-adherence to antihypertensive medication increases the risk of cardiovascular events and other end organ complications (Lee *et al*., 2021; Li *et al*., 2021). Non-adherence to antihypertensive medications has been identified as a major barrier to blood pressure in low and middle countries, with existing estimates indicating that as high as 63.4% of patients with hypertension in these countries do not comply with their medications (Nielsen *et al.*, 2017).

Though there is no national study that has examined the level of antihypertensive medication adherence in Kenya, the few available studies indicate that between 43% and 85.4% of hypertensive patients in the country are non-adherent to their prescribed medications (Moss *et al.*, 2021; Xiong *et al.*, 2022). This therefore brings to fore the need for research to explore the underlying factors for medication non-adherence and to evaluate possible interventions to support long-term medication adherence among patients on hypertension treatment.

2.6 Factors Associated with Antihypertensive Medication non-Adherence

Medication adherence is a complex behavior that may be influenced by a combination of multiple factors; some relating to a patient, while others occur within the wider health system environment. In recognizing the multifactorial nature of adherence, the World Health Organization (WHO) developed a framework to guide researchers on how to identify and evaluate the different factors that may contribute to non-adherence to prescribed health measures (World Health Organization, 2003). This framework

comprises of four elements: patient-related factors, social-economic factors, condition-related factors, therapy-related factors and health system/health provider-related factors.

Patient related factors include knowledge, beliefs/perceptions and health literacy about a given medical condition. The link between knowledge related factors and adherence to antihypertensive medication has been widely studied in multiple settings, with the findings consistently showing a positive association. A cross sectional study was conducted in Indonesia in 2018 to explore the relationship between hypertension knowledge and self-reported medication adherence among patients on treatment for hypertension (Rahmawati & Bajorek, 2018). In this study, patients who had good knowledge about hypertension were 7.1 times more likely to be adherent to their medications compared to those with poor knowledge (95% CI, 3.3-15.2). Similar findings were also recorded in another study conducted by Algabbani *et al* in Saudi Arabia in 2020. In the findings of this study, which aimed at assessing treatment adherence among patients with hypertension and the associated factors, patients who had good hypertension knowledge were seven times more likely to be adherent to medications compared to their counterparts who had poor knowledge (Algabbani & Algabbani, 2020).

In Africa, a number of studies have been conducted to assess the level of antihypertensive medication adherence and the associated factors. A recent systematic review of several studies assessing factors associated with medication adherence in Ethiopia reported that possession of good knowledge about hypertension was significantly associated with self-reported medication adherence (pooled odds ratio, 2.98, 95% CI, 1.72,4.24) (Gemeda *et al*., 2020). In a qualitative study undertaken in Uganda, it was

established that having a good understanding of hypertension was a facilitator to improved medication adherence (Najjuma *et al.*, 2020).

In Kenya, two studies assessing the level of antihypertensive medication adherence and the associated factors are currently available in the literature. Moss *et al* conducted a study to assess the level of antihypertensive medication compliance and the associated factors among hypertensive patients on follow up in health care facilities in Kilifi County, Kenya (Moss *et al.*, 2021). In their findings, it was established that only 14.6% of the patients were adherent to their medications, and knowledge about hypertension was a significant predictor of medication compliance (Moss *et al.*, 2021). Another study conducted by Otenyo and Kereri among hypertensive patients on follow up in Nakuru County Referral Hospital found that 66.7 % of the patients interviewed had suboptimal adherence to their prescribed medications (Otenyo & Kereri, 2021b).

Several demographic and socioeconomic factors such as age, gender, income level and education have also been associated with antihypertensive medication adherence. In a previous systematic review conducted on factors associated with poor adherence to antihypertensive medication among hypertensive patients in low and middle income countries, it was found that patients with low wealth index had an 86% higher likelihood of being non-adherent to their medications compared to those in the higher wealth index bracket (Macquart de Terline *et al.*, 2019). In the same review, it was also reported that 26.5% of the patients included in the studies admitted having stopped their medications on financial grounds. Other previous studies have reported a similar positive association between out of pocket expenditure on medications and adherence (Baker-Goering *et al.*, 2019; Dillon *et al.*, 2018).

The influence of age, gender and educational level on antihypertensive medication adherence has been examined in previous studies. In a nationwide cohort study conducted in South Korea in 2019, it was established that age was positively associated with medication adherence; the likelihood of adherence significantly increased with age (Kim *et al.*, 2019). A similar association between age and medication adherence was also established in a study conducted in Japan in 2020, where patients belonging to the older age groups were more likely to be adherent compared to those in the lower age brackets (Nishimura *et al.*, 2020). Prior studies have established a positive link between educational attainment and medication adherence: patients with higher levels of education are more likely to be adherent to medications compared to those with low education (van der Laan *et al.*, 2017). However, the relationship between gender and medication adherence has been inconsistent in the literature, with some studies showing an increased likelihood of non-adherence among the male gender, while others have not found any significant associations (van der Laan *et al.*, 2017).

Condition related factors such as presence or absence of comorbidities and duration of diagnosis have been found to influence medication adherence. Existing studies have shown that presence of comorbidities is negatively associated with medication adherence (Gemeda *et al*., 2020). It has also been shown that patients with longer durations of diagnosis of hypertension are more likely to be adherent to medications compared to those who have lived with the condition for shorter periods (Algabanni & Algabbani, 2020; Shakya *et al.*, 2020).

Medication adherence among patients with hypertension has also been shown to be influenced by therapy related factors such as the number of antihypertensive medications

and the associated adverse effects (Algabbani & Algabbani, 2020; Asgedom *et al.*, 2018; Gebreyohannes *et al.*, 2019). Health care provider/health system related factors to medication adherence include: lack of patient education, counseling and involvement of patients in clinical decision making, and weak medication delivery and distribution systems (Burnier & Egan, 2019; Edward *et al.*, 2021).

2.7 Role of mHealth in Medication Adherence

mHealth is defined as the use mobile and wireless devices for purposes of improving and delivering health care (Dugas *et al.*, 2020). Globally, mobile phones have almost become ubiquitous, and this development has opened up opportunities for utilization of the devices to support health care delivery in diverse areas (Dugas *et al.*, 2020). In chronic disease management, mHealth interventions have been applied in sharing health information and empowering patients to undertake long-term self-management of their conditions (Fan & Zhao, 2022; Stampe *et al.*, 2021). mHealth interventions may take a variety of forms: sending medication reminders or educational SMS messages; making phone calls to patients to share health information and use of interactive mobile applications to support self-management (Fan & Zhao, 2022).

A number of trials testing the effectiveness of mhealth interventions in improving medication adherence among hypertension patients on treatment have been undertaken in different parts of the world, with the cumulative findings to date showing positive outcomes (Xiong *et al.*, 2018). Varleta *et al* conducted a randomized controlled trial in Chile in 2017, to evaluate the effectiveness of SMS text messaging in improving medication adherence among hypertensive patients on follow up care in different primary care centers (Varleta *et al.*, 2017). In their findings, it was established that use of the

sms messages resulted to a 30% higher rate of medication adherence among patients in the experimental arm compared to those in the control group. Bhandari *et al* conducted a feasibility randomized two-arm trial to test the effectiveness and acceptability of a mobile phone text messaging intervention to improve blood pressure control among patients with hypertension in Nepal (Bhandari *et al.*, 2022). The findings from this study indicated that patients in the intervention arm had a significantly higher level of medication adherence and blood pressure control compared to those receiving standard care only. Abughosh *et al* undertook an interventional study in the US to evaluate whether making follow up phone calls to hypertension patients undergoing follow up in an outpatient clinic would result to an improvement in medication adherence (Abughosh *et al.*, 2016). At the end of six months period of follow up, the investigators of the study found that the level of medication adherence among patients who had received the study's intervention was higher by 34.8% compared to those continued on usual care only.

In Africa, studies on applicability of mHealth in supporting hypertension treatment are scarce, and so far, only one published study is available in the literature. This study was a randomized controlled trial undertaken by Bobrow *et al* in South Africa, in 2016, with the aim of testing the effectiveness of SMS messages in supporting treatment adherence among patients with hypertension (Bobrow *et al.*, 2016). At the end of 12 months of follow up, the investigators found that the proportion of patients who were adherent to their medications was higher by 13.4% among patients who had received educational SMS messages compared to those in the control group. In Kenya, there is no published

study that has evaluated the applicability of mhealth in improving medication adherence and blood pressure control among hypertension patients on treatment.

2.8 mHealth initiatives in Kenya

In Kenya, several mHealth based service delivery innovations have been implemented in different sectors of the economy, owing to the widespread mobile phone ownership in the country, currently standing at over 80% (CAK, 2018). In 2011, the Kenyan Ministry of Health launched a national policy initiative on *e-health*, with five strategic focus areas, namely: Telemedicine, *mhealth* (delivery of health care through a mobile phone device), health information systems, *e-learning* and health information for citizens (MoH, Kenya, 2011). Since then, several mHealth projects have been successfully tried on improving treatment outcomes for various infectious diseases such as malaria, TB and HIV & AIDS (Njoroge *et al.*, 2017). The interventions conducted in these studies have shown that use of *sms* messages and phone calls on patients undergoing follow-up significantly results to improved medication adherence and retention in care. However, no *mhealth* intervention has been conducted to date on a chronic non-communicable disease such as hypertension in the country.

2.9 Summary of Literature Review and Gaps Identified

Hypertension is the world's leading preventable risk factor for cardiovascular diseases and all-cause mortality. A large proportion of persons living hypertension have uncontrolled blood pressure, with the burden disproportionately affecting low and middle income countries. In Sub Saharan Africa (SSA), uncontrolled hypertension is a major cause for heart failure, stroke and kidney disease, therefore making it a significant pub-

lic health problem in the region. Based on cumulative research conducted in this area, non-adherence to prescribed antihypertensive medications has been recognized as the most important barrier contributing to poor blood pressure control among people living with hypertension. This situation has therefore created a need for research to identify the different factors that may be hindering medication adherence among hypertensive patients, and more importantly, to come up with interventions to address the identified barriers.

After a review of the existing related literature, it was established that there is scarcity of information on the level of medication non-adherence and the associated factors among patients with hypertension in Kenya. There are also gaps in availability of evidence on interventions that may be applied to optimize medication adherence among patients with hypertension in the country. mHealth interventions have been successfully applied in supporting antihypertensive medication adherence in developed countries, but evidence on the same in low and middle income countries such as Kenya is lacking. These literature gaps therefore informed the design of the current study.

CHAPTER THREE: MATERIALS AND METHODS

3.1 Introduction

This chapter covers information about the overall methodological approach adopted in this study. Specifically, the chapter includes details about the study design, study location, study population, sampling methods, sample size determination, description the intervention and data collection instruments employed in the study. In addition, the data collection process, validity and reliability of study instruments and the methods applied in data analysis are also described.

3.2 Research Design

This was an interventional study conducted in two phases. In Phase I, a baseline cross sectional survey was undertaken to assess the level of antihypertensive medication non-adherence and the associated factors among hypertensive patients on follow up in selected tertiary health care facilities in Nyeri County. The information about the factors associated with medication non-adherence obtained in phase I was then utilized to formulate a tailored mobile phone based educational intervention to support medication adherence among patients living with hypertension. The intervention was evaluated in phase II, through a randomized controlled trial design. A post intervention survey was also conducted six months after completion of the trial to assess the sustained effect of the intervention on patients' beliefs and perceptions about hypertension. In-depth interviews and key informant interviews were also conducted to assess the perceived benefits and the potential for implementability of the study's mHealth intervention. Details

about the methodologies applied in implementing each of the two phases of this study are given in the subsequent sections.

3.2.1 Phase I: Cross Sectional Survey

The cross sectional design was adopted in phase I to address the first two objectives of this study which were: 1) to determine the prevalence of antihypertensive medication non adherence among hypertensive patients on follow up and 2) to identify factors associated with medication non adherence among hypertensive patients on follow up. The survey was undertaken between October and December, 2019.

The cross sectional design is appropriate to use in situations where information about prevalence of a given health problem in a specified population is required (Kesmodel, 2018). This design is also utilized for exploratory analysis to identify possible factors associated with the health problem in question.

In the current study setting, there was no published data about prevalence and associated factors of medication non-adherence among hypertensive patients on follow up. The cross sectional survey targeted known hypertensive patients undergoing follow up care in two referral hospitals in Nyeri County. Medication adherence was assessed using a validated medication adherence questionnaire (described later in section 3.7). Patients who were found to be non-adherent to their prescribed medicines were then selected for inclusion into the randomized controlled trial conducted in phase II.

3.2.2 Phase II: Randomized Controlled Trial

The second phase of this study comprised of a single blind randomized trial (RCT) aimed at addressing objectives 3 and 4; to investigate the effectiveness of applying a mobile phone based intervention to improve antihypertensive medication adherence and blood pressure control among hypertensive patients undergoing follow-up care. The trial was undertaken between January and December 2020.

The randomized controlled trial design is regarded as the gold standard for evaluation of efficacy or effectiveness of a given intervention for a specified health outcome (Hariton & Locascio, 2018). Further details about the study's intervention and the randomization and blinding procedures undertaken in this study are covered in section 3.10.

3.3 Study Variables and Measurements

3.3.1 Dependent Variables

The dependent variable for both the cross sectional survey and RCT was adherence/non-adherence to antihypertensive medication among hypertensive patients undergoing follow up care in the selected study sites. Medication adherence is defined as the extent to which patients take medications as instructed by their health care providers (Burnier & Vrijens, 2018). In health research, a number of methods have been developed to measure adherence to medication, but none of these has been identified as a gold standard (Anghel *et al.*, 2019). Hence, it is recommended that in order to maximize validity of results, a combination of measures be adopted in studies (Pednekar *et al.*, 2019). In this study, therefore, medication adherence for the selected patients was assessed using two standardized measures that have been validated and adopted in multiple settings for assessment of persistence and compliance to prescribed treatment regi-

mens for patients on follow up for chronic illnesses: Medication adherence questionnaire (MAQ) and proportion of days covered (PDC) (Pednekar *et al.*, 2019).

MAQ is self-report tool comprising of four yes/no questions, each with a 0/1 score. Based on this scale, anyone who scores zero is considered adherent while someone scoring ≥ 1 is considered non-adherent (Nguyen *et al.*, 2016). PDC is an objective adherence measurement technique that is calculated based on prescription and medication refill data available from existing pharmacy records in facilities where patients obtain their medicines from (Baumgartner *et al.*, 2018; Hong *et al.*, 2020). It is computed as a proportion, with the numerator being the number of days a patient received all the prescribed medication and the denominator being the total number of days included within a specified interval of follow-up. Based on multiple studies that have utilized PDC, a cutoff of 80% is usually used to categorize someone as either adherent (≥ 80%) or non-adherent (< 80%) (Baumgartner *et al.*, 2018). In the RCT component of this study, PDC was adopted as the measure of adherence, with the primary end point being change in the proportion of patients who were adherent to medication over a period of six months after the mobile phone based educational intervention was implemented.

In the Nyeri County Referral Hospital where this study was carried out, there is an electronic medical records system which captures comprehensive medical data for all patients seen in the outpatient department (OPD). During the study period (October, 2019 to December, 2020), the hospital was also one of the facilities implementing the national universal health cover programme (UHC), where, all enrolled patients were getting all medical services and prescribed medicines free of charge. In the hospital, prescrip-

tion of medicines is usually done through the electronic medical records system, where patients only need to present their outpatient numbers to the pharmacy department for dispensing of their medications.

Under the UHC programme, patients were dispensed with medication for 30 days, after which they would come back for refill depending on the duration of the prescription. Given the existing electronic medical records system which captures medication prescription and dispensing data, it was thus possible to apply the PDC method of adherence measurement among the selected study subjects. At baseline, the adherence level of all the study subjects, both in the intervention and control groups, was determined by calculation of PDC from medication dispensing data obtained in the preceding three months before the study. Another measurement of PDC was done following the intervention, at the end of six months of follow up. The specified interval for calculation of PDC was determined for each patient as the period between the index date and the end of six months duration. The index date was the date coinciding with the depletion of the medication units dispensed in the preceding visit to the hospital. The end date was the date coinciding with a lapse of six months from the index date. Information about the individual dispensing events that occurred for each patient in the specified time interval was pulled from the electronic medical records system and abstracted using a medication data form- see appendix 6.

The number of days a patient was covered with their prescribed medication was calculated by dividing the total number of dispensed medication units by the number of units to be taken per day. If a patient was on multiple antihypertensive medications, the num-

ber of days covered for each medication was calculated, and the lowest value was picked as the number of days the patient was covered with all medications. The cumulative number of days a patient was covered with medication in all the dispensing events occurring within the specified time interval was summed up to get the numerator for calculation of PDC. The denominator was the total number of days within the specified interval, in this case 180 days (equivalent to six months). This approach is recommended in calculation of PDC in order to avoid a situation where the number of days covered may be higher than the number of days within the specified period of interest, and therefore resulting to a score that is higher than 100% (Pednekar *et al.*, 2019). The PDC method is an indirect measure of adherence that is applicable when patients receive medications from a specified dispensing facility (Prieto-Merino *et al.*, 2021). Patients who fail to take medications as specified in their dosage regimen, usually have a lower refill rate, which subsequently translates into a lower PDC, and therefore lower adherence. Therefore, for PDC to be applied appropriately, it is important to ascertain at the end of follow up whether 1) the patients are alive 2) the medications are consistently available and 3) the patients did not source for medications from elsewhere. Thus, at the end of follow up, all patients underwent an exit interview in order to collect information related to the above conditions- see appendix 12.

The intervention undertaken in this study was educational in nature, comprising of mobile phone delivered health messages to improve hypertension related knowledge among hypertensive patients. Existing evidence indicates that knowledge is positively associated with adherence to prescribed medications (Algabbani & Algabbani, 2020); therefore it was hypothesized that improving hypertension knowledge among the pa-

tients in the intervention arm would result to an improvement in medication adherence. Clinically, adherence to antihypertensive medications is expected to translate into improved blood pressure control, and subsequently resulting to reduced cardiovascular disease risk. Hence in the trial, hypertension related knowledge and blood pressure control were measured as secondary outcome variables, both at baseline and the end of follow up. Categorization of blood pressure as controlled or not controlled was done according to the existing Ministry of Health clinical guidelines on diagnosis and management of cardiovascular diseases; patients were considered to have controlled blood pressure if they had a reading below 140/90mmmHg (MoH, Kenya 2018). Data on blood pressure was abstracted from the patients' medical records. The tool used in measuring hypertension related knowledge is described in section 3.7.

3.3.2 Independent Variables

The independent variables for the cross sectional survey were socio-demographic characteristics and medication adherence related factors derived from questions included in the adherence assessment questionnaire. Knowledge about hypertension was assessed using a structured questionnaire and dichotomized into two categories: Good knowledge and poor knowledge (see section 3.7). For the RCT arm of the study, the independent variable was a dichotomous variable derived from the group assignment status of each individual study participant, that is, either a patient received the intervention (experimental group) or was continued on usual care (control group). Other covariates included baseline characteristics such as age, gender, level of education, employment status and number of prescribed medicines.

3.4 Study Location

This study was conducted in Nyeri County, located in the central region of Kenya, with a population of 759,164 people (Kenya National Bureau of Statistics, 2019). The County measures 2361 square kilometers in area, with six sub counties namely, Kieni West, Kieni East, Mukuruwe-ini Mathira, Othaya and Tetu (County Government of Nyeri, 2021). The main economic activity undertaken in the County is farming, with coffee and tea being the predominant cash crops grown in the area. Nyeri County was chosen as the study location based on the existing statistics showing that the county is a high burden area for hypertension and other non-communicable diseases (Turpin *et al.*, 2018). The study was conducted in two tertiary care hospitals within Nyeri County, namely: Nyeri County Referral Hospital and Consolata Mathari Mission Hospital. The two hospitals were purposively selected on basis of being the major referral hospitals, and therefore serving a diverse group of patients in the county. Nyeri County Referral Hospital is a level 5 hospital that provides both general and specilialized health care services to residents of the entire Nyeri County. The hospital runs medical outpatient clinics where patients with different conditions including hypertension, cardiovascular disease, diabetes mellitus and other disorders are seen on scheduled visits. Consolata Mathari Mission Hospital is a faith based tertiary hospital that is run under the Catholic Diocese of Nyeri. The facility offers both general and speciliazed health services to residents of Nyeri Municipality and the surrounding rural populations. The hospital also runs outpatient medical clinics, where patients with different conditions are scheduled to be seen by medical specialists on designated days of the week.

3.5 Study Population

The study population comprised of hypertensive patients undergoing follow-up care in the two referral hospitals in Nyeri County. Details about the eligibility criteria for selection of study participants are given below.

3.5.1 Inclusion criteria

For the cross sectional survey, eligible participants were all consenting hypertensive patients who were currently on treatment. Patients to be included in the RCT were selected from the pool of patients enrolled in the survey after meeting the following criteria: 1) owning a personal mobile phone and being familiar with use of *sms* messages for communication and 2) being non-adherent to antihypertensive medication as per the score obtained in the medication adherence questionnaire (MAQ). Since the intervention undergoing investigation in the trial was delivered through a mobile phone, only patients in possession of mobile phones were eligible to participate in the study.

3.5.2 Exclusion Criteria

Hypertensive patients who were newly diagnosed and not yet started on medication were excluded from both the cross sectional survey and RCT. Exclusion of newly diagnosed patients was based on the fact that the study was assessing medication adherence, and therefore this outcome would only apply to patients who had been previously diagnosed of the condition and were taking antihypertensive medications. Patients who had any co-morbidity were also excluded from the randomized controlled trial. Presence of comorbidities has been associated with medication adherence in previous studies (Abegaz *et al.*, 2017), hence including this group in the RCT, may have introduced con-

founding in case there would have been a chance variation in constitution of the study arms after randomization.

3.6 Sample Size Determination

The formulae and calculation performed in determination of the sample size for each of the two designs adopted in this study are presented in the subsequent sections below.

3.6.1 Sample size for the baseline cross sectional survey

The minimum number of study subjects required to estimate the prevalence of antihypertensive medication non-adherence among hypertensive patients on follow-up in the two selected hospitals in Nyeri County was determined based on the following formula:

$$n = \frac{Z^2 p(1-p)}{d^2}$$

Where:

n= sample size

Z= 1.96; this corresponds to the z value for a confidence level of 95% in the normal distribution curve.

p= 68.2%; estimated prevalence of antihypertensive medication non-adherence (Achieng' *et al.*, 2009)

d= 5%; the margin of error/precision for estimation of the prevalence of antihypertensive medication non-adherence

$$n = \frac{1.96^2 * 0.682(1-0.682)}{0.05^2} = 333.2$$

The above sample size was adjusted for an estimated N=5000; this was arrived at after reviewing the existing outpatient clinic records which indicated that about 4625 hyper-

tensive patients were seen in MOPC of the two selected study hospitals in the year 2019. The formula applied in this computation is given below:

$$n = \frac{\mathrm{n}}{1 + [\frac{\mathrm{n}}{\mathrm{N}}]}$$

$$n = \frac{333.2}{1 + [\frac{333.2}{5000}]} = 312.4$$

In order to correct for a possible non-response rate of 10%, the above sample size was further adjusted as follows:

$$n = \frac{n}{(1 - \%\, non\ response\ rate)}$$

$$n = \frac{312.4}{(1 - 0.1)} = 347.1$$

Hence, a total of 348 hypertensive patients were required to estimate the prevalence of medication non adherence among the targeted patient population.

The number of subjects to be enrolled per study site was proportionately determined based on the total number of hypertensive patients seen in each of the two facilities in the preceding year before the study. The breakdown of the sample size per study site is given in Table 1 below:

Table 3.1: Sample size distribution across study sites

Site	Number of hypertensive patients seen in 2019	%	Sub-sample size
Nyeri CRH	3746	81	282
Consolata Mathari Mission Hospital	879	19	66
Total	4625	100	348

3.6.2 Sample size for the randomized controlled trial

The number of participants required to test the hypothesized effectiveness of the study's intervention in improving medication adherence was calculated by use of the *open epi* statistical software (Sullivan *et al.*, 2009). The sample size was computed taking into account the following parameters:

Type I error (α): 5%

Type II error (β): 10%

Power (1- β): 90%

Two sided confidence level: 95%

Proportion of outcome in the control group: 1.54% (Abughosh *et al.*, 2016)

Proportion of outcome in the interventional group: 36.36%

Effect size: 34.82%

Formula:

$$n_1 = \frac{\left(Z_{\alpha/2} + Z_{1-\beta}\right)^2 p\dot{q}(1-\dot{p})\,(r+1)}{r\left(p_{1-p_2}\right)^2}$$

Where;

$n_2 = r\, n_1$

n_1 = number of exposed

n_2 = number of unexposed

$Z_{\alpha/2}$ = standard normal deviate for two tailed test based on alpha level

r = ratio of unexposed to exposed

p_1 = proportion of exposed with outcome

p_2 = proportion of unexposed with outcome;

and where: p = $\frac{p_1 + p_2}{r+1}$ and q=1-p

The output from the *Open epi* statistical software, indicated that a total of 60 participants (30 per group), would be required in order to test the study's hypothesis with a 90% statistical power, and at 5% significance level; this value was obtained after application of continuity correction factor (Sullivan *et al.*, 2009). This sample size was further adjusted for a possible attrition rate of 40%, yielding a total of 100 patients as shown in the computation below:

$$n = \frac{n}{(1 - \%\, attrition\, rate)}$$

$$n = \frac{60}{(1-0.4)} = 100$$

Available evidence indicates that an attrition rate of >20% is large enough to severely impact the internal validity of a given study (Ferreira & Patino, 2019) ; hence adjusting for an attrition rate of 40% was sufficient to allow for adequate statistical analysis, in the event of a worst case scenario where a significant number of participants may be lost to follow up. In order to optimize the power to detect a statistically significant difference between the outcome in the intervention arm and that in the control group, the sample size was further increased by 20% to 120.

3.7 Sampling Method

For the cross sectional survey, systematic random sampling technique was applied in selection of the individual study participants for inclusion in the study. Study partici-

pants were selected from hypertensive patients visiting the scheduled medical outpatient clinics (MOPC) held on designated days of the week in the two hospitals. In order to meet the total sample size of 348 hypertensive patients required for the baseline survey, recruitment of the study subjects was undertaken over a period of three months (12 weeks), with a weekly target of 20-30 patients.

Patients with various medical conditions are usually scheduled to be seen in MOPC clinics that are held on designated days of the week (Thursdays for Consolata Mathari Mission Hospital and Tuesdays for Nyeri County Referral Hospital). With the help of the Hospital Records Officer covering the outpatient department, the list of booked patients on each material clinic day was viewed through to enumerate eligible hypertensive patients based on the study's inclusion criteria. The listing of the hypertensive patients meeting the inclusion criteria constituted the sampling frame from which the study subjects were selected through systematic random sampling process. The sampling interval (K) was determined by dividing the total number of patients included in the sampling frame by the target number of patients to be enrolled in each material clinic day. The index patient was chosen from the first K^{th} units in the sampling frame through the simple random sampling method. A breakdown of the numbers of patients enrolled in each of the 12 clinics covered within the recruitment duration of the study is given in appendix 8.

Recruitment of study participants for the RCT arm adopted the consecutive sampling method. For randomized trials involving patients visiting a hospital, it may not be possible to get a random sample from the entire target population, and therefore consecu-

tive sampling is usually a preferred approach for selection of study subjects in such studies (Elfil & Negida, 2017). Patients who were found to be non-adherent based on their responses in the medication adherence questionnaire administered in the baseline survey, and meeting the other aspects of inclusion criteria were serially enrolled into the trial until the desired sample size was achieved. Details about how the selected study participants were randomized to the either of the two study groups are given in section 3.10.

3.8 Research Instruments

For the cross sectional survey, data on medication adherence and the associated factors was collected using a semi-structured questionnaire (appendix 2). The questionnaire contained items to capture data on socio-demographic information, hypertension related knowledge and adherence self-report questions adopted from a validated medication adherence questionnaire (MAQ) (Pednekar *et al.*, 2019). MAQ is a self-report tool that has been demonstrated in multiple settings as a reliable and valid measure of medication adherence (Pednekar *et al.*, 2019). The tool comprises of four yes/no questions, with a response of "yes" being allocated a score of one and "no" zero. Each completed questionnaire adds up to a total score of 4, with someone scoring ≥ 1 being categorized as non-adherent and a score of zero being classified as adherent. The operationalization criteria for this variable was adopted from a previous study that had applied the same tool in assessing medication adherence among patients with hypertension (Nguyen *et al.*, 2016).

Knowledge about hypertension was assessed using a set of four questions derived from previous related studies that have examined the relationship between hypertension

knowledge and medication adherence (Abu *et al.*, 2018; Chimberengwa *et al.*, 2019; Olowe & Ross, 2017). Giving a correct response per question earned a score of one point, with the total score being four. The overall hypertension related knowledge score was calculated as a percentage, with those scoring ≥70% being categorized as having good knowledge and those with < 70% classified as having poor knowledge. The cut off of 70% was adopted from a previous study that had assessed hypertension related knowledge among hypertensive patients (Fahad M. Algabbani & Aljoharah M. Algabbani, 2020). Other details captured in the questionnaire were personal mobile phone ownership and usage characteristics, including phone number, duration of phone ownership and an alternative phone number and contact person.

In the RCT arm, a data abstraction form was used to extract individual patient prescription and medication refill data from the Nyeri County Referral Hospital electronic medical records system (appendix 6). In the post intervention survey, two validated tools were utilized to assess the patients' perceptions and beliefs about hypertension and their prescribed medications: Beliefs about Medication Questionnaire (BMQ) and Brief Illness Perception Questionnaire (BIPQ). BMQ is a validated tool that assesses people's beliefs about their prescribed medicines (Świątoniowska-Lonc *et al.*, 2021). The tool comprises of two subscales, namely, BMQ-Specific and BMQ-General. BMQ-Specific contains items aimed at assessing beliefs about medications for a certain specified condition, while BMQ-General evaluates beliefs about medicines for a patient having any unspecified condition. In implementation, any of the two subscales can be applied depending on the specified objectives of a given study. In this study, the BMQ-Specific subscale was used to assess the beliefs held by hypertensive patients regarding their

prescribed antihypertensive medicines- see appendix 3. BMQ-Specific scale comprises of 10 items, categorized into two sections- *necessity* and *concerns* about medications. The *necessity* section comprises of five items that assess the extent to which an individual believes that the medicines prescribed to him or her are necessary in maintaining his or her health; each item is scored on a five- point Likert scale (Strongly disagree=1; Disagree=2; Neither agree=3 or disagree; Agree=4; Strongly agree=5). Having a higher score on this scale represents stronger beliefs about the necessity of taking medicines. The *concerns* sections also comprises of five items just like the necessity section, but with a focus on assessing the extent to an individual believes that taking the prescribed medicines may result to adverse health consequences. Lower scores on this scale indicate weaker beliefs that medications may cause unwanted effects such as dependency and long-term toxicity.

BIPQ is a nine-item tool that has been used in multiple studies and settings to assess the cognitive and emotional representations of illness in people (Basu & Poole, 2016; Chew *et al.*, 2017; Dias Neto *et al.*, 2021). Each question is rated on 0-10 scale. The questionnaire can be implemented as a whole or by different items depending on the domain in focus. In this study, four of the nine items which assess the patient's perceptions and understanding of their illness were included in the survey tool- see appendix 4. These items were selected based on a previous similar study that had assessed illness perceptions among patients with hypertension (Nguyen *et al.*, 2016). The domains assessed included: 1) perception on timeline of the illness; 2) personal control; 3) treatment control and 3) coherence. The BIPQ scale does not have a composite score, but rather, each

item is rated and interpreted individually on a continuous linear measurement scale. Higher scores indicate stronger perception of a given item.

The tools utilized in qualitative research (in-depth interviews and key informant interviews) are given in appendices 13 & 14. Details about the measures applied to enhance validity and reliability of the various instruments utilized in data collection are covered in the sections below.

3.8.1 Validity

Validity is the degree to which results from a test or study represents the actual phenomenon under investigation (Patino & Ferreira, 2018). The primary outcome variable (medication adherence) was measured by use of two standardized measures that have been validated and adopted in multiple settings in assessment of medication adherence: Medication Adherence Questionnaire (MAQ) and Proportion of Days Covered (PDC) (Pednekar *et al.,* 2019).

The original version of MAQ is in English; hence it was necessary to translate the questionnaire into Swahili, in order to make it utilizable in the study population. Validity of the translated versions was ensured by conducting both forward and back translation. For each of the two languages, two independent translators were engaged: One to translate from English to the second language and the other to back translate to the original version in English. Any variations between the back translated and the original versions were noted and the necessary improvements done to enhance accuracy. Further improvements were done on the questionnaire following pre-testing of the tool which was undertaken before implementation of the questionnaire in data collection. The medica-

tion refill data abstraction form which was used to collect data for calculation of PDC was validated through reviews and corrections by pharmacists and medical specialists practicing in Nyeri County Referral Hospital.

Internal validity of the RCT was enhanced through randomized assignment of the enrolled participants to control for influence of extraneous variables (confounding) except for the intervention under investigation; details on how randomization was done are covered in section 3.10. Randomization plays a pivotal role in experimental research, where it is aimed at achieving a balance of participant characteristics (both observed and unobserved) between the study groups, thereby allowing for attribution of the difference in outcome to the study intervention (Hariton & Locascio, 2018). Contamination of the control group was minimized by having the eligible patients enrolled on various clinic dates, hence minimizing the possibility of sharing information between patients in both arms of the trial.

3.8.2 Reliability

Reliability is the extent to which a study instrument produces replicable observations or results on repeated measurements (Matheson, 2019). Reliability in this study was addressed by using data collection tools that had been utilized in similar settings and found to be reliable (Pednekar *et al.*, 2019). Further, reliability in implementation of the study was enhanced through standardized training of all research assistants and having clearly written instructions on the data collection tools. The principal investigator was also engaged in ongoing field work supervision to ensure all data collection activities were conducted as per the given guidelines and procedures.

3.9 Pre-test

Before full deployment of the study instruments in the field, a pretest of all the study tools was initially done at Karatina Sub County Hospital, Nyeri County. The area and population selected for the pretest had similar socio-demographic characteristics like the actual population for the study. The study questionnaires were administered to 34 participants (about 10% of the sample size for the baseline survey). The necessary adjustments to ensure accuracy, clarity and completeness of the study instruments were done after the pretest.

3.10 Data Collection Processes

Hypertensive patients who had been selected from the list of booked patients were approached and taken through a general overview of the ongoing study by trained research assistants under supervision of the principal investigator; those who were willing to participate were then invited to give informed consent-see Appendix 1. The patients were also informed that if necessary, further communication will be done to them through phone calls and text messages, and therefore explained on the need to give their current active phone numbers. Patients, who consented to participate in the study, were then interviewed using the study questionnaire to get baseline information on their adherence to antihypertensive medication and the associated factors. Clinical details including current blood pressure reading and the prescribed medications were abstracted from the patients' medical records.

Objective data about medication adherence for patients enrolled in the RCT was abstracted from the existing hospital electronic medical records system by trained medical

records officers, both at baseline and at the end of the six months of follow-up. Specifically, the number of days a patient was covered with medications during the follow up period was abstracted from the electronic medical records system (details about the measurement of the trial outcome have been given in section 3.2.1).

At the end of follow up, in-depth interviews were undertaken in a conveniently selected group of 7 patients drawn from the experimental arm to get feedback on their experiences with the study's intervention. Additionally, key informant interviews were held with 3 selected health care managers to gather their perspectives on the anticipated benefits and the feasibility of implementing the study's intervention. The informants included: The Nursing Officer In-charge of Outpatient Department, Nyeri County Referral Hospital, Deputy Director, Department of Health Research and Director of Health Services, Nyeri County. During all phases of data collection, the research staff involved were kept unaware of both the study's hypothesis and the assignment status of each of the enrolled study participants.

3.11 Randomization

Assignment of study participants to either of the two groups in the RCT arm adopted the blocked randomization method. Blocked randomization is a technique where persons participating in a trial are grouped into certain sets, each comprising of a preset number of individuals (block size); people in each block are then randomly assigned to either the interventional arm or control group, achieving 1:1 distribution in both groups. Compared to other methods of randomization (simple and unequal), blocked randomization is a preferred method of randomized assignment in studies with relatively small

sample sizes, given that it usually avoids the pitfall of unequal numbers of participants in the different arms of a trial (Lim & In, 2019).

The study enlisted the services of an independent statistician who implemented the randomization procedures using an open source randomization software (*Random Allocation Software*) (Saghaei, 2004). For purposes of blinding, the statistician was not informed of the study's hypothesis. The procedure undertaken in randomization is described below.

First, a randomization sequence for the entire sample of 120 subjects was generated using a fixed block size of 6 to achieve a ratio of 1:1 distribution between the intervention and control groups; the ordering of the allocations per block was done randomly. The block size of 6 was determined based on the fact that it is a multiple of the number of treatment groups included in this study, which are 2. Block sizes are usually determined by researchers, provided that they are multiples of the number of treatment groups included in a trial (Lim & In, 2019).

Eligible participants for inclusion in the trial were identified from patients who had been interviewed and found to be non-adherent to their medications based on self-report (the tool utilized in this has been described in section 3.7). Patients meeting the inclusion criteria were enumerated into a serialized master list containing all patient identifier details and baseline information. The master list served as the repository of key patient information to be utilized in subsequent follow up activities. Another version of the list (randomization list) was subsequently extracted from the master list to be utilized in random allocation. For purposes of concealment, the randomization list only

contained serial numbers and patient phone numbers. Leaving other details was considered appropriate, since knowledge about other patient particulars may influence the allocation into the study groups. The randomization list was then handed over to the study statistician to randomly assign the study participants into either of the two arms of the trial. The assignment status for each patient was derived from the corresponding serial number captured in the randomization list. A list of patients who had been assigned to the intervention arm was generated to be subsequently utilized in implementation of the study's intervention. Patients randomized to the control arm were continued on usual care offered in the clinic only, and did not receive an additional intervention.

3.12 Intervention and Follow up

The intervention undertaken in this study sought to address patient related barriers to antihypertensive medication adherence, with a focus on filling the knowledge gaps identified during the baseline survey. Details about how the intervention was designed and implemented are covered in the subsequent sections.

3.12.1 Design of the Intervention

The mHealth intervention undertaken in this study comprised of phone calls and *sms* text messages sent to hypertensive patients to educate them about the asymptomatic and chronic nature of hypertension, and the need for long term adherence to prescribed medications. The intervention was premised on the existing literature about health literacy, which shows that in order for a person to adopt a treatment recommendation, it is vital that he/she first understands the disease or health condition that he/she is being managed for (Y. M. Lee *et al.*, 2017).

Previous studies that used *sms* messages alone for adherence health education, especially in low and middle countries where literacy levels are low, have documented a low effect on adherence (Amankwaa *et al.*, 2018; Bobrow et al., 2016; Rodrigues *et al.*, 2012). Hence in this study, it was found appropriate that both aspects of mobile phone communication (*sms* messages and phone calls) be applied in order to allow for two way communication between the health care provider and the patient. The content of information included in both the *sms* messages and phone calls was tailored to address specific hypertension knowledge gaps identified during the baseline survey. The messages emphasized on the chronic and asymptomatic nature of hypertension of hypertension; the need for continued intake of medications and the risks associated with uncontrolled blood pressure. The content of the messages was also informed by the Kenyan Ministry of Health guidelines on cardiovascular diseases-see appendices 5 & 7 (MoH, Kenya, 2018). The draft health messages were also subjected to expert review by medical specialists practicing in Nyeri County Referral Hospital, with all suggested inputs implemented before roll out in the field.

3.12.2 Implementation of the Intervention and Follow-up

At the beginning, all patients randomized to the experimental arm were called on their mobile phones by a trained nurse, where they were taken through the basics of hypertension, including the asymptomatic nature of the condition and the importance of continued intake of prescribed medication to prevent long-term hypertension related complications. Thereafter, the patients received monthly phone calls for six months, to further remind them and emphasize the need for persistence with their prescribed medica-

tions. During the follow-up calls, patients were also given the opportunity to pose any questions or concerns they might have had about hypertension and their medications.

Patients in the experimental arm were also sent *sms* messages containing key information about hypertension on a weekly basis, for a period of six weeks; in total each patient received six messages, each covering a certain aspect of hypertension and education on the importance of medication adherence (appendix 5).

The messages were sent via a commercial bulk sms messaging system, *bulksms*; a brief description of this system is given in appendix 10. In operationalizing the messaging system, a database of all patients randomized to the intervention arm was first created with each patient identified by the serial number assigned in the earlier generated randomization list; the current phone numbers for each of the patients enrolled was also appended in the database. The medication adherence educative *sms* messages were then uploaded and scheduled to be automatically distributed to all patients registered in the database. Patients in the control arm were continued on the usual care offered in the hospital's medical outpatient clinic and did not receive any phone calls or *sms* text messages. All patients were followed up between January and December, 2020. At the end of follow up, all patients were tracked in their next scheduled clinic visits to ascertain their retention in follow up and also to get feedback on their experiences with medication dispensing services offered in the hospital's pharmacy.

3.13 Data management and analysis

All data was entered into Microsoft (Ms) Excel spreadsheet, and then subsequently exported to STATA Version 11.2 (StataCorp, College Station, Texas) for analysis. Data

for continuous variables was summarized using means and standard deviation, while that for categorical variables was described using proportions. In the cross sectional survey, the primary outcome variable was medication adherence, which was dichotomized into two outcomes: adherent vs non adherent. The prevalence of antihypertensive medication non-adherence was determined by calculating a proportion, with the numerator being the number of patients who were non-adherent to their prescribed medicines, and the denominator being the total number of patients interviewed. Identification of the factors associated with medication non-adherence was done in two stages. Firstly, bivariate analysis was done using chi square and fisher's exact tests to explore any association between the different independent variables (socio-demographic, behavioral and clinical characteristics) and medication adherence. In step two, covariates were selected for possible inclusion in multivariate analysis at $p<0.2$ cut off; this threshold was within the recommended range of p values (0.15-0.2) for optimal variable selection (Chowdhury & Turin, 2020). Multivariate analysis (with medication adherence as the outcome variable) was undertaken by fitting a multiple logistic regression model using the stepwise forward selection method, at 5% probability of entry.

Analysis of data from the RCT arm of the study was done as per the guidelines given in the *Consolidated Standards of Reporting Trials* (CONSORT) 2010 statement (Moher *et al.*, 2010). The baseline characteristics and outcome measurements for participants in both arms of the trial were summarized and compared using descriptive statistics, including proportions for categorical variables and mean for continuous variables; in line with guidelines given in CONSORT, no significance testing was applied in comparing these characteristics between the two trial arms. The outcome data for the trial was ana-

lyzed through the intention to treat approach (ITT). In ITT, study subjects are compared based on the groups they were originally randomized to, regardless of whether they may have received a treatment or intervention other than what they were allocated to (McCoy, 2017). Under the said type of analysis, patients who do not comply with the allocated treatment or drop off from the study are not excluded from the group in which they were initially allocated to. The fundamental principle behind the ITT approach is that it preserves the ideal structure created by the randomized assignment of study subjects into the different arms of the trial (McCoy, 2017).

The primary endpoint for the RCT was the proportion of hypertensive patients who were adherent to antihypertensive medication at six months of follow up after implementation of the study's intervention. Medication adherence was measured as a binary variable with two outcomes: adherent and non-adherent. The effect of the intervention on medication adherence was determined by comparing the proportion of patients who were adherent to their prescribed medications in the intervention arm vs. those who were in the control group; the chi square test of independence was applied in this analysis. A binary logistic regression model was also performed to generate odds ratios as a measure of likelihood of being adherent to the prescribed medications if someone had received the intervention.

The effect of the study's intervention on the other two secondary outcome variables (hypertension related knowledge and blood pressure control), was also determined through comparisons of proportions between the two groups and computation of odds ratios. All analysis in this study was done at 5% significance level, with p values and

95% confidence intervals being generated and interpreted at all the relevant stages of statistical computation. Data from qualitative research was analyzed through thematic coding, employing a systematic and iterative process to extract, categorize, and interpret the insights and perspectives shared by participants.

3.14 Trial Description as per the Consolidated Standards of Reporting Trials (CONSORT) Guidelines

All procedures and activities undertaken in the RCT arm of this study were done according to the guidelines provided in the most recent version of CONSORT statement (Moher *et al.,* 2010). Figure 2 shows the study flow chart as per the CONSORT guidelines. Between December, 2019 and January, 2020, a total of 274 hypertensive patients being seen in Nyeri CRH were assessed for eligibility, of whom 120 were randomly allocated to either receive the study's mobile phone based intervention (n=60) or continue with usual care (n=60).

All patients in both study groups were followed up between January and December 2020. At the end of follow up, a total of eight patients (three in the interventional group and five in the control arm) did not show up in their next scheduled clinic visit, and on further contacting, it was established that they had transferred to other health care facilities. These patients were treated as lost to follow up since it was not possible to get their outcome measures; the modalities on how this phenomenon was handled in analysis is described later in this section. The patients who were retained in follow up underwent an exit interview during their next scheduled clinic. From the interviews, it was established that all of them were getting their medications from the hospital's outpatient pharmacy and none of them reported having missed any medication during any visit to

the pharmacy. As described earlier in section 3.2.1, ascertaining this information was essential in determining the applicability of the PDC method of assessing medication adherence.

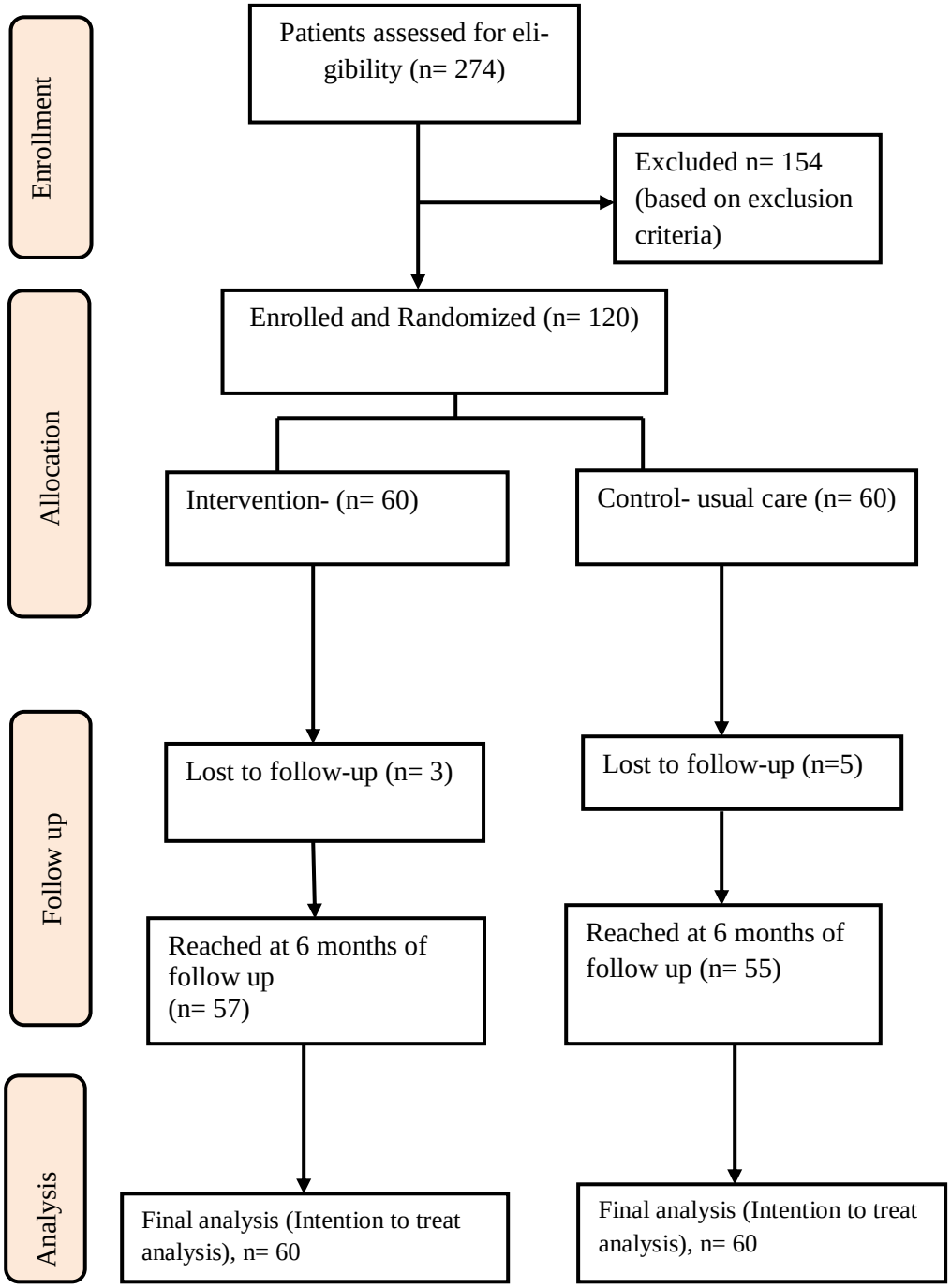
The overall analysis undertaken in this trial adopted the intention to treat model, where all the 120 patients who were initially randomized to the two study groups were included in the final analysis. The missing outcome data for the eight patients who were lost to follow-up were inputted using the worst case scenario approach. In the worst case scenario method, poor outcomes are assigned to study participants lost to follow up in the experimental arm, while those in the control arm are assigned good outcomes (Rombach *et al.*, 2020). In our case here in this trial, the five patients lost to follow up in the control arm were assigned good outcomes (being adherent, having good hypertension knowledge and having controlled blood pressure). The converse was done to the three patients lost to follow up in the experimental arm, that is, they were assigned poor outcomes (being non-adherent, having poor hypertension knowledge and having uncontrolled blood pressure).

3.15 Logistical and ethical considerations

This study was approved by the Graduate School of Kenyatta University (Appendix 16). Ethical clearance and approval was obtained from the Kenyatta University Ethics Review Committee (KUERC) (Appendix 17). A permit to conduct the study was also sought from the National Commission for Science, Technology and Innovation (NACOSTI) (Appendix 18). Before commencement of fieldwork, formal permission to conduct the study was sought from the Nyeri County Department of Health and the Hospi-

tal Management Boards of the two hospitals where the study was conducted (Appendix 19). Written informed consent was sought from all potential study participants before enrollment (Appendix 1). Privacy and confidentiality of personal patient information was ensured by having anonymized data collection forms that did not include names of study participants.

Figure 3.1: Study Flow Chart



CHAPTER FOUR: RESULTS

4.1 Introduction

This chapter covers details about the results obtained from this study, with key findings organized and presented as per the various study objectives that initially informed the design of the study. In the first section of the chapter, a description of the socio-demographic characteristics of the study participants is given, and then subsequently followed by presentation of findings per each of the four study objectives.

4.2 Description of Study Sample Characteristics

Out of a total of 348 hypertensive patients targeted for the baseline survey, 339 of them participated, translating into a response rate of 97.4%. The participants predominantly comprised of older persons, with a mean age of 65 years (+/- 12). The female gender accounted for a large majority of the participants, comprising of about two thirds of the study sample. The other socio-demographic and clinical characteristics of the study participants are shown in Tables 4.1. and 4.2, respectively.

Table 4.1: Socio-Demographic Characteristics of Study Participants

Characteristic	**Frequency (n=339)**	**%**
Age (years)		
30-44	19	5.6
45-59	101	29.8
≥60	219	64.6
Total	339	100
Sex		
Male	118	34.8
Female	221	65.2
Total	339	100
Educational level		
None	57	16.8
Primary	169	49.9
Secondary	99	29.2
College/University	14	4.1
Total	339	100
Marital Status		
Never married	31	9.1
Married	259	76.4
Divorced/separated	12	3.5
Widowed	37	10.9
Total	339	100
Religion		
Christian	335	98.8
Muslim	4	1.2
Total	339	100
Employment Status		
Formally employed	34	10.0
Unemployed	98	28.9
Self employed	207	61.1
Total	339	100
Phone ownership/usage characteristics		
Owns a personal mobile phone:		
Yes	304	89.7
No	35	10.3
Total	339	100
Uses *sms* messages for communication		
Yes	270	88.8
No	34	11.2
Total	304	100

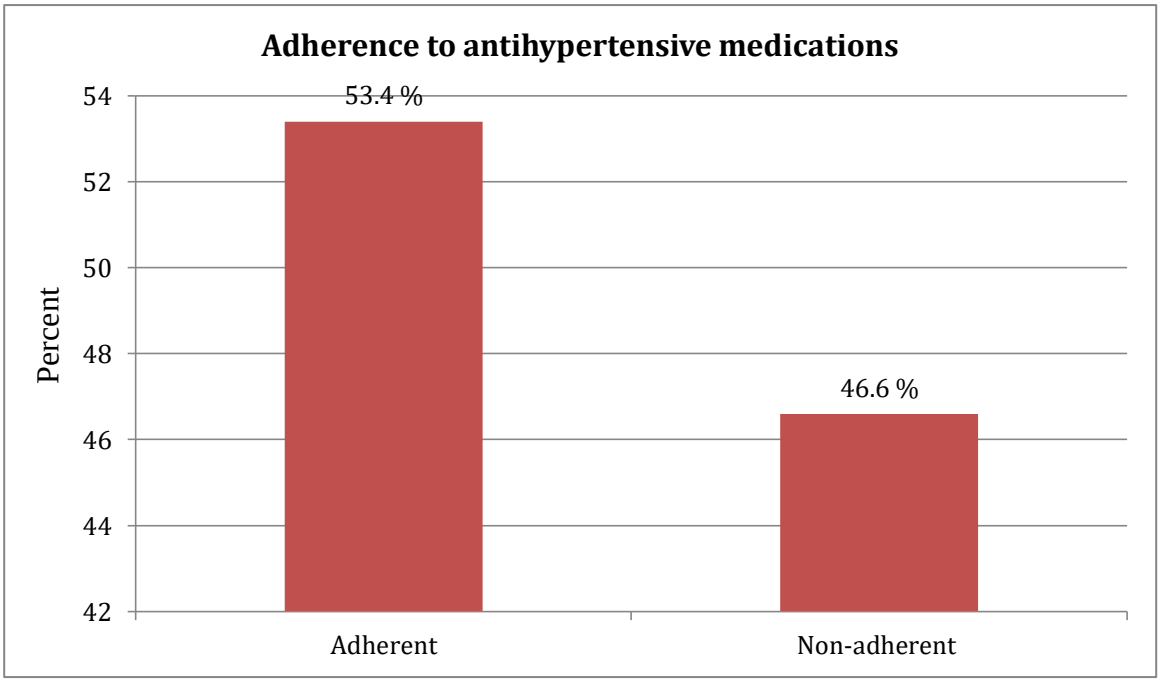
Table 4.2: Clinical characteristics of study participants

Characteristic	**Frequency (n=339)**	**%**
Antihypertensive medications prescribed		
Diuretics		
Hydrochlorothiazide	238	70.2
Furosemide	10	3
Spironolactone	6	1.8
Angiotensin Converting Enzyme (ACE) inhibitors		
Enalapril	196	57.8
Angiotensin Receptor Blockers (ARBs)		
Lorsatan	83	24.5
Calcium Channel Blockers (CCBs)		
Nifedipine- Retard	92	27.1
Amlodipine	39	11.5
Beta Blockers		
Propranolol	5	1.5
Atenolol	95	28
Carvedilol	8	2.4
Number of medications prescribed		
One	130	38.3
Two or more	209	61.7
Daily dosing frequency		
Once	244	72
Twice or more	95	28
Co morbidity profile		
Diabetes mellitus	76	22.4
Osteoarthritis	4	1.2
Peptic ulcer disease	11	3.2
Heart disease	8	2.4
Blood pressure status		
<140/90 mmHg	153	45.1
≥140/90 mmHg	186	54.9

4.3 Objective 1: To determine the prevalence of antihypertensive medication non adherence among hypertensive patients.

Out of a total of 339 hypertensive patients who participated in the baseline cross sectional survey, 46.6 % were found to be non-adherent to their prescribed medications- see Figure 4.1 The distribution of non-adherence by the various socio demographic characteristics and behavioral factors is given in Table 4.3.

Figure 4.1 Adherence to antihypertensive medications



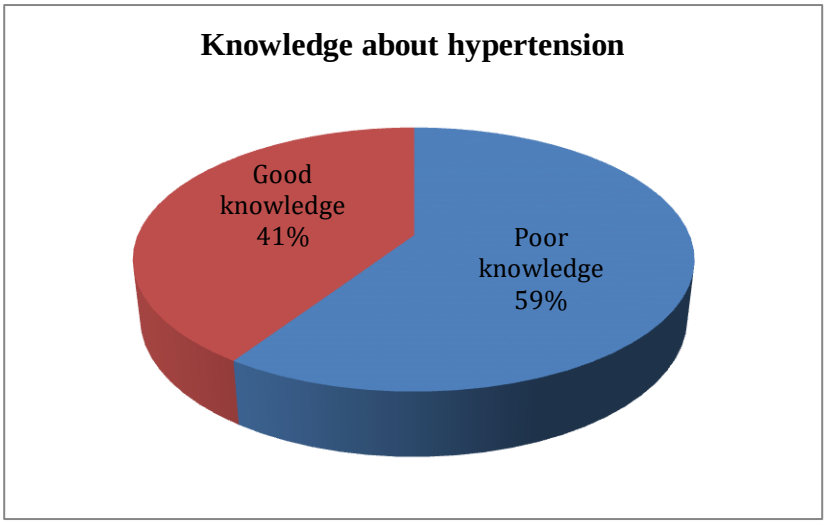
4.4 Objective 2: To identify factors associated with medication non-adherence among hypertensive patients.

4.4.1 Knowledge about hypertension

In this study, over half of patients interviewed (59.9%) were found to have poor knowledge about hypertension as assessed using a self-report tool. When asked about the target blood pressure reading for good blood pressure control, only 18.3% of the interviewed patients were able to correctly state the normal values. The understanding

that hypertension is an asymptomatic condition was also poor among the patients, with close to two thirds of those interviewed (60.8%) being unaware that an individual can be having high blood pressure even when they feel fine. Knowledge about the long-term complications of poorly controlled blood pressure was also poor among the interviewed patients, with 43.7% of them being unable to name at least one hypertension mediated organ complication. The findings from the baseline survey also indicated that the long-term nature of hypertension treatment was poorly understood among hypertensive patients; close to half (46.6%) of those interviewed did not know that they were supposed to take their medications throughout, unless advised to stop by their health care providers.

Figure 4.2 : Knowledge about hypertension



4.4.2 Factors associated with medication non-adherence

Table 4.3 shows the findings of bivariate analysis to identify variables associated with medication non-adherence. The variables that were significant at $p<0.2$, and therefore selected for inclusion in the multiple logistic regression model included: educational level, number of prescribed medications, daily dosing frequency, and knowledge about hypertension and presence/absence of a co-morbidity.

Table 4.4 presents the findings of the multiple logistic regression model fitted to compute the adjusted odds ratios of the various factors associated with medication non-adherence. The factors that were associated with medication non-adherence on adjusted analysis included: 1) Knowledge about hypertension; 2) Daily medication dosing frequency; and 3) Number of prescribed medicine. The likelihood of being non-adherent to prescribed medications was 5.6 times higher for those who those who had good knowledge about hypertension compared to those with poor knowledge. Taking two or more medications was associated with 2.8 times higher odds of non-adherence compared to being on one drug. The daily dosing frequency of prescribed medications was also a significant correlate of non-adherence; patients taking two or more doses of their pills per day were 2.3 times more likely to be non-adherent compared to those on once daily dosing.

Table 4.3: Bivariate Analysis of Variables Associated with Medication Non-Adherence

Variable	Medication Adherence		Test statistic	P value
	Adherent Frequency (%)	Non Adherent Frequency (%)		
Socio-demographic characteristics				
Gender			Chi square X^2 =0.84 df=1	0.361
Male	67 (37.0)	51 (32.3)		
Female	114 (63)	107 (67.7)		
Total	181 (100)	158 (100)		
Age			Chi square X^2 =3.1 df=2	0.211
30-44	12 (6.6)	7 (4.4)		
45-59	47 (26)	54 (34.2)		
≥60	122 (67.4)	97 (61.4)		
Total	181 (100)	158 (100)		
Education			Fisher's exact	0.122
None	26 (14.4)	31 (19.6)		
Primary level	94 (51.9)	75 (47.5)		
Secondary level	57 (31.5)	42 (26.6)		
College/university level	4 (2.2)	10 (6.3)		
Total	181 (100)	158 (100)		
Employment			Chi square X^2 =1.7 df=2	0.420
Formally employed	15(8.3)	19 (12.0)		
Unemployed	56 (30.9)	42 (26.6)		
Self employed	110 (60.8)	97 (61.4)		
Total	181 (100)	158 (100)		
Marital status			Chi square X^2 =2.4 df=3	0.494
Never married	16 (8.8)	15 (9.5)		
Married	134 (74)	125 (79.1)		
Divorced/separated	7 (3.9)	5 (3.2)		
Widowed	24 (13.3)	13 (8.2)		
Total	181 (100)	158 (100)		
Religion			Fisher's exact	0.342
Christian	180 (99.5)	155 (98.1)		
Muslim	1 (0.5)	3 (1.9)		
Total	181 (100)	158 (100)		
Number of prescribed medications:			Chi square X^2 =21.3 df=1	<0.0001*
One	90 (49.7)	40 (25.3)		
Two or more	91 (50.3)	118(74.7)		
Total	181 (100)	158 (100)		
Daily dosing frequency			Chi square X^2 =9.5 df=1	0.002*
Once	143 (79)	101 (63.9)		
Twice or more	38 (21)	57 (36.1)		
Total	181 (100)	158 (100)		
Level of hypertension related knowledge			Chi square X^2 =58.3 df=1	<0.0001*
Good	107 (59.1)	29 (18.4)		
Poor	74 (40.9)	129 (81.6)		
Total	181 (100)	158 (100)		
Co-morbidity			Chi square X^2 =3.1 df=1	0.080
Absent	138 (76.2)	107 (67.7)		
Present	43 (23.8)	51 (32.3)		
Total	181 (100)	158 (100)		

*Significant at 5% significance level;
df: degrees of freedom

Table 4.4: A multiple logistic regression model of factors associated with medication non-adherence.

Variable	Adjusted Odds Ratio (AOR)	95% confidence interval	P value
Level of knowledge about hypertension			
Good (reference)	1	3.3, 9.4	<0.001*
Poor	5.6		
Number of prescribed medications:			
One (reference)	1	1.7, 4.7	0.001*
Two or more	2.8		
Daily dosing frequency			
Once (reference)	1	1.3, 4.0	0.003*
Twice or more	2.3		

*Significant at 5% significance level.

4.5 Objective 3: To test the effectiveness of applying a mobile phone based intervention in optimizing adherence to antihypertensive medication.

4.5.1 Baseline comparison of the study groups

The baseline characteristics of the study participants in each of the two arms of the randomized controlled trial are presented in Table 4.5. Both study groups were similar by various socio-demographic characteristics including age and sex among other variables. The two groups were also comparable by baseline clinical characteristics such as blood pressure control and number of prescribed medications.

Table 4.5: Baseline Comparison of Study Groups

Characteristic	**Control group (n=60) Frequency (%)**	**Intervention group (n=60) Frequency (%)**
Socio-demographic characteristics		
Gender		
Male	12 (20%)	11 (18.3%)
Female	48 (80%)	49 (81.7%)
Total	60 (100%)	60 (100%)
Age (years)		
30-44	3 (5%)	2 (3.3%)
45-59	21 (35%)	17 (28.3%)
≥60	36 (60%)	41 (68.3%)
Total	60 (100%)	60 (100%)
Education		
Primary level	33 (55%)	37 (61.7%)
Secondary level	23 (38.3%)	21 (35%)
College/university level	4 (6.7%)	2 (3.3%)
Total	60 (100%)	60 (100%)
Employment		
Formally employed	7 (11.7%)	8 (13.3%)
Unemployed	14 (23.3%)	17 (28.3%)
Self employed	39 (65%)	35 (58.3%)
Total	60 (100%)	60 (100%)
Marital status		
Never married	5 (8.3%)	6 (10%)
Married	44 (73.3%)	45 (75%)
Divorced/separated	3 (5%)	5 (8.3%)
Widowed	8 (13.3%)	4 (6.7%)
Total	60 (100%)	60 (100%)
Religion		
Christian	56 (93.3%)	58 (96.7%)
Muslim	4 (6.7%)	2 (3.3%)
Total	60 (100%)	60 (100%)
Clinical characteristics		
Number of medicines prescribed:		
One	22 (36.7%)	20 (33.3%)
Two or more	38 (63.3%)	40 (66.7%)
Total	60 (100%)	60 (100%)
Daily dosing frequency		
Once	43 (71.7%)	45 (75%)
Twice or more	17 (28.3%)	15 (25%)
Total	60 (100%)	60 (100%)
Blood pressure control		
Controlled	10 (16.7%)	8 (13.3%)
Uncontrolled	50 (83.3%)	52 (86.7%)
Total	60 (100%)	60 (100%)

4.5.2 Effect of the intervention on knowledge about hypertension

The study's intervention led to a statistically significant improvement in hypertension related knowledge among patients in the experimental group over the six months of follow up. Table 4.8 and Figure 6 show the level of hypertension related knowledge both at baseline and at the end of follow up. The effect of the intervention on hypertension related knowledge was quantified through logistic regression analysis as shown in Table 4.6. At the end of follow up, the odds of having good knowledge about hypertension was 6.4 times higher for those who had received the study's intervention compared to those in the control arm.

Table 4.6: Comparison of level of hypertension related knowledge between the intervention and control groups, both at baseline and at the end of 6 months of follow-up

Dependent Variable	Time of measurement	Outcomes	Control group (n=60)	Intervention group (n=60)	Test statistic	P value
Hypertension related knowledge	At baseline	Good knowledge	11 (18.3%)	13 (21.7%)	Chi square $X^2 = 0.21$ df=1	0.648
		Poor knowledge	49 (89.7%)	47 (78.3%)		
	At 6 months	Good knowledge	12 (20%)	37 (61.7%)	Chi square $X^2 = 21.6$ df=1	<0.001*
		Poor knowledge	48 (80%)	23 (38.3%)		

*: Significant at 5% significance level.

Figure 4.4: Level of hypertension related knowledge at baseline and after 6 months

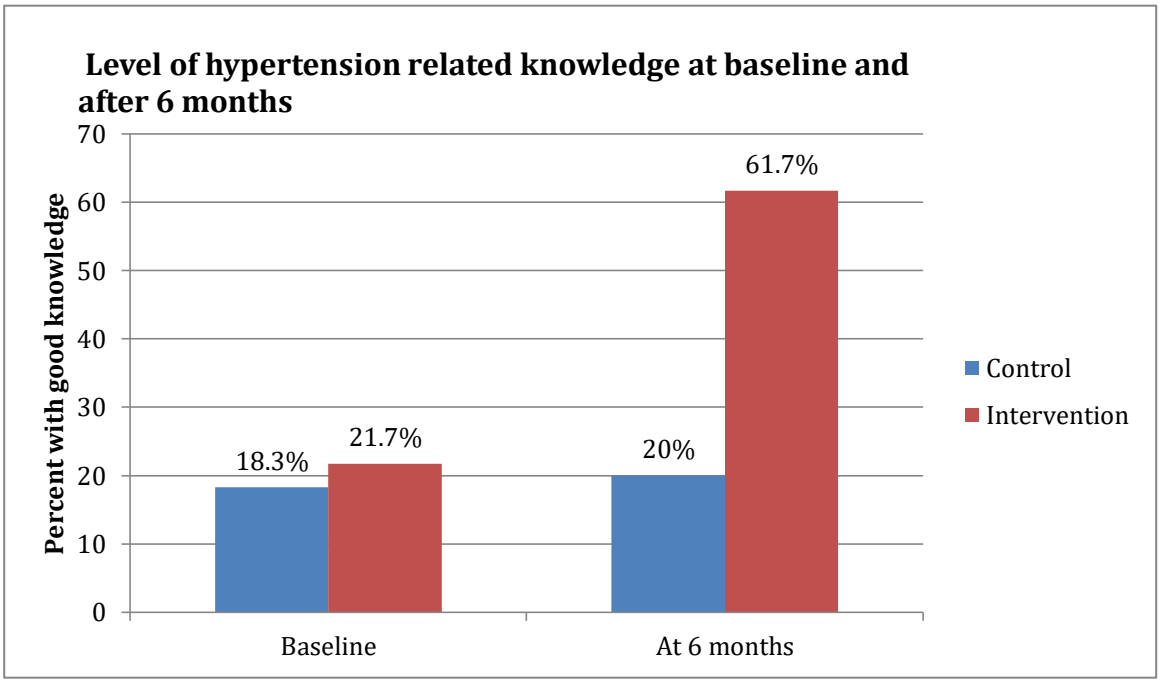


Table 4.7: Logistic regression on effect of the mobile phone intervention on hypertension related knowledge at the end of 6 months of follow up.

Groups	Odds ratio	95% Confidence Interval	P value
Control group (Reference)	1	2.8, 14.6	<0.001*
Intervention group	6.4		

*: Significant at 5% significance level.

4.5.3 Effect of the mobile phone intervention on antihypertensive medication adherence

Table 4.7 shows the change in medication adherence six months after implementation of the mobile phone based intervention. At baseline, participants in both arms of the trial had comparable levels of medication adherence: 10% and 11.7% for the intervention-

al arm and the control group respectively. At the end of 6 months of follow up, the proportion of hypertensive patients who were adherent to their medications was 38.3% higher in the interventional group compared to that of the control group, an indication that the study's intervention had a positive impact on medication adherence (P<0.001). The odds of being adherent to antihypertensive medication was 6.1 times higher for those who had been put on the mobile phone based intervention compared to those who were in the control group (95% CI 2.6, 14.3).

Table 4.8: Comparison of level of medication adherence between the intervention and control groups, both at baseline and at the end of 6 months of follow-up

Dependent Variable	**Time of measurement**	**Outcomes**	**Control group (n=60)**	**Intervention group (n=60)**	**Test statistic**	**P value**
Medication adherence	At baseline	Adherent	7 (11.7%)	6 (10%)	Chi square $X^2 = 0.086$ df=1	0.769
		Non adherent	53 (88.3%)	54 (90%)		
	At 6 months	Adherent	10 (16.7%)	33 (55%)	Chi square $X^2 = 19.2$ df=1	<0.001*
		Non adherent	50 (83.3%)	27 (45%)		

*: Significant at 5% significance level.

Figure 4.3: Level of medication adherence at baseline and after 6 months of follow up

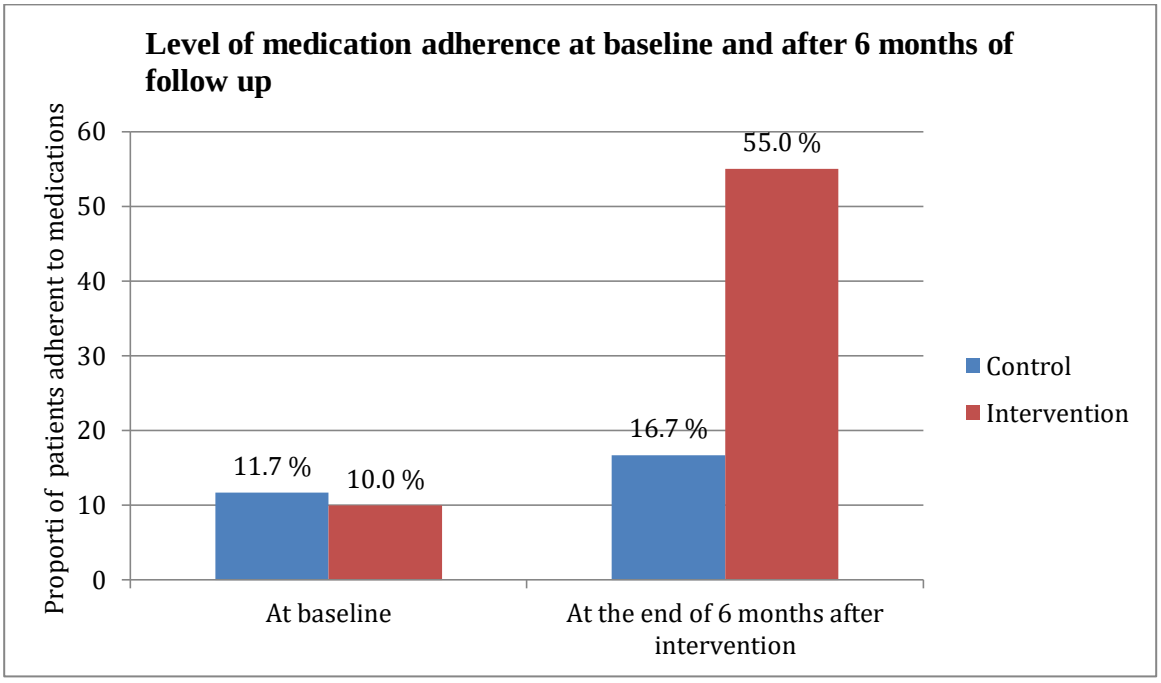


Table 4.9: Logistic regression on effect of the mobile phone intervention on medication adherence at the end of 6 months of follow up.

Groups	Odds ratio	95% Confidence Interval	P value
Control group (Reference)	1	2.6, 14.3	<0.001*
Intervention group	6.1		

*: Significant at 5% significance level.

4.5.4. Influence of the intervention on patients' beliefs about antihypertensive medications

At the end of a 6-month period following completion of the trial, the intervention was found to have positively influenced the beliefs held by patients in relation to their prescribed medications. Table 4.10 shows the scores obtained from measurement scales

assessing the beliefs held by patients regarding the necessity of taking their medicines and perceived concerns of negative consequences of using their medications. Based on the scores recorded, patients who had received the mobile phone intervention had stronger beliefs about the necessity of taking their prescribed medicines compared to those in the control arm; higher scores indicated stronger beliefs on the attribute being assessed by items in the BMQ-S scale. Similarly, patients in the experimental arm had weaker beliefs that their medicines may have negative health consequences on them.

Table 4.10: Beliefs about medication (BMQ-S) scores at the end 6 months post intervention follow up

BMQ Scores	Control (n=55) Mean+/- SD	Intervention (n=57) Mean+/- SD	Test statistic	Degrees of freedom (df)	p Value
Necessity score	12.5 +/- 3.0	19.2 +/- 5.1	*t* test	110	<0.001*
Concerns score	16.4 +/- 3.3	10.0 +/- 3.9	*t* test	110	<0.001*

*: Significant at 5% significance level.

4.5.5 Influence of the intervention on patients' perceptions about hypertension

Table 4.11 shows the illness perception scores obtained from patients in both arms of the trial. The trial's intervention which was educational in nature, positively influenced the patients' perceptions about hypertension. Compared to patients in the control arm, patients who had received the study's intervention had a higher score on their understanding that hypertension is a chronic condition that requires lifelong management. The patients who had received the intervention also expressed more confidence that their prescribed medications were effective in controlling their condition. Patients in the experimental arm also scored higher on self-reported understanding of hypertension.

However, the intervention had a modest effect on the extent to which patients perceived themselves to be in control of their illness.

Table 4.11: Brief illness perception questionnaire (BIPQ) scores at the end of 6 months of post intervention follow up

BIPQ Domains and Items	**Control (n=55) Scores (Mean +/- SD)**	**Intervention (n=57) Scores (Mean +/- SD)**	**Tests statistic**	**Degrees of freedom (df)**	**p Value**
Timeline How long do you feel your illness will continue (0=Very short time- 10=Forever)	4.3 +/- 1.4	8.2 +/- 1.0	*t* test	110	<0.001*
Personal control How much control do you feel you have over your illness? 0=Absolutely no control-10=extreme amount	3.3 +/- 1.1	5.1 +/- 1.2	*t* test	110	<0.001*
Treatment control How much do you think your treatment can help your illness? (0=Not at all-10=extremely helpful)	4.5 +/- 1.7	8.7 +/- 0.9	*t* test	110	<0.001*
Coherence How well do you feel you understand your illness? (0=Don't understand-10=understand very clearly)	3.8 +/- 1.6	8.6 +/- 1.1	*t* test	110	<0.001*

4.6 Objective 4: To determine the effect of the study's mobile phone intervention on blood pressure control

Table 4.12 shows the levels of blood pressure control of the patients enrolled in the two arms of the study, both at baseline and at the end of six months of follow up. At baseline, only 15% of all study participants had their blood pressures within the recommended limits (<140/90 mmHg), and the level of blood pressure control did not differ significantly between the two groups. At the end of six months of follow up, the proportion of patients with controlled blood pressure among those in the intervention arm was higher by 33.3%, compared to that of the control group. The blood pressure improvement effect of the study's intervention was further observed after a logistic regression analysis, which showed that the likelihood of having well controlled blood pressure was 4.6 times higher for those who had received the study's intervention compared to those in the control group- see Table 4.13.

Table 4.12: Comparison of level of blood pressure control between the intervention and control groups, both at baseline and at the end of 6 months of follow up.

Dependent Variable	**Time of measurement**	**Outcomes**	**Control group (n=60)**	**Intervention group (n=60)**	**Test statistic**	**P value**
Blood pressure control	At baseline	BP controlled	10 (16.7%)	8 (13.3%)	Chi square $X^2 = 0.26$ df=1	0.609
		BP not controlled	50 (83.3%)	52 (86.7%)		
	At 6 months	BP controlled	12 (20%)	32 (53.3%)	Chi square $X^2 = 14.4$ df=1	<0.001*
		BP not controlled	48 (80%)	28 (46.7%)		

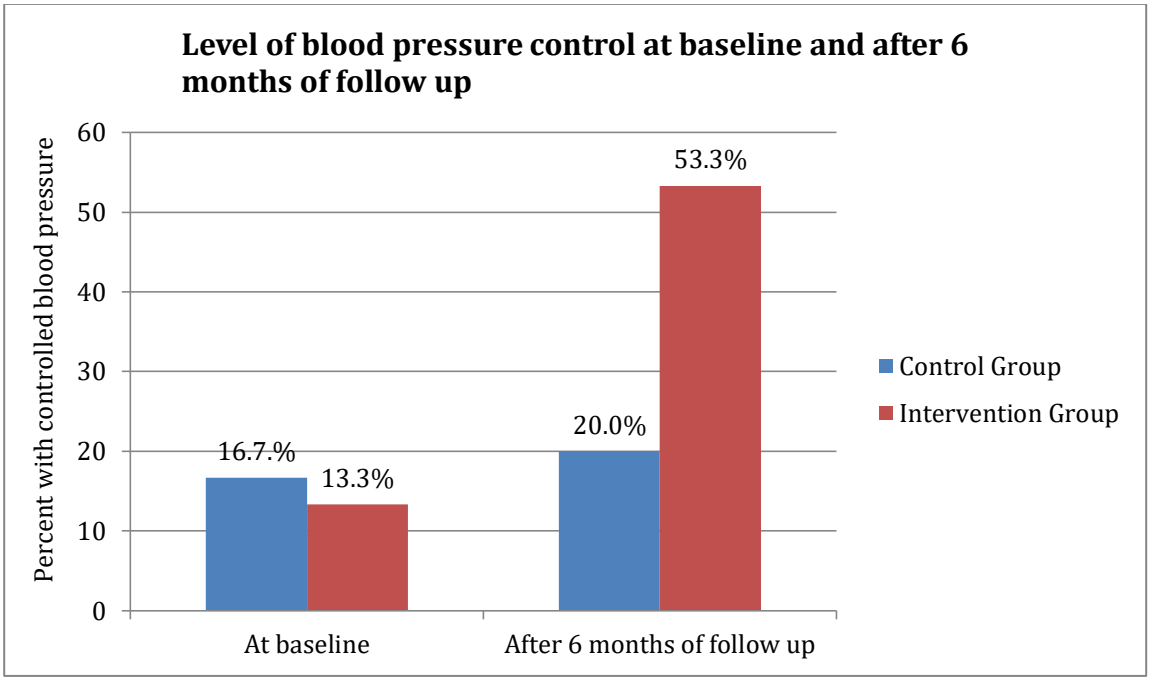
*: Significant at 5% significance level.

Table 4.13: Logistic regression model on effect of the mobile phone intervention on blood pressure control at the end of 6 months of follow up.

Groups	Odds Ratio	95% Confidence Interval	P value
Control group (Reference)	1	2.0, 10.3	<0.001
Intervention group	4.6		

*: Significant at 5% significance level.

Figure 4.5: Level of blood pressure control at baseline and after 6 months of follow up



4.7 Patient experiences with the study's mHealth intervention

Qualitative data obtained from selected patients who received the study's intervention indicated an improvement in the patients' knowledge about various aspects of hypertension. Many patients reported that their understanding of the chronic nature of hyperten-

sion substantially improved after having been enrolled in the study's mHealth intervention.

"*Previously, I had not fully understood this disease of blood pressure. I used to think that I will get cured of the disease after using my prescribed medicines for some time. But now I know, I should not stop the medicines without advice from my doctor*" (A patient on follow-up care for hypertension in Nyeri Medical Outpatient Clinic)

Patients who had been put on the intervention also appeared to have gained an understanding of the asymptomatic nature of hypertension. When asked to highlight any new information they may have received from the messages shared with them, several patients reported that they now understood that blood pressure may be high even when they were not experiencing any symptoms.

"*For now, if there is one thing that those messages helped me in knowing is that this disease of 'pressure' usually does not have symptoms. Previously I used to think that pressure would only be high when I'm stressed or feeling dizzy, but now I know the pressure might be elevated even when I feel fine. I used to think that I should only be taking medicines when I feel like the pressure is high, but now I know better*." (A patient on follow-up care for hypertension in Nyeri Medical Outpatient Clinic)

The mHealth intervention also appeared to have enhanced the patients' understanding of the risks associated with uncontrolled blood pressure. Several of the patients interviewed reported that the health messages shared with them enabled them to understand the likely risks of having poorly controlled blood pressure such as stroke, heart disease and kidney failure.

"*Previously I used to wonder why I should continuing using these medicines for blood pressure, and yet most of the time I am just okay, without any health problem. But now, I am informed that skipping the medicines may leave my blood pressure high and thereafter I may develop certain health problems such as stroke. In fact I have seen several people in my neighborhood who suddenly collapsed and got paralyzed, and now I understand this disease of pressure may have been the cause"* (A patient on follow-up care for hypertension in Nyeri Medical Outpatient Clinic)

However, despite several patients showing improved understanding of various aspects of hypertension, some patients indicated in their responses that they still needed to be explained further on whether it is possible for someone to be given medicines that can 'cure' the disease; just the same way they get treated for other ailments.

"*Yes I have been informed that it is important I continue taking my medicines for blood pressure all through, but is there a way I can be given medicines that can cure me of this disease?"* (A patient on follow-up care for hypertension in Nyeri Medical Outpatient Clinic)

4.8 Perspectives on the expected benefits and implementability of the study's intervention

Responses from key informants highlighted that the mHealth intervention undertaken in the study was implementable in the existing health care system, given the widespread possession of mobile phones in the population. The informants noted that the intervention would offer a cost effective platform for offering important health messages to ad-

dress medication non-adherence, which they noted, was a major hindrance to blood pressure control. One of the key informants noted:

"*Indeed the findings emerging from this study come at a time when interventions are urgently needed to address the issue of medication non-adherence among hypertensive patients on follow up*". (Director of Research, Nyeri County Department of Health)

The informants also expressed optimism that the intervention may not only apply to supporting medication adherence among hypertensive patients, but can also be extended to other chronic illnesses, for which compliance to prolonged treatment is required.

"*Medication non-adherence is a common problem across many chronic illnesses that require prolonged treatment. I think the mHealth intervention applied in this study may also be extended to other chronic conditions to optimize treatment outcomes*" (Nursing Officer In charge, Nyeri Medical Outpatient Clinic)

The potential cost effectiveness of the mHealth intervention in improving treatment outcomes for patients on follow up for hypertension was alluded by one of the key informants as noted below:

"*Implementing such a mHealth based strategy to share important health messages with patients would probably require fewer resources as compared to having patients undergo scheduled face to face health education sessions which would require additional health care personnel*" (Director of Health, Nyeri County Department of Health)

CHAPTER FIVE: DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

5.1 Discussion

This section gives interpretations and explanations for the different findings generated from this study. Relations between the study's results and the existing body of knowledge corresponding to the different aspects of the problem under investigation are also drawn. The discussion of the different findings has been organized around thematic areas derived from specific objectives that informed design of the study.

5.1.1 Characteristics of Study Participants

The purpose of this study was to test the effectiveness of implementing a mHealth based intervention to improve medication adherence among patients on follow up for hypertension in Nyeri County. The study was undertaken in two phases; phase one comprised of a baseline cross sectional survey to assess the level of antihypertensive medication adherence among the selected study participants, while phase two entailed a randomized controlled trial to test the effectiveness of mHealth in supporting patients living with hypertension to adhere to their prescribed medications.

The study sample comprised of hypertensive patients undergoing follow-up care in two referral hospitals, serving a diverse population of Nyeri County residents. Of the 339 hypertensive patients enrolled in the baseline cross sectional survey on antihypertensive medication adherence, about two thirds of them were women. The higher representation of women among the patient population surveyed in this study may be explained by the gender-based disparity in health-seeking behavior that has been documented in other similar surveys (Cheong *et al.*, 2020; Kimando *et al.*, 2017). Though the underlying rea-

sons remain unclear, previous studies in different settings have reported that women are more likely than men to seek health care services (Thompson *et al.*, 2016).

Similar to findings obtained from previous related studies (Kimando *et al.*, 2017; Muthuki *et al.*, 2020), a large majority of the hypertensive patients included in our study sample were older people, aged 60 years and above. Another cross sectional survey on health seeking behaviors among adults drawn from diverse rural settings in Kenya, also found a higher representation of elderly people among those diagnosed with hypertension (Karinja *et al.*, 2019). Advanced age has been recognized in epidemiological studies as a risk factor for hypertension and other non-communicable diseases, with many cases of the condition usually diagnosed in the older age category (Shukuri *et al.*, 2019; Wekesah *et al.*, 2018). Phone ownership among the patient population surveyed in this study was high (over 80%), a finding that is consistent with current statistics indicating that possession of mobile phones in Kenya is almost becoming ubiquitous (Communication Authroity of Kenya, 2018; Krell *et al.*, 2021).

In the interventional arm of the study, the baseline socio-demographic and clinical characteristics of study participants randomized to either of the two study groups (experimental and control groups) were similar, an indication that the randomization process was effective in achieving a sufficient level of comparability to control any potential source of confounding between the trial's independent and dependent variables. In randomized controlled trials, randomization is regarded as a vital procedure to eliminate any likely influence from a third extraneous factor (confounding variable) that may dis-

tort the relationship between a specified independent variable and an outcome variable (Hariton & Locascio, 2018).

5.1.2 Prevalence of medication non-adherence among hypertensive patients.

In the first phase of this study, a cross sectional survey was undertaken to determine the prevalence of antihypertensive medication non-adherence among hypertensive patients undergoing follow-up in two selected tertiary care hospitals in Nyeri County. The findings of this survey indicated that nearly half (46.6%) of hypertensive patients on follow-up in the two hospitals were non-adherent to their prescribed antihypertensive medications. Non-adherence to antihypertensive medication contributes to suboptimal blood pressure control, leading to an increased risk of developing end-organ disorders such as ischemic heart disease, kidney disease, and stroke (Oparil *et al.*, 2018). The level of medication non-adherence found in this study is comparable to findings from a previous study by Otenyo *et al*., which reported that 42.4% of hypertensive patients on follow up in a hospital in Mombasa County, Kenya, had sub-optimal adherence to their prescribed medications (Otenyo & Maranga, 2018). However, other studies conducted previously in different settings in Kenya recorded a higher level of medication non-adherence. A study conducted by Moss *et al* among hypertensive patients on follow up in health facilities in Kilifi county, coastal Kenya, found that 85.4% of the patients surveyed had sub-optimal adherence to their prescribed medications (Moss *et al.,* 2021). Another study by Otenyo *et al* conducted among hypertensive patients on follow- up in Nakuru County Referral Hospital in Nakuru County, found that 66.7% of the patients had low adherence to their medications (S. O. Otenyo & Kereri, 2021a). This variation may be attributed to the fact that our study was conducted in a setting where patients were obtain-

ing their prescribed medications at no costs under an existing national programme on universal health coverage (described earlier in methods section). Previous research has identified co-payments for medications as a barrier to adherence (van der Laan *et al.*, 2017).

The high proportion of hypertensive patients identified to be non-adherent to their medications in this study, adds to the growing body of evidence that medication non-adherence is a significant health problem, especially in developing countries. An earlier metanalysis study reported that 63.4% of hypertensive patients on follow up in low and middle income countries were non-adherent to their medications based on self-report (Nielsen *et al.*, 2017). In the African setting, it has been reported that the chronic and asymptomatic nature of hypertension is not well appreciated, and consequently, many patients usually skip doses or discontinue themselves of medications when they are not experiencing any symptoms (Agyei-Baffour *et al.*, 2018; Chimberengwa *et al.*, 2019; Najjuma *et al.*, 2020; Temu *et al.*, 2017). A previous survey conducted among residents of Nyeri County reported a lack of understanding of the asymptomatic nature of hypertension among the study participants (Freiberg *et al.*, 2016).

5.1.3 Factors associated with medication non-adherence among hypertensive patients.

On multivariate analysis, the factors associated with non-adherence to antihypertensive medication included having poor knowledge about hypertension, being on multiple medications and receiving two or more doses of drugs per day. The odds of being non-adherent to prescribed antihypertensive medications was 5.6 times higher for patients with poor knowledge about hypertension compared to those with good knowledge. This

finding is consistent with several previous studies that have established a strong link between knowledge about hypertension and medication adherence. A cross sectional study conducted among patients with hypertension in Saudi Arabia found that patients with good knowledge about hypertension were seven times more likely to be adherent to their prescribed medications compared to those with poor knowledge (F. M. Algabbani & A. M. Algabbani, 2020). Another study conducted in Ethiopia among patients on follow up care for hypertension in a tertiary hospital also reported a positive association between knowledge about the condition and medication adherence (Teshome *et al.,* 2017). In a cross sectional study conducted in Indonesia among people with hypertension, it was established that patients who had good hypertension knowledge were 7.1 times more likely to be adherent to their medications compared to those with poor knowledge (Rahmawati & Bajorek, 2018).

In this study, close to half (46.6%) of the patients interviewed in the baseline survey did not know that they were supposed to take their medicines throughout unless advised otherwise by their health care providers. Previous studies done in African populations have reported poor understanding of the chronic nature of hypertension. A qualitative study done among hypertensive patients in Uganda found that over a third of the patients interviewed did not know that hypertension is a chronic illness that requires lifelong treatment (Lynch *et al.,* 2019). In a survey conducted on health seeking behaviors among patients with hypertension and diabetes in diverse rural care settings in Kenya, a significant number of patients (30%) reported that they usually discontinue themselves of medication when they feel like they have ‘recovered’ from the disease (Karinja *et al.*, 2019). Similar misconceptions that hypertension is a short-lived curable disease were

also documented in a previous study done in South Africa (Mpinda *et al.*, 2014). A systematic review conducted in Nigeria on hypertension-related beliefs among persons drawn from different ethnic origins reported that a majority of people in the country believed that hypertension is temporary and not chronic (Akinlua *et al.*, 2016).

A majority of the hypertensive patients interviewed in the baseline survey (60.8%) were found to be lacking knowledge that hypertension is an asymptomatic disease. Despite hypertension being described in the medical literature as a "silent killer," existing literature indicates that the asymptomatic nature of this condition is poorly appreciated in African populations (Akoko *et al.*, 2017; Lynch *et al.*, 2019). Lack of proper understanding about the asymptomatic course of hypertension progression among hypertensive patients can negatively impact their adherence to prescribed medications (Bokhour & Kressin, 2015; Michel Burnier & Brent M. Egan, 2019). For instance, if a patient associates high blood pressure with experiencing a particular symptom, they may only take their medicines when they 'feel' that the pressure is high. Existing evidence shows that health literacy is an important determinant of uptake of healthy behaviors and self-care practices among patients with chronic illnesses (van der Gaag *et al.*, 2022). Hence, it is important that strategies are put in place to enhance understanding of the different aspects of hypertension among hypertensive patients in different care settings.

Being on multiple medications was significantly associated with increased odds of being non-adherent to prescribed medications. This finding is consistent with a study conducted in Cameroon, which found that patients who were on multiple antihypertensive drugs were more likely to be non-adherent to their medicines compared to those on a

single drug (Adidja *et al.,* 2018). Several other studies conducted in different settings have also established an inverse association between the number of prescribed antihypertensive medications and adherence (Gupta *et al.,* 2017; Jankowska-Polańska *et al.,* 2017; Kulkarni *et al.,* 2021; Napolitano *et al.,* 2016; Teshome *et al.,* 2017). Being on multiple medications may contribute to what has been described in the literature as 'pill burden,' where patients have a challenge in following the specified frequencies for taking different drugs at certain times (Vrijens *et al.,* 2017).

Patients who were receiving two or more doses of their prescribed medicines per day were also found to have a higher likelihood of being non-adherent to their medications. This finding is consistent with several previous studies that have established a positive association between the frequency of daily dosing and antihypertensive medication non-adherence (Adidja *et al.,* 2018; Asgedom *et al.,* 2018; M. Burnier & B. M. Egan, 2019). There is also a growing body of evidence that single pill fixed dose drug combinations simplify drug taking behavior and subsequently improve adherence (Michel Burnier & Brent M. Egan, 2019; Vrijens *et al.,* 2017). These findings are thus significant and relevant in guiding formulation of practice guidelines that promote adoption of monotherapy and fixed drug combinations as a strategy to enhance antihypertensive medication adherence.

5.1.4 Effectiveness of mHealth on antihypertensive medication adherence.

In the second phase of this study, a randomized controlled trial was implemented to investigate the effectiveness of applying a mobile phone delivered educational intervention to improve medication adherence among patients on follow-up care for hypertension in Nyeri County Referral Hospital. The findings of this trial, implemented over six month duration, revealed that patients who received the intervention had a 38.7% higher level of adherence compared to those in the control group. The odds of being adherent to prescribed medications was six times higher for patients who received the mHealth intervention compared to those in the control group. These findings add to the growing body of evidence on the effectiveness of mHealth based interventions in improving medication adherence and cardiovascular outcomes among hypertensive patients (Palmer *et al.,* 2018).

In a randomized controlled trial conducted in Chile, patients who received an *sms* based educational intervention on hypertension had a 30% higher level of medication adherence compared to those in the control group (Varleta *et al.,* 2017). In another interventional study, which involved a phone call to hypertensive patients on follow up in a hospital in Texas, US, patients who received the intervention were three times more likely to have persisted with their prescribed medications compared to those in the control group (Abughosh *et al.,* 2016). In a recent meta-analysis study, it was reported that mHealth interventions that shared health information to enhance patient understanding of hypertension significantly led to an improvement in medication adherence and blood pressure self-monitoring among patients on follow up for hypertension (R. Li *et al.*, 2020).

The medication adherence improvement effect observed in our study is higher than that recorded in a similar study done in South Africa (Kirsten Bobrow *et al.*, 2016). The South African study was a randomized controlled trial designed to test the effectiveness of an *sms* based intervention in improving medication adherence and blood pressure control among hypertensive patients on follow up in an outpatient clinic in Cape Town. In the study, patients receiving the *sms* intervention over a 12 month duration had a 13.4% higher level of medication adherence compared to those in the control group. In our current study, the level of medication adherence among patients in the experimental arm was 38.7% higher than that of their counterparts in the control arm. The higher level of effect observed in our current study may be explained in two ways.

Firstly, our study was conducted in two phases, where in the first phase, a survey was undertaken to establish the baseline understanding of hypertension among hypertensive patients in the target population. Based on the knowledge gaps and misconceptions identified in the survey, tailored health messages were formulated to enhance the patients' understanding of the different aspects of hypertension including, the asymptomatic nature of the condition and the need for lifelong treatment. The formulation of text messages in the South African trial was based on theoretical models, without factoring the local understanding and perception of hypertension among the study subjects included the trial.

Secondly, in our study, the intervention involved both *sms* messages and follow-up phone calls to engage patients on any hypertension related queries. In the South African study, the intervention involved only *sms* messages without a phone call. Previous stud-

ies have pointed towards the need to make mobile phone based interventions interactive to allow for a two way engagement between health professionals and patients (Mao *et al.*, 2020). It has also been established that mHealth interventions with a high potential for success are those that combine sms messages and interactive communication (R. Li *et al.*, 2020).

Other than medication adherence, which was the primary outcome variable in this study, the effect of the intervention was also explored on other intermediary variables including knowledge, beliefs and perceptions about hypertension and antihypertensive medications. Patients who received the intervention were 6.4 times more likely to possess good knowledge about hypertension compared to those in the control group. Previous research has demonstrated a strong link between knowledge about hypertension and medication adherence (F. M. Algabbani & A. M. Algabbani, 2020; Xiong *et al.*, 2022). Hence, the positive effect of the trial's intervention on adherence may be partly explained by the improvement in hypertension related knowledge among patients in the experimental arm of the study. The trial's intervention also positively influenced the patients' understanding and perception of hypertension as a chronic illness that requires long-term treatment. The beliefs that long-term use of antihypertensive medications may lead to negative health outcomes were significantly weaker among patients who received the trial's intervention compared to those in the control arm. This phenomenon is therefore likely to have positively contributed to an improvement in medication taking behavior among patients who received the study's intervention.

5.1.5 Effectiveness of mHealth on blood pressure control.

The effect of the mobile phone intervention on blood pressure control among participants of the trial was examined as a secondary outcome variable. At the end of the six months of follow up, the proportion of patients who had achieved blood pressure control was higher by 33.3% among patients in the experimental arm, compared to those in the control group. The odds of having well controlled blood pressure were 4.6 times higher for those who had received the study's intervention compared to those in the control arm. This finding is corroborated by data from other related studies, where use of educational mobile phone based interventions has been found to contribute to improvement of blood pressure control among hypertensive patients.

In an interventional study in Mumbai, India, hypertensive patients who received health educative phone calls from their health care providers recorded a 25.2% higher level of blood pressure control compared to those in the control arm (Kannure *et al.*, 2021). Similar findings have also been reported in two recent meta-analysis studies, where application of mHealth interventions including phone calls, text messages and mobile applications were found to significantly contribute to improvement in blood pressure control (Lu *et al.*, 2019; Mao *et al.*, 2020). The improvement in blood pressure control among patients who received the study's intervention can also be explained from the observed positive effect of the intervention on medication adherence. Emerging evidence suggests that medication adherence is one of the most important determinants of blood pressure control among people living with hypertension (Chia *et al.*, 2021; Niteesh K. Choudhry *et al.*, 2022).

5.1.6 Perceived benefits and implementability of the study's intervention.

Patients who interacted with the study's intervention demonstrated enhanced self-understanding of their condition, and also expressed willingness to continue taking their medicines as instructed by their health care providers. Analysis of responses from several patients who were interviewed indicated that the educational mHealth intervention undertaken in this study may have substantially helped in imparting correct knowledge about various commonly misunderstood aspects of hypertension such as the chronic and asymptomatic nature of the condition. Existing evidence shows that mHealth interventions significantly contribute to improvement in patients' health literacy and subsequently resulting to overall improvement in medication adherence and self-management (Cao *et al.*, 2022; Garner *et al.*, 2020).

Responses from key informants, who comprised of health care managers and policy makers drawn from Nyeri County Department of Health, indicated that the mHealth intervention undertaken in this study was a viable strategy to support medication adherence and improve treatment outcomes among patients on follow up for hypertension. In Kenya, there is a national policy initiative (eHealth strategy) that is aimed at up-scaling use of technology in delivery of health care delivery, and therefore the evidence generated in this study will go a long way in facilitating achievement of the envisaged goals in this initiative. As noted by the key informants, adoption of the mHealth intervention undertaken in this study is highly feasible, given the high mobile phone penetration in the country, currently standing at 80% (CAK, 2018).

5.2 Conclusions

This study found that a mobile phone delivered health educational intervention is an effective strategy to support medication adherence among hypertensive patients on follow-up care. The intervention also positively impacted blood pressure control among the patients on follow up.

Findings from a baseline survey conducted in the first phase of this study indicated that medication non-adherence is an important problem among hypertensive patients on follow up; nearly half of hypertensive patients on follow in the two study hospitals were non-adherent to their prescribed medications. The factors associated with medication non-adherence based on findings from the survey were poor knowledge about hypertension and being on complex treatment regimens comprising of multiple medications and frequent daily dosing.

5.3 Recommendations

Based on the evidence generated from this study, a number of recommendations have been proposed to contribute to solving the problems identified in the health care system. The recommendations have been grouped into various categories based on the targeted implementers.

5.3.1 Recommendations for health care providers

i) Health care providers should incorporate adherence supportive interventions in their routine care of patients with hypertension. Measures seeking to address antihypertensive medication non-adherence should among other factors, focus on enhancing patients' understanding of the chronic and asymptomatic

nature of the condition, and the health complications associated with uncontrolled blood pressure.

ii) The use of simplified dosing regimens with fewer medications and once daily dosing frequency should be encouraged where appropriate.

5.3.2 Recommendations for health policy makers

i) Hypertension treatment guidelines should incorporate interventions for supporting medication adherence to optimize patient treatment outcomes. Mobile phone based interventions including automated bulk text messaging and voice calls can be designed and utilized to enhance patients' understanding of hypertension, therefore contributing to addressing patient related barriers to medication adherence and blood pressure control.

ii) The health care system can leverage the expansive mobile phone coverage among the Kenyan population to develop tailored adherence supportive interventions with the potential to reach out to a wider segment of hypertensive patients on follow-up in different health care facilities in the country.

5.3.3 Suggestions for further research

i) While the findings of this study provide evidence for effectiveness of a mobile phone based intervention in improving medication adherence, further research on the cost effectiveness of the intervention can be conducted to facilitate evidence based decision making and resource allocation.

ii) Given that this study mainly focused on patient related factors for antihypertensive medication adherence, it would be of interest to have further research conducted to understand and address the health system wide factors associated with medication non-adherence in different care settings in the country.

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APPENDICES

Appendix 1: Informed Consent Form

Part A: Research Details

Name of Principal Investigator**:** Ernest Mutua

Name of Organization**:** Kenyatta University

Study Title: Use of Mobile Phone Based Intervention in Improving Medication Adherence among Hypertensive Patients in Nyeri County, Kenya

Target group: Persons with hypertension in Nyeri County

Part B: Introduction

We are conducting a study on hypertension in Nyeri County and you have been selected to be one of the participants. I would therefore like to explain to you what the study is all about so that you can be able to make a choice on whether you will participate or not.

Part C: Purpose

This study is aimed at testing an intervention that may potentially be helpful in improving adherence to hypertensive medication.

In this study, I will ask you a few questions, for which you will be free to respond to in any way you find appropriate. You are free not to answer any question you might feel uncomfortable about. Please feel free to ask any question before or during the interview that you may wish to have clarified. Depending on the group you will be assigned to in the study, you may be called on your mobile phone and aslo receive some sms health messages about hypertension.

Part D: Benefit

Once completed, the findings of the study will be utilized to formulate interventions to enhance the care you receive for hypertension in the facilities you are followed up.

Part E: Confidentiality

The information you give in this study will be treated with utmost confidentiality and your details will not be used for any other purposes except for the study. You will not be required to write your name on the data forms in order to prevent undue exposure of your information.

Part F: Risks

The study as designed does not pose any risk to you or your health. Your choice to participate or not participate in this study will not affect the usual care you usually receive in the facilities you are followed up.

Do you have any questions regarding this study that you might want me to respond to? Please free to ask if any.

If you agree to participate in this study, please sign below or put a thumb print as appropriate.

Part G: Certificate of Consent

I have read through the information provided herein, or it has been read to me. I have also been presented with an opportunity to ask questions about this study, and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to offer to participate in this research.

Name of Participant_____

Signature of Participant _____

Date _____

If illiterate, a Witness will be enjoined as follows:

I have witnessed the consent form being read to the potential participant named below accurately, and the individual has had the opportunity to ask questions. I confirm that the individual has consented freely to participate in the study.

Name of Witness_____

Signature of Witness _____

Date _____

Name of Participant_____

Thumb print of Participant

Statement by the Researcher/Person Taking Consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability, ensured that the participant understands all the procedures pertaining to the study.

I confirm that the participant had an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has consented freely and voluntarily to participate in this study without any coercion.

The participant will be provided with a copy of this ICF.

Name of Person Taking Consent_____

Signature of Person Taking Consent _____

Date_____

Swahili Version

Sehemu ya A: Maelezo ya Utafiti

Jina la Mtafiti Mkuu**:** Ernest Mutua

Jina la Shirika**:** Chuo Kikuu cha Kenyatta

Kichwa cha Utafiti: Matumizi ya Simu ya Mkono katika Kuboresha Utumizi wa Madawa kwa Wagonjwa wa presha katika Kata ya Nyeri, Kenya

Kikundi cha Lengo: Watu wenye ugonjwa wa presha katika kata ya Nyeri.

Sehemu ya B: Utangulizi

Tunafanya utafiti juu ya ugonjwa wa presha katika kata ya Nyeri na umechaguliwa kuwa mmoja wa washiriki. Kwa hivyo ningependa kukuelezea ni nini utafiti unahusu ili uweze kufanya uchaguzi juu ya kama utashiriki au la.

Sehemu ya C: Sababu

Utafiti huu unanuia kutafuta mbinu zinaowekwa kukusaidia kutumia madawa zako za presha vizuri.

Katika huu utafiti, nitakuuliza maswali machache, ambayo utakuwa huru kujibu kwa njia yoyote unavyoona inafaa. Uko na uhuru wa kutojibu swali lolote lenye ungehisi haikosawa kwako. Tafadhali jisikie huru kuuliza swali lolote kabla au wakati wa mahojiano ambayo ungependa nifafanue. Kulingana na kikundi cha utafiti utakachowekwa, unaweza kupata ujumbe wa afya wa sms kuhusu ugonjwa wa presha.

Sehemu ya D: Manufaa

Mara tu baada ya kukamilika, matokeo ya utafiti huu yatatumika ili kuandaa hatua za kuboresha huduma za kutibu ugonjwa wa presha.

Sehemu ya E: Siri

Ujumbe utakaohutoa ukiwa katika huu utafiti utakuwa siri yako na hautatumiwa kwa njia nyingine yoyote isipokua ya utafiti. Ndio ujumbe wako husikuwe unaeza kuonekana ovyo, hautahitajika kuandika jina yako katika fomu tutakatotumia kukuuliza maswali.

Sehemu ya F: Hatari

Utafiti huu kama ulivyo hauna hatari yoyote kwako au kwa afya yako.

Chaguo lako la kushiriki au kutoshiriki katika utafiti huu haliathiri huduma ya kawaida ambayo unapata katika vituo unavyotibiwa.

Je, una maswali yoyote kuhusu utafiti huu ambao ungependa nikujibu? Tafadhali jisikie huru kuuliza ikiwa unao.

Ikiwa unakubaliana kushiriki katika utafiti huu, tafadhali weka sahihi hapa chini au uweke kichwa cha kidole

Sehemu ya G : Hati ya Ruhusa

Nimesoma habari iliyotolewa hapa kwa hii fomu, au nimesomewa. Pia nimewasilishwa na fursa ya kuuliza maswali kuhusu utafiti huu, na maswali yoyote niliyoyauliza yamejibiwa kwa kuridhika kwangu. Ninakubali kwa hiari yangu kushiriki katika utafiti huu.

Jina la Mshiriki_____

Sahihi ya Mshiriki _____

Tarehe _____

Kwa Wenye Hawajui Kuandika au Kusoma:

Nimeshuhudia fomu ya idhini ikisomwa kwa mshiriki mwenya jina lake hapa chini, na nikaakikisha amepata fursa ya kuuliza maswali. Ninathibitisha kwamba mtu huyu amekubali kwa uhuru kushiriki katika utafiti huu.

Jina la Shahidi_____

Sahihi ya Shahidi _____

Tarehe _____

Jina la Mshiriki_____Alama ya Kidole

Taarifa ya Mtafiti / Mtu Anayechukua Kibali

Nimesomea mshiriki mtarajiwa habari iliyohapa kwa hii fomu na ninaakikisha kwamba mshiriki ameelewa taratibu zote zinazohusiana na huu utafiti.

Ninathibitisha kuwa mshiriki alikuwa na nafasi ya kuuliza maswali kuhusu huu utafiti, na maswali yote aliyoyauliza amejibiwa kwa usahihi na kwa uwezo wangu wote. Ninathibitisha kuwa mshiriki huyu amekubali kwa hiari yake kushiriki katika utafiti huu bila kulazimishwa.

Mshiriki atapewa nakala ya fomu hii.

Jina la Mtafiti / Mtu Anayechukua Kibali_ _____

Sahihi ya Mtafiti / Mtu Anayechukua Kibali _____

Tarehe _____

Appendix 2: Medication Adherence and Hypertension related Knowledge Questionnaire

Identification of Clients

Habari yako. Nisaidie na cheti kyako cha kliniki. *Get the patient clinic identification/follow up card and check on the details. Check whether the patient is among the preselected list of patients to be interviewed on the material clinic day.*

Introduction and establishment of rapport

"Mimi na wenzangu wengine hapa ni maafisa wa utafiti unaofanywa kuhusu ugonjwa wa presha. Ukiniruhusu, nitakuuliza maswali kuhusu vile unavyoendelea na matibabu yako ya huu ugonjwa. Maswali yote utakayo jibu yatakuwa ya huu utafiti na haitatatumika vinginevyo. Matokeo ya huu utafiti yatasaidia kubuni njia mwafaka za kuimarisha matibabu yako ya presha.

Je utaniruhusu tuendelee kuongea? *If the client verbally consents, take them through the process of signing the informed consent form, and thereafter implement the interview.*

QUESTIONNAIRE SERIAL NUMBER: ……..

Part A: Socio-Demographic Data

Outpatient File No: ……

Gender: **0**□ Male **1**□ Female Year of Birth…….Age……

Residence (**Makaazi**): …….

Education Level: **0**□ None **1**□ Completed primary **2**□ Completed secondary **3**□ Completed College/University

Kiwango ya Elimu: □ Hajasoma □ Amekamilisha shule ya msingi □ Amekamilisha sekondari □ Amekamilisha Chuo/Chuo Kikuu

Marital status: **0**□Never married **1**□Married **2**□Divorced/separated **3**□Widowed

Hali ya Kuoa/Kuolewa: □ Hajawahi kuolewa □ Ameolewa □ Ametoka kwa ndoa □ Mjane

Employment status: **0**□ Formally employed **1**□Unemployed **2**□Self employed

Hali ya Ajira: □ Ameajiriwa □ Hajaajiriwa □ Amejiajiri

Monthly income if applicable…….

Mapato ya kila mwezi ikiwa ameajiriwa .....

Religion: **0**□ Christian **1**□ Muslim **2**□ Other, specify……..

Dini: □ Mkristo □ Muislamu □ Nyingine…….

Mobile Phone ownership and usage data:

Do you own a personal mobile phone □Yes □No

If yes, write down the number……..

Uko na simu yako ya rununu? □Ndio □La

Kama akona simu, andika namabri hapa……..

For those owning a phone: Do you usually use *sms* messages for communication?……..

□Yes…..□No…..

Kwa wenye wako na simu: Je, huwa unatumia ujumbe wa sms kwa mawasiliano?

□Ndio □La

Part B: Clinical Data (To be filled from the patients' medical records/file)

Date first seen in clinic: …….

Diagnosis……Date of diagnosis……..

State any other diagnosis, other than hypertension…….

Blood pressure reading……

Weight…… Height……

Current antihypertensive medication……

…….

……

PART C: Medication Adherence

1. Do you at times forget to take your medicines for hypertension?

   0□ Yes **1**□ No

   Je, kuna wakati unasahau kutumia dawa zako za presha?

   □ **Ndiyo** □ **La**

2. Are there times when you feel there is no need of taking your medicines for hypertension?

   0□ Yes **1**□ No

   Je, kuna nyakati ambapo unahisi hakuna haja ya kutumia dawa zako za presha?

   □ **Ndiyo** □ **La**

3. When you feel better, do you sometimes stop taking your medicines for hypertension?

   0□ Yes **1**□ No

   Je, wakati mwingine, kama unajihisi vyema, unaacha kutumia dawa zako za presha?

□ Ndiyo □ La

4. Sometimes if you feel worse when you take your medicines for hypertension, do you stop taking them?

   0□ Yes **1**□ No

   Wakati mwingine ukitumia dawa zako za presha na ujihisi kana kwamba zi-nakupea madhara, je unaacha kuzitumia?

   □ Ndiyo □ La

Part D: Knowledge about Hypertension

1. Do you know the blood pressure reading that indicates good control of hypertension?

   □ Yes □ No

   If yes, indicate the reading…… *(If the response is <140/90 mmHg or mentions any BP reading <140/90 mmHg, score 1 point. Any other response score 0)*

   Je, unajua kipimo cha shinikizo la damu ambacho kinaonyesha udhibiti mzuri wa shinikizo la damu?

   □ Ndiyo □ La

   Ikiwa ndio, sema ni kiwango gani……..

2. **Do you know of any health problems that can arise from having high blood pressure? □ Yes □ No**

   If yes, specify……..(*If any of these is mentioned, score 1 point: heart disease, stroke, kidney disease. Any other response or don't know, score 0.*)

   Je, unafahamu matatizo yoyote ya kiafya yanayoweza kusababishwa na shinikizo la damu?

   □ Ndiyo □ La

Ikiwa ndio, taja……..

3. Can someone be having high blood pressure without experiencing any symptoms?
   □Yes [1] □ No □ Don't know *(If yes, score 1 point. If no or don't know, score 0)*
   Je, mtu anaweza kuwa na shinikizo la damu bila kupata dalili zozote?
   □ Ndiyo □ La □ Sijui

4. For how long are you going to be taking your medicines for hypertension?
   □ For a short while until I feel okay
   □ Only when I feel like my blood pressure is high
   □ Throughout unless advised by my health care provider to stop [1]
   □ Don't' know
   □ Other…
   (If the response is 'throughout unless advised by my health care provider to stop' score 1 point. Any other response, score 0)
   Je, utatumia dawa zako za shinikizo la damu kwa muda gani?
   □ Kwa muda mfupi hadi ninahisi sawa
   □ Ni wakati tu ninahisi shinikizo la damu liko juu
   □ Kwa muda wote isipokuwa nishauriwe na mtoa huduma wangu wa afya kua-cha
   □ Sijui
   □ Jibu nyingine…….

Appendix 3: Beliefs about Medicines Questionnaire (BMQ)

Necessity Scale

1. **My health, at present, depends on my medicines**

   [1] Strongly disagree [2] Disagree [3] Neither agree or disagree [4] Agree

   [5] Strongly agree

   Afya yangu kwa sasa inategemea dawa zangu.

   [1] Sikubaliani kabisa [2] Nakataa [3] Sikubali wala sikatai [4] Nakubali

   [5] Nakubali sana

2. **My life would be impossible without my medicines**

   [1] Strongly disagree [2] Disagree [3] Neither agree or disagree [4] Agree

   [5] Strongly agree

   Maisha yangu haingewezekana bila dawa zangu.

   [1] Sikubaliani kabisa [2] Nakataa [3] Sikubali wala sikatai [4] Nakubali

   [5] Nakubali sana

3. **Without my medicines I would become very ill**

   [1] Strongly disagree [2] Disagree [3] Neither agree or disagree [4] Agree

   [5] Strongly agree

   Bila dawa zangu ningekuwa mgonjwa sana.

   [1] Sikubaliani kabisa [2] Nakataa [3] Sikubali wala sikatai [4] Nakubali

   [5] Nakubali sana

4. **My health in the future will depend on my medicines**

   [1] Strongly disagree [2] Disagree [3] Neither agree or disagree [4] Agree

   [5] Strongly agree

Afya yangu katika siku zijazo itategemea dawa zangu.

[1] Sikubaliani kabisa [2] Nakataa [3] Sikubali wala sikatai [4] Nakubali

[5] Nakubali sana

5. **My medicines protect me from becoming worse**

   [1] Strongly disagree [2] Disagree [3] Neither agree or disagree [4] Agree

   [5] Strongly agree

   Dawa zangu hunilinda dhidi ya kuwa mgonjwa.

   [1] Sikubaliani kabisa [2] Nakataa [3] Sikubali wala sikatai [4] Nakubali

   [5] Nakubali sana

Concerns Scale

1. **Having to take medicines worries me**

   [1] Strongly disagree [2] Disagree [3] Neither agree or disagree [4] Agree

   [5] Strongly agree

   Kunywa dawa kunanitia wasiwasi.

   [1] Nakataa sana [2] Nakataa [3] Sikubali wala sikatai [4] Nakubali

   [5] Nakubali sana

2. **I sometimes worry about the long-term effects of my medicines**

   [1] Strongly disagree [2] Disagree [3] Neither agree or disagree [4] Agree

   [5] Strongly agree

   Wakati mwingine mimi huwa na wasiwasi kuhusu madhara ya muda mrefu ya dawa zangu.

   [1] Nakataa sana [2] Nakataa [3] Sikubali wala sikatai [4] Nakubali

[5] Nakubali sana

3. **My medicines are a mystery to me**

   [1] Strongly disagree [2] Disagree [3] Neither agree or disagree [4] Agree

   [5] Strongly agree

   Dawa zangu ni siri kwangu.

   [1] Nakataa sana [2] Nakataa [3] Sikubali wala sikatai [4] Nakubali

   [5] Nakubali sana

4. **My medicines disrupt my life**

   [1] Strongly disagree [2] Disagree [3] Neither agree or disagree [4] Agree

   [5] Strongly agree

   Dawa zangu huharibu maisha yangu.

   [1] Nakataa sana [2] Nakataa [3] Sikubali wala sikatai [4] Nakubali

   [5] Nakubali sana

5. **I sometimes worry about becoming too dependent on my medicines**

   [1] Strongly disagree [2] Disagree [3] Neither agree or disagree [4] Agree

   [5] Strongly agree

   Wakati fulani mimi huwa na wasiwasi kuhusu kutegemea sana dawa zangu.

   [1] Nakataa sana [2] Nakataa [3] Sikubali wala sikatai [4] Nakubali

   [5] Nakubali sana

Appendix 4: Brief Illness Perception Questionnaire (BIPQ)

1. **Timeline**

   How long do you think your illness will continue?

   [0]- Very short time [1] [2] [3] [4] [5] [6] [7] [8] [9] [10]-Forever

   Unafikiri ugonjwa wako utaendelea hadi lini?

   [0]- Muda mfupi sana [1] [2] [3] [4] [5] [6] [7] [8] [9] [10]- Milele

2. **Personal control**

   How much control do you feel you have over your illness?

   [0]- Absolutely no control [1] [2] [3] [4] [5] [6] [7] [8] [9]

   [10]- Extreme amount

   Je, unahisi una udhibiti kiasi gani juu ya ugonjwa wako?

   [0]- Hakuna udhibiti kabisa [1] [2] [3] [4] [5] [6] [7] [8] [9]

   [10]- Kiasi kikubwa

3. **Treatment control**

   How much do you think your treatment can help your illness?

   [0]- Not at all [1] [2] [3] [4] [5] [6] [7] [8] [9]

   [10]- Extremely helpful

   Je, unafikiri matibabu yako yanaweza kusaidia ugonjwa wako kwa kiasi gani?

   0]- Hapana kabisa [1] [2] [3] [4] [5] [6] [7] [8] [9]

   [10]- Inasaidia sana

4. Coherence

How well do you feel you understand your illness?

[0]- Don't understand [1] [2] [3] [4] [5] [6] [7] [8] [9]

[10]- Understand very clearly

Je, unahisi jinsi gani unaelewa ugonjwa wako?

[0]- Sielewi [1] [2] [3] [4] [5] [6] [7] [8] [9]

[10]- Ninaelewa kwa uwazi sana

Appendix 5: SMS Hypertension Education Messages

Week 1

This message is from Nyeri PGH clinic where you are usually treated for hypertension. Remember, during your last visit in the clinic, you were prescribed medicines and advised to take them daily throughout as indicated in the package label. Taking these medicines daily will keep your blood pressure controlled and therefore reduce your risk of getting diseases like heart disease, kidney failure and stroke.

Week 2

This message is from Nyeri PGH clinic where you are usually treated for hypertension. Untreated high blood pressure can cause heart disease, kidney failure or stroke. The drugs you have been given are effective and safe for use in controlling your blood pressure. It is important that you remember that these drugs should be taken daily without missing a dose even when you feel fine.

Week 3

This message is from Nyeri PGH clinic where you are usually treated for hypertension. Remember as your health care providers, we are very concerned to keep you in your best health. Like we have advised you earlier, it is important that you do not miss any dose of the drugs you have been prescribed in order to keep your blood pressure under control. Hence, it is important you remember to refill your medicines before finishing all the tablets so that you do not miss any dose.

Week 4

This message is from Nyeri PGH clinic where you are usually treated for hypertension.

As you have been informed, hypertension that is not well managed can cause serious complications in your body like heart disease, stroke and kidney disease. It is important that you take your medicines daily even when you feel okay. Remember blood pressure has been described as a silent killer because usually it does not present with symptoms, and could actually be high even during those times you feel relaxed.

Week 5

This message is from Nyeri PGH clinic where you are usually treated for hypertension. If your medications do not have a special instruction "do not take with food', you can minimize forgetting to take the pills, by harmonizing your medication intake with meal-times. For example, if you are taking the medicines once daily, take after breakfast. If you are taking the medicines twice daily, take the first dose after breakfast in the morning and then the other dose later during suppertime in the evening.

Week 6

This message is from Nyeri PGH clinic where you are usually treated for hypertension. Remember, taking your medicines daily without missing any dose will keep your blood pressure controlled and therefore you will reduce the risk of getting diseases such as heart disease, kidney disease and stroke. Also remember to keep your appointments of reporting back to the clinic for regular review.

Swahili version

Wiki 1

Ujumbe huu unatoka kwenye kliniki ya PGH ambapo unatibiwa ugonjwa wa presha. Kumbuka, wakati wa ziara yako ya mwisho kwenye kliniki, uliandikiwa dawa na ukashauriwa huwe unazitumia kila siku kama ilivyoonyeshwa kwenye lebo ya paki-

ti. Kutumia dawa hizi kila siku kutunza presha yako inapunguza hatari yako ya kupata magonjwa kama ugonjwa wa moyo, ugonjwa wa figo na kiharusi (stroke).

Wiki 2

Ujumbe huu unatoka kwenye kliniki ya PGH ambapo unatibiwa ugonjwa wa presha. Kuwa na presha iliyo juu kunaweza kusababisha ugonjwa wa moyo, kushindwa kwa figo au kiharusi. Madawa ambayo umepewa ni salama kwa matumizi ili kudhibiti presha yako. Ni muhimu kukumbuka kuwa dawa hizi zinapaswa kutumiwa kila siku bila kukosa hata wakati unapojihisi vizuri.

Wiki 3

Ujumbe huu unatoka kwenye kliniki ya PGH ambapo unatibiwa ugonjwa wa presha . Kumbuka kama wahudumu wa afya, tunahusika sana kukusaidia kuimarisha afya yako. Kama tulivyokushauri hapo awali, ni muhimu usikose madawa ambayo umeagizwa kwa wakati wowote ili kuweka presha yako kwenye kiwango kilichopendekezwa. Kwa hivyo, ni muhimu ukumbuke kuchukua madawa zingine kabla ya kumaliza tembe zote ili usikose kwa wakati wowote.

Wiki 4

Ujumbe huu unatoka kwenye kliniki ya PGH ambapo unatibiwa ugonjwa wa presha.

Kama ulivyoshauriwa hapo mbeleni, ugonjwa wa presha unaweza kusababisha matatizo makubwa katika mwili wako kama ugonjwa wa moyo, ugonjwa wa kiharusi na figo. Ni muhimu utumie madawa yako kila siku hata wakati unapojihisi sawa. Kumbuka ugonjwa wa presha umeelezewa kuwa hatari kwa sababu unadhuru mwili bila kutoa dalili, na kwa kweli presha inaweza kuwa juu hata wakati ule unajihisi sawa.

Wiki 5

Ujumbe huu unatoka kwenye kliniki ya PGH ambapo unatibiwa ugonjwa wa presha. Ikiwa dawa zako hazina maagizo maalum "usichukunywe pamoja na chakula", unaweza kupunguza kusahau kuchukua vidonge, kwa kuweka pakiti ya dawa kwenye meza kuto-ka mahali unapokula. Kwa mfano, ikiwa unatumia dawa mara moja kwa siku, chukua baada ya kifungua kinywa; ikiwa unatumia dawa mara mbili kwa siku, chukua baada ya kifungua kinywa asubuhi na baadaye wakati wa chakula cha jioni.

Wiki 6

Ujumbe huu unatoka kwenye kliniki ya PGH ambapo unatibiwa ugonjwa wa presha. Kumbuka, kutumia madawa yako kila siku kama ulivyoangizwa kuna punguza hatari ya kupata magonjwa kama vile ugonjwa wa moyo, magonjwa ya figo na kiharusi. Pia kumbuka huwe unarudi kwenye kliniki kwa ukaguzi wa mara kwa mara.

<u>Kikuyu Version</u>

Week 1

Ino ni ndumiriri kuma thibitari PGH iria uthondekagirwo murimo wa kuhaishia thakame. Ririkana riria wiriga thibitari oriu ica ikuhi, niwandikiirwo dawa na ukirwo unyuage o muthenya hindi ciothe. Kumeria dawa ici o muthenya guteithagia thakame yaku ndikahaice koguo ukanyihia kanya ka murimu wa ngoro na higo.

Week 2

Ino ni ndumiriri kuma thibitari, PGH iria uthondekagirwo murimo wa kuhaicia thakame. Kwaga kumenyerera murimu wa kuhaishia thakame kurehaga mirimu ya ngo-

ro na higo ikaga kuruta wira wega. Dawa iria uhetwo ni cia bata na ni njega hari kugi-ririria thakame kuhaica. Hari bata kuririkana ati dawa ici ibatie kunyuo o muthenya ha-tari gutiriria onangikorwo nduraigua ta wi murwaru. Gutiriria kunyua gutumaga thakame ihaishe na ukagia mathina ma ngoro na higo. Ungiugua uru warikia kumeria dawa ici, ndugatige kunywa, hari bata gucoka thibitari orio niguo urorwo.

Week 3

Ino ni ndumiriri kuma thibitari, PGH iria uthondekagirwo murimo wa kuhaishia thakame. Ririkana toria ithui amenyereri a ugima waku wa mwiri ,twina bata na ugima waku wa mwiri. Koguo hari bata uririkane kugura dawa ciaku utananina niguo ndugatiririe. Angikorwo niurathie thabari nja ya mucii waku, ririkana gukua dawa ciaku niguo ndugatiririe ona hanini.

Week 4

Ino ni ndumiriri kuma thibitari PGH iria uthondekagirwo murimo wa kuhaishia thakame.Toria tuthiite na mbere nagukumenyithia,murimu wa kuhicia thakame ungiaga kumenyererwo wega niurehaga mathina maingi ta murimu wa ngoro na higo. Ririkana kumeria dawa ici oro muthenya onangikorwo nduraigua wi murwaru. Ririkana ati murimu uyu uikaine ta wa kuraga mundu o kahora akirite tondu mundu ndakoragwo na dalili na thakame yahota gukorwo iri iguru nginya riria uhurukite.

Week 5

Ino ni ndumiriri kuma thibitari PGH iria uthondekagirwo murimo wa kuhaishia thakame. Toria tuthiite na mbere na gugutariria, niguo kunyihia kanya ga kuriganirwo kumeria dawa ciaku, no uigagirire kabagiti ka dawa icio methaini yaku haria uriagira irio, akorwo umeragia rita rimwe muthenya, meria warikia kunywa cai wa kiroko, akorwo umeragia maita meri muthenya meria kiroko wanyua cai na hwaini warikia kuria irio. Ririkana kumeria dawa ici o muthenya kugiragiriria mirimu ya ngoro na higo iria yumanaga na kuhaicia thakame.

Week 6

Ino ni ndumiriri kuma thibitari PGH iria uthondekagirwo murimo wa kuhaishia thakame. Ririkana kumeria dawa ciaku hatari gutiriria niguo kurigiriria mirimu ya ngoro na higo. Ririkana gucoka thibitari muthenya uria wandikirwo niguo uthie na mbere na kurorwo.

Appendix 6: Medication Refill Data Abstraction Form

OPD NO.		Drugs Details							
	Date of issue	S/NO	Prescribed drug(s)	Dose	Fre-quency	Stren gth of pills	No. of pills given	No. of days covered	Comple-tion date
		Drugs Details							
OPD NO.	Date of issue	S/NO	Prescribed drug(s)	Dose	Fre-quency	Strength of pills	No. of pills giv-en	No. of days cov-ered	Comple-tion date

Appendix 7: Hypertension Education Voice Call Content

Introductory call

How are you today?

I am calling you from the clinic where you are usually treated for hypertension. The purpose of calling is to know how you are progressing with the management of your blood pressure and share with you important information about your health.

Remember, during your last visit in the clinic you were given medicines and advised to take them throughout as indicated in the package label. Taking these medicines daily will keep your blood pressure controlled and therefore reduce your risk of getting diseases like heart disease, kidney failure and stroke. Your blood pressure might be high even when you feel relaxed and just fine. In fact, this condition has also been described as a 'silent killer' because it quietly causes damage to your important organs like the heart, kidney and brain even when you don't feel like you are sick. Therefore it is very important that you always take your drugs every day as you have been advised to keep your blood pressure controlled. It is also important for you to understand that hypertension is a chronic/lifelong condition that someone lives with, and therefore you should never discontinue taking your prescribed medicines on your own unless under instruction by your health care provider.

Remember, taking your medicines without missing will keep your blood pressure controlled and therefore you will reduce the risk of getting diseases such as heart disease, kidney disease and stroke.

Do you have any question or concern that you would want me to address?

In order to help you understand what hypertension is and the importance of taking medicine daily we will be sending you sms messages to your phone for health education.

Thank you for your time!

Follow up calls

How are you?

The purpose of calling is to find out from you how you are faring with your treatment for hypertension.

Are you taking your medicines daily? Do you have any concerns regarding your treatment that you would want me to address?

I would like to remind you of some important information we had shared before regarding hypertension. First you should take your medicines daily without skipping any day or dose. Remember hypertension does not have any symptoms and your blood pressure could be high even when you feel fine. Secondly, you need to note that hypertension is a lifelong condition and therefore you should never stop taking your medications without getting advice from your health care provider. In the event that you experience any intolerable adverse effects after taking your medicines, report to your health care facility immediately for review. Lastly, please note that taking your medicines daily enables you to achieve adequate blood pressure control, and eventually your risk of developing complications such as stroke, kidney disease and heart ailments is significantly reduced.

I will call you again in the following month to know your progress.

Thank you for your time!

Introductory Call- Swahili version

Hujambo leo?

Napiga simu kutoka kliniki ambapo huwa unatibiwa ugonjwa wa presha.

Sababu yangu ya kupiga simu ni kujua jinsi unavyoendelea na matibabu ya ugonjwa wa presha na pia kukuelimisha kuhusu afya yako.

Kumbuka, wakati wa ziara yako ya mwisho kwenye kliniki, ulipewa dawa na ukashauriwa kuwa unazitumia kila siku kama ilivyoonyeshwa kwenye lebo ya pakiti. Kutumia dawa hizi kila siku kutunza presha yako inapunguza hatari yako ya kupata magonjwa kama ugonjwa wa moyo, kushindwa kwa figo na kiharusi. Presha yako inaweza kuwa juu hata wakati unahisi ukiwa sawa bila shida yoyote. Kwa kweli , hali hii pia imeelezewa kama ‘muuaji wa kimya’ kwa sababu inaweza kusababisha uharibifu kwa viungo vyako muhimu kama moyo, figo na ubongo hata wakati wewe hujihisi mgonjwa. Kwa hiyo ni muhimu sana kwamba kila siku utumie madawa yako kama ulivyoshauriwa ili kuweka presha yako kwenye kiwango kilichopendekezwa. Pia ni muhimu kwako kuelewa kwamba shinikizo la damu ni hali ya kudumu/ya maisha yote ambayo mtu anaishi nayo, na kwa hiyo hupaswi kamwe kuacha kutumia dawa ulizoagiza peke yako isipokuwa chini ya maelekezo ya mtoa huduma wako wa afya.

Je, una swali lolote ungependa kuniuliza?

Ili kukusaidia kuelewa zaidi maana ya huu ugonjwa wa presha na umuhimu wa kutumia dawa ulizoandikiwa, tutakuwa tunakutumia ujumbe wa sms kwa simu yako kwa elimu zaidi.

Asante kwa muda wako!

Follow up call- Swahili Version

Habari yako?

Madhumuni ya kupiga simu ni kujua kutoka kwako jinsi unaendelea na matibabu yako ya shinikizo la damu.

Je, unachukua dawa zako kila siku? Je, una wasiwasi wowote kuhusu matibabu yako ambao ungependa nishughulikie?

Ningependa kuwakumbusha baadhi ya taarifa muhimu tulizoshiriki kabla ya kuhusu shinikizo la damu. Kwanza unapaswa kunywa dawa zako kila siku bila kuruka siku yoyote au kipimo. Kumbuka shinikizo la damu halina dalili zozote na shinikizo lako la damu linaweza kuwa juu hata unapojisikia vizuri. Pili, unahitaji kutambua kwamba shinikizo la damu ni hali ya maisha yote na kwa hiyo hupaswi kamwe kuacha kutumia dawa zako bila kupata ushauri kutoka kwa mtoa huduma wako wa afya. Iwapo utapata athari mbaya zisizoweza kuepukika baada ya kutumia dawa zako, ripoti kwenye kituo chako cha huduma ya afya mara moja kwa ukaguzi. Hatimaye, tafadhali kumbuka kwamba kuchukua dawa zako kila siku hukuwezesha kufikia udhibiti wa kutosha wa shinikizo la damu, na hatimaye hatari yako ya kupatwa na matatizo kama vile kiharusi, ugonjwa wa figo na magonjwa ya moyo hupunguzwa kwa kiasi kikubwa. Nitakupigia tena mwezi unaofuata kujua maendeleo yako.

Asante kwa muda wako!

Appendix 8: Clinic Attendance and Sampling Data

Clinic attendance and sampling data						
Study site	Date	Number of booked eligible patients	Targeted number for recruitment	Kth	Interviewed	Non-responders
Nyeri CRH	6/10/019	65	25	3	25	
	13/10/019	70	25	3	22	3
	20/10/019	60	25	2	25	
	27/10/019	50	30	2	28	2
	3/11/019	75	30	3	30	
	10/11/019	55	25	2	25	
	17/11/019	77	25	3	25	
	24/11/019	80	25	3	24	1
	1/12/019	76	25	3	25	
	8/12/019	65	20	3	20	
	15/12/019	60	26	2	25	1
	Total		281		274	7
Consolata Mathari Mission Hospital	5/11/019	40	17	2	16	1
	12/11/019	45	18	3	18	
	19/11/019	40	19	2	18	1
	26/11/019	43	13	3	13	
	Total		67		65	2

Total number targeted	348.00
Total number of responders	339.00
Response Rate (%)	97.4

Appendix 9: Blocked Randomization Sequence

001: Int	0002: Ctrl	0003: Ctrl	0004: Int	0005: Int	0006: Ctrl
0007: Int	0008: Int	0009: Ctrl	0010: Ctrl	0011: Ctrl	0012: Int
0013: Int	0014: Ctrl	0015: Ctrl	0016: Int	0017: Ctrl	0018: Int
0019: Int	0020: Ctrl	0021: Int	0022: Int	0023: Ctrl	0024: Ctrl
0025: Int	0026: Ctrl	0027: Ctrl	0028: Int	0029: Ctrl	0030: Int
0031: Ctrl	0032: Int	0033: Int	0034: Ctrl	0035: Ctrl	0036: Int
0037: Int	0038: Int	0039: Ctrl	0040: Ctrl	0041: Int	0042: Ctrl
0043: Ctrl	0044: Int	0045: Ctrl	0046: Int	0047: Ctrl	0048: Int

0049: Int	0050: Ctrl	0051: Int	0052: Ctrl	0053: Int	0054: Ctrl
0055: Ctrl	0056: Ctrl	0057: Ctrl	0058: Int	0059: Int	0060: Int
0061: Int	0062: Ctrl	0063: Ctrl	0064: Ctrl	0065: Int	0066: Int
0067: Ctrl	0068: Ctrl	0069: Int	0070: Int	0071: Int	0072: Ctrl
0073: Int	0074: Int	0075: Ctrl	0076: Ctrl	0077: Ctrl	0078: Int
0079: Int	0080: Int	0081: Ctrl	0082: Ctrl	0083: Int	0084: Ctrl
0085: Ctrl	0086: Ctrl	0087: Int	0088: Int	0089: Int	0090: Ctrl
0091: Int	0092: Int	0093: Ctrl	0094: Int	0095: Ctrl	0096: Ctrl

0097: Int	0098: Ctrl	0099: Int	0100: Ctrl	0101: Int	0102: Ctrl
0103: Int	0104: Ctrl	0105: Ctrl	0106: Ctrl	0107: Int	0108: Int
0109: Int	0110: Ctrl	0111: Ctrl	0112: Int	0113: Int	0114: Ctrl
0115: Ctrl	0116: Ctrl	0117: Int	0118: Ctrl	0119: Int	0120: Int

Key:

Int: Intervention group

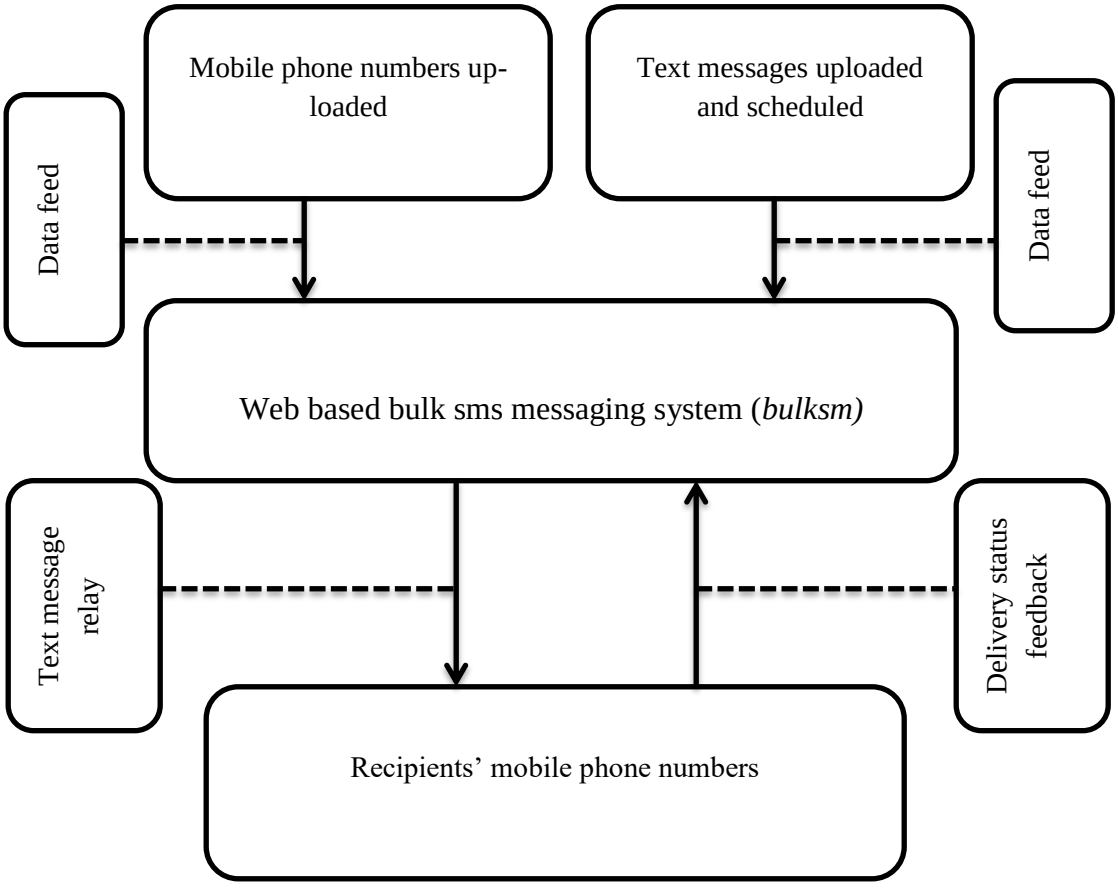
Ctrl: Control group

Block size=6

Appendix 10: Description of the *bulksms* Messaging System

Sending of messages to patients randomized to the experimental arm was done via a bulk sms messaging service provided by *Celerity Systems Ltd*, an ICT Company incorporated in South Africa (https://www.bulksms.com/company/). The messaging system is housed in an internet based portal named *bulksms*, where clients can subscribe for a set of messages packaged in bundles to be sent to mobile phones of designated persons. The system allows for uploading of phone numbers of persons in possession of mobile phones, which are further grouped into cohorts and assigned a specific collective identifier. This therefore allows for selection of the group ID, which then pulls out all contacts intended to be recipients of any message for circulation. The messaging system also has a function for uploading and scheduling messages to allow for automated delivery on specified dates; there is also an integrated communication loop that sends feedback on the delivery status of all sent messages. A schematic representation for the work flow of the messaging system that was implemented in the study is given in figure 4 below.

Figure 9.1: Work flow of text messaging system



Appendix 11: Sms Delivery Data

Patient Serial No.	Week 1 sms	Week 2 sms	Week 3 sms	Week 4 sms	Week 5 sms	Week 6 sms
01	√	√	√	√	√	√
02	√	√	√	√	√	√
03	√	√	√	√	√	√
04	√	√	√	√	√	√
05	√	√	√	√	√	√
06	√	√	√	√	√	√
07	√	√	√	√	√	√
08	√	√	√	√	√	√
09	√	√	√	√	√	√
10	√	√	√	√	√	√
11	√	√	√	√	√	√
12	√	√	√	√	√	√
13	√	√	√	√	√	√
14	√	√	√	√	√	√
15	√	√	√	√	√	√
16	√	√	√	√	√	√
17	√	√	√	√	√	√
18	√	√	√	√	√	√
19	√	√	√	√	√	√
20	√	√	√	√	√	√
21	√	√	√	√	√	√
22	√	√	√	√	√	√
23	√	√	√	√	√	√
24	√	√	√	√	√	√
25	√	√	√	√	√	√
26	√	√	√	√	√	√
27	√	√	√	√	√	√
28	√	√	√	√	√	√
30	√	√	√	√	√	√
31	√	√	√	√	√	√
32	√	√	√	√	√	√

33	√	√	√	√	√	√
34	√	√	√	√	√	√
35	√	√	√	√	√	√
36	√	√	√	√	√	√
37	√	√	√	√	√	√
38	√	√	√	√	√	√
39	√	√	√	√	√	√
40	√	√	√	√	√	√
41	√	√	√	√	√	√
42	√	√	√	√	√	√
43	√	√	√	√	√	√
44	√	√	√	√	√	√
45	√	√	√	√	√	√
46	√	√	√	√	√	√
47	√	√	√	√	√	√
48	√	√	√	√	√	√
49	√	√	√	√	√	√
50	√	√	√	√	√	√
51	√	√	√	√	√	√
52	√	√	√	√	√	√
53	√	√	√	√	√	√
54	√	√	√	√	√	√
55	√	√	√	√	√	√
56	√	√	√	√	√	√
57	√	√	√	√	√	√
58	√	√	√	√	√	√
59	√	√	√	√	√	√
60	√	√	√	√	√	√

Key

Received: √

Not received: ☒

Appendix 12: Exit Interview Questionnaire

1. In the last 6 months (From January this year, 2020), have you ever gone to the hospital pharmacy with your prescription and found the drugs prescribed to you missing?

   □Yes □ No

   If yes, did you purchase them from elsewhere? □Yes □ No

2. In the last 6 months (From January this year, 2020), is there a time you opted to buy your medicines from a private pharmacy other than obtaining them from the Nyeri county referral hospital? □Yes □ No

Swahili Version

1. Je, katika kipindi cha miezi 6 iliyopita (Kuanzia Januari mwaka huu, 2020), umewahi kwenda kwenye duka la dawa na kukuta dawa ulizoandikiwa hazipo?

□ Ndio □ La

Ikiwa ndio, je, ulinunua kutoka mahali pengine? □ Ndio □ La

2. Katika miezi 6 iliyopita (Kuanzia Januari mwaka huu, 2020), kuna wakati ulichagua kununua dawa zako kutoka kwa duka la dawa la kibinafsi zaidi ya kuzipata kutoka hospitali ya rufaa ya kaunti ya Nyeri? □ Ndio □ La

Appendix 13: In-Depth Interview Guide

Participants: Patients who received the trial's mHealth intervention

Date of Interview……. Time…….

Location/Study Site…….. Interviewer Name……..

Introduction

Recently you participated in a study where you were sent messages and phone calls made to you to share information about hypertension. I would therefore like to get information on your experiences with the intervention undertaken.

Background Information

Outpatient File No:……

Gender: □ Male □ Female Year of Birth…….Age……

Residence (**Makaazi**):…….

Education Level: □None □Completed primary □Completed secondary □Completed College/University

Kiwango ya Elimu: □ Hajasoma □ Amekamilisha shule ya msingi □ Amekamilisha sekondari □ Amekamilisha Chuo/Chuo Kikuu

Marital status: □Never married □Married □Divorced/separated □Widowed

Hali ya Kuoa/Kuolewa: □ Hajawahi kuolewa □ Ameolewa □ Ametoka kwa ndoa □ Mjane

Employment status: □Formally employed □Unemployed □Self employed

Hali ya Ajira: □ Ameajiriwa □ Hajaajiriwa □ Amejiajiri

Monthly income if applicable…….

Mapato ya kila mwezi ikiwa ameajiriwa .....

Religion: □ Christian □ Muslim □ Other, specify……..

Dini: □ Mkristo □ Muislamu □ Nyingine…….

Questions

1. For how long have you lived with hypertension?

   Je, umeishi na presha kwa muda gani?

2. What was your reaction when you were first diagnosed with hypertension?

   Je, uliitikiaje ulipogunduliwa kuwa na shinikizo la damu kwa mara ya kwanza?

3. Did you seek care elsewhere?

   Je, ulitafuta huduma mahali pengine?

4. How are you going on with your treatment for hypertension?

   Je, unaendeleaje na matibabu yako ya shinikizo la damu?

5. Tell me before the project, how were you fairing on with your condition?

   Niambie kabla ya huu mradi, ulikuwa unaendeleaje na hali yako?

6. In what way do you feel the intervention benefited you in managing your condition, hypertension?

   Ni kwa njia gani unahisi kuhusika katika huu mradi kulikufaidi katika kudhibiti hali yako, shinikizo la damu?

7. What new information do you think you achieved from the messages shared with you?

   Je, unadhani umepata taarifa gani mpya kutoka kwa jumbe zilizoshirikiwa nawe?

8. What would you recommend to be done towards improving your services in treatment of hypertension?

   Je, ungependekeza nini kufanywa ili kuboresha huduma zako katika matibabu ya shinikizo la damu?

9. What can you remember well about the messages that you received?

   Unaweza kukumbuka nini vizuri kuhusu jumbe ulizopokea?

10. On what aspect of hypertension would you like to get more information on?

    Je, ungependa kupata taarifa zaidi kuhusu kipengele gani cha shinikizo la damu?

Appendix 14: Key Information Interview Guides

Informant 1: Nursing Officer In Charge, Medical Outpatient Clinic (MOPC), Nyeri County Referral Hospital

Background Information

Date of Interview…….. Time……..

Facility…… Designation……

Introduction

How are you!

I am a researcher undertaking a study on medication adherence among hypertensive patients on follow up care. If you allow me, I would like to ask you a few questions in relation to your experiences and views regarding non non-communicable diseases (NCDs) and care of patients on follow up for hypertension in this clinic. I will also share with you preliminary findings on a study we have completed assessing effectiveness of mHealth in improving medication adherence among hypertensive patients.

Interviewer name

Interview guiding questions

1. For how long have you been working in your current position/station?
2. What are the common non-communicable diseases (NCDs) that you encounter in this facility?
3. What do you think are the common risk factors driving the occurrence of NCDs in Nyeri County?
4. What do you think needs to be done to curb the rising cases of NCDs in Nyeri County and the Country at large?

5. How are you fairing on with health service delivery in the outpatient medication clinic (MPOC)?
6. Among the patients seen in MOPC, approximately what do you think is the proportion of those on follow up for hypertension?
7. To what extent do you think the patients on treatment for hypertension achieve the recommended blood pressure level?
8. Among patients not achieving the desired level of blood pressure control, what do you think may be the contributing factors?
9. A recently concluded study among patients on follow up for hypertension in Nyeri County Referral Hospital MOPC showed that sending sms messages and making phone calls to educate the patients about hypertension results to improvement in medication adherence and subsequently an improvement in blood pressure control. In what way do you think this intervention can impact on the care for hypertensive patients in this clinic?
10. In what way do you feel this intervention can be mainstreamed into the routine care of hypertensive patients on follow up?

Informant 2: Deputy Director, Department of Health Research, Nyeri County

Background Information

Date of Interview…….. Time……..

Work Station…… Designa-

tion/Position……

Introduction

How are you!

I am a researcher undertaking a study on medication adherence among hypertensive patients on follow up care. If you allow me, I would like to ask you a few questions in relation to your views on the current status of non-communicable diseases (NCDs) in Nyeri County and what needs to be done in order to mitigate the emerging disease burden. I will also share with you preliminary findings on a study we have completed assessing effectiveness of *mhealth* in improving medication adherence among hypertensive patients.

Interview guiding questions

1. For how long have you been working in your current position/station?
2. What are the common non-communicable diseases (NCDs) that are seen in health care facilities within Nyeri County?
3. What do you think are the common risk factors driving the occurrence of NCDs in Nyeri County?
4. What do you think needs to be done to curb the rising cases of NCDs in Nyeri County and the Country at large?

5. Currently available data indicates that many hypertensive patients (over 80%) do not have their blood pressure within the recommended levels. What do you think may be some of the contributing factors to this problem?
6. In what way do you think research can address the identified challenges in hypertension control?
7. What is your view about medication non-adherence as a barrier to hypertension control?
8. A recently concluded study among patients on follow up for hypertension in Nyeri County Referral Hospital MOPC showed that sending sms messages and making phone calls to educate the patients about hypertension results to improvement in medication adherence and subsequently an improvement in blood pressure control. In what way do you think this intervention can impact on the care for hypertensive patients in this clinic?
9. In what way do you feel this intervention can be mainstreamed into the routine care of hypertensive patients on follow up?

Informant 3: Director of Health Services, Nyeri County

Background Information

Date of Interview…….. **Time……..**

Work Station…… **Designation/Position……**

Introduction

How are you!

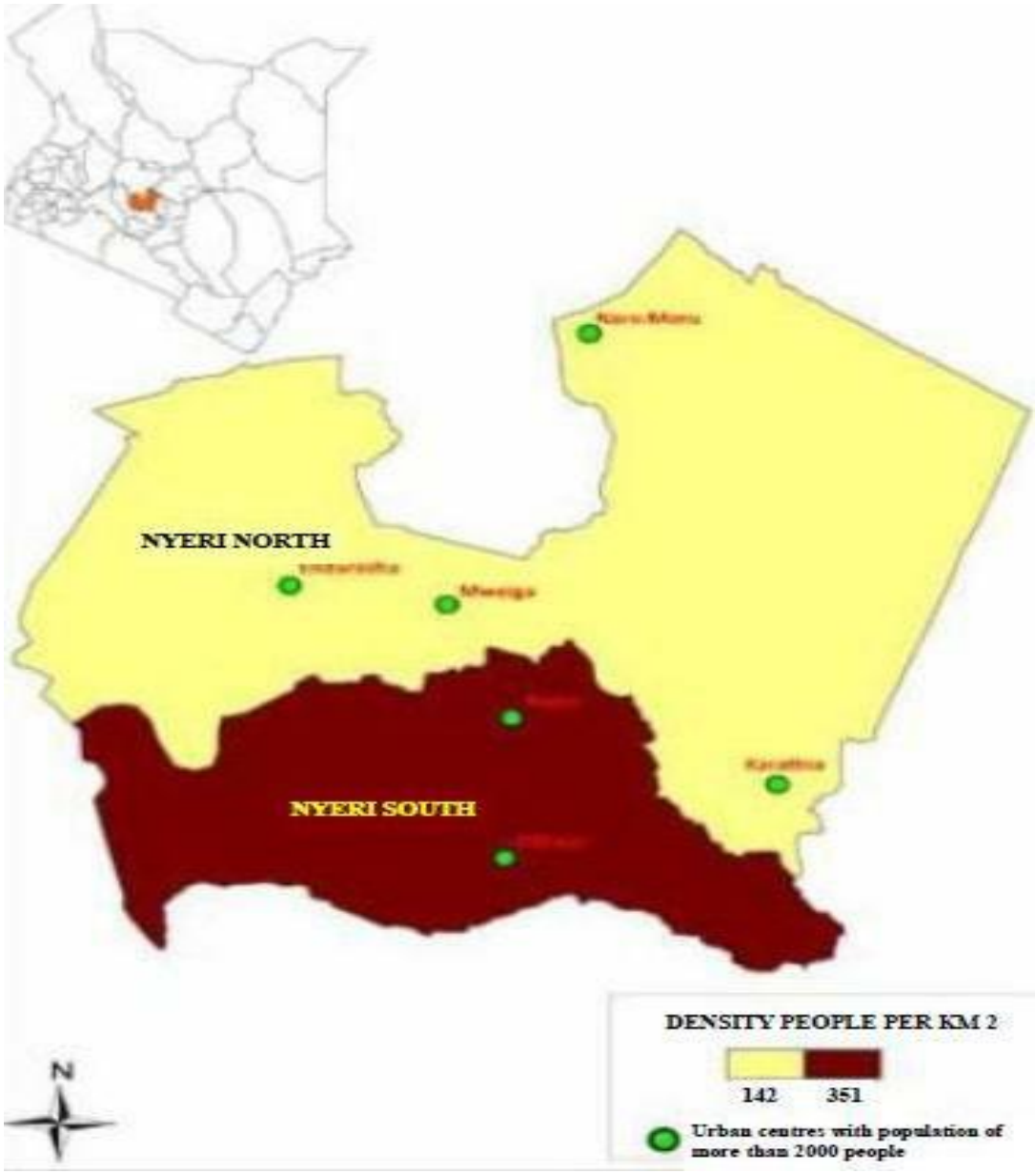
I am a researcher undertaking a study on medication adherence among hypertensive patients on follow up care. If you allow me, I would like to ask you a few questions in relation to your perspectives on the burden of non-communicable diseases (NCDs) including hypertension in Nyeri County and the strategies that you think can be applied to address the problem. I will also share with you preliminary findings on a study we have completed assessing effectiveness of *mhealth* in improving medication adherence among hypertensive patients.

Interview guiding questions

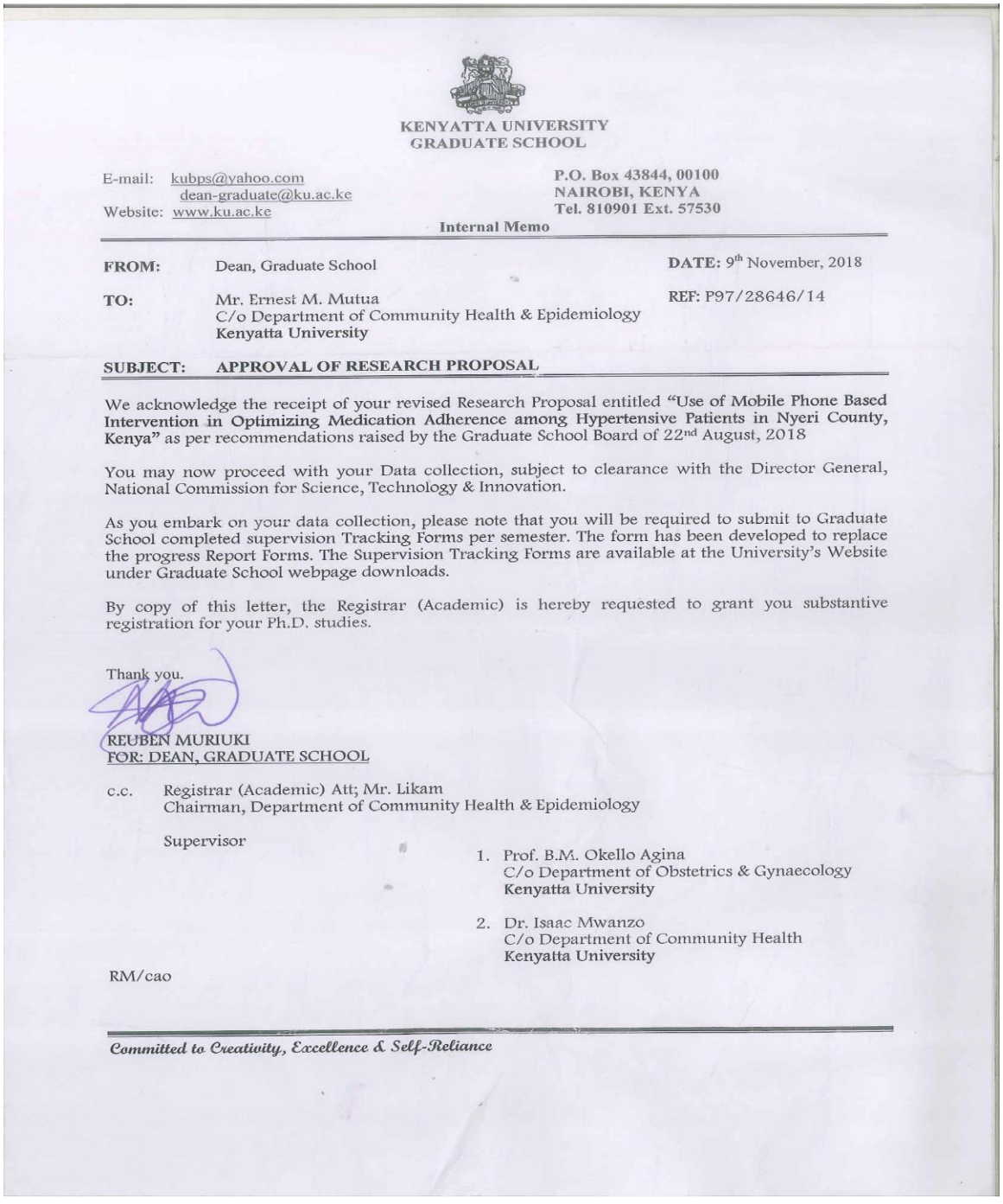
1. For how long have you been working in your current position/station?
2. What are the common non-communicable diseases (NCDs) that are seen in health care facilities within Nyeri County?
3. What do you think are the common risk factors driving the occurrence of NCDs in Nyeri County?
4. What do you think needs to be done to curb the rising cases of NCDs in Nyeri County and the Country at large?

5. Currently available data indicates that many hypertensive patients (over 80%) do not have their blood pressure within the recommended levels. What do you think may be some of the contributing factors to this problem?
6. What is your view about medication non-adherence as a barrier to hypertension control?
7. A recently concluded study among patients on follow up for hypertension in Nyeri County Referral Hospital MOPC showed that sending sms messages and making phone calls to educate the patients about hypertension results to improvement in medication adherence and subsequently an improvement in blood pressure control. In what way do you think this intervention can impact on the care for hypertensive patients in this clinic?
8. In what way do you feel this intervention can be mainstreamed into the routine care of hypertensive patients on follow up?
9. In what other ways do you think the burden of hypertension can be addressed in Nyeri County, and probably the entire Country at large?

Appendix 15: Map of Nyeri County



Appendix 16: Letter of approval from Graduate School



KENYATTA UNIVERSITY
GRADUATE SCHOOL

E-mail: kubps@yahoo.com
dean-graduate@ku.ac.ke
Website: www.ku.ac.ke

P.O. Box 43844, 00100
NAIROBI, KENYA
Tel. 810901 Ext. 57530

Internal Memo

FROM: Dean, Graduate School

DATE: 9th November, 2018

TO: Mr. Ernest M. Mutua
C/o Department of Community Health & Epidemiology
Kenyatta University

REF: P97/28646/14

SUBJECT: APPROVAL OF RESEARCH PROPOSAL

We acknowledge the receipt of your revised Research Proposal entitled **"Use of Mobile Phone Based Intervention in Optimizing Medication Adherence among Hypertensive Patients in Nyeri County, Kenya"** as per recommendations raised by the Graduate School Board of 22nd August, 2018

You may now proceed with your Data collection, subject to clearance with the Director General, National Commission for Science, Technology & Innovation.

As you embark on your data collection, please note that you will be required to submit to Graduate School completed supervision Tracking Forms per semester. The form has been developed to replace the progress Report Forms. The Supervision Tracking Forms are available at the University's Website under Graduate School webpage downloads.

By copy of this letter, the Registrar (Academic) is hereby requested to grant you substantive registration for your Ph.D. studies.

Thank you.

REUBEN MURIUKI
FOR: DEAN, GRADUATE SCHOOL

c.c. Registrar (Academic) Att; Mr. Likam
Chairman, Department of Community Health & Epidemiology

Supervisor

1. Prof. B.M. Okello Agina
   C/o Department of Obstetrics & Gynaecology
   Kenyatta University
2. Dr. Isaac Mwanzo
   C/o Department of Community Health
   Kenyatta University

RM/cao

Committed to Creativity, Excellence & Self-Reliance

Appendix 17: Ethical Approval from KUERC

KENYATTA UNIVERSITY
ETHICS REVIEW COMMITTEE

Fax: 8711242/8711575
Email: chairman.kuerc@ku.ac.ke
kuerc.secretary@ku.ac.ke
Website: www.ku.ac.ke

P. O. Box 43844,
Nairobi, 00100
Tel: 8710901/12

Our Ref: **KU/ERC/ APPROVAL/VOL.1** (267) Date: 16th April, 2019

Ernest Muthami Mutua
P.0 Box 48413-00100
Nairobi

Dear Mr. Muthami

APPLICATION NUMBER: PKU/975/11027 USE OF MOBILE PHONE BASED INTERVENTION IN OPTIMIZING MEDICATION ADHERENCE AMONG HYPERTENSIVE PATIENTS IN NYERI COUNTY

1. IDENTIFICATION OF PROTOCOL

The application before the committee is with a research topic **"Use Of Mobile Phone Based Intervention In Optimizing Medication Adherence Among Hypertensive Patients In Nyeri County"** received on 4h February, 2019, and discussed on 12th March, 2019.

2. **APPLICANT**

Ernest Muthami Mutua

3. **SITE**
Nyeri County

4. **DECISION**

The committee has considered the research protocol in accordance with the Kenyatta University Research Policy (section 7.2.1.3) and the Kenyatta University Ethics Review Committee Guidelines and **APPROVED that the research may proceed for a period of ONE year from 12th March, 2019**

5. ADVICE/CONDITIONS

i. Progress reports are submitted to the KU-ERC every six months and a full report is submitted at the end of the study.
ii. Serious and unexpected adverse events related to the conduct of the study are reported to this committee immediately they occur.
iii. Notify the Kenyatta University Ethics Committee of any amendments to the protocol.
iv. Submit an electronic copy of the protocol to KUERC.

When replying, kindly quote the application number above.
If you accept the decision reached and advice and conditions given please sign in the space provided below and return to KU-ERC a copy of the letter.

KENYATTA UNIVERSITY OFFICE OF THE CHAIRMAN 16 APR 2019 P.O. BOX 43844 - 00100 NAIROBI ETHICS REVIEW COMMITTEE

PROF. JUDITH KIMIYWE
CHAIRMAN ETHICS REVIEW COMMITTEE

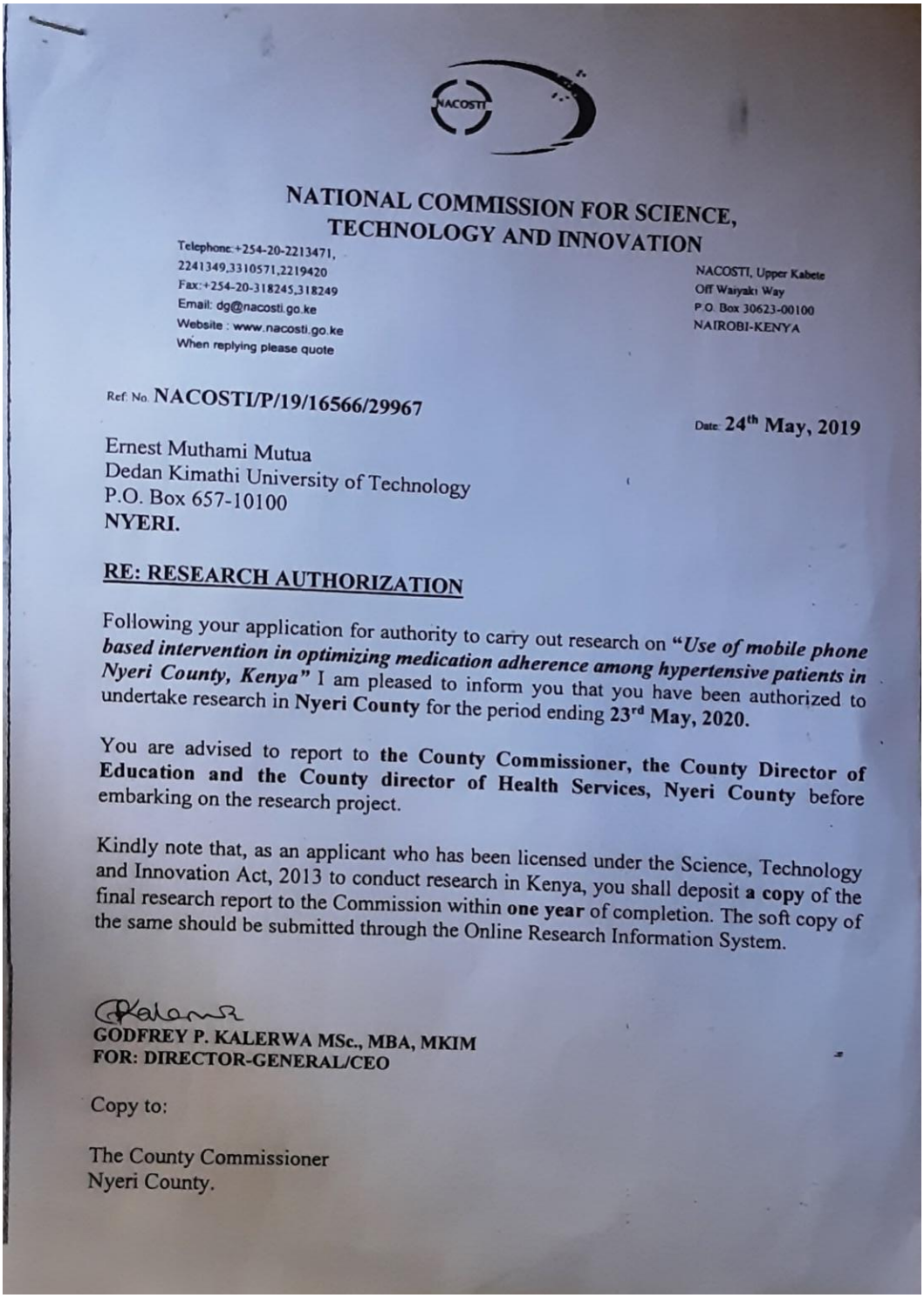
I ERNEST MUTHAMI MUTUA accept the advice given and will fulfill the conditions therein.

Signature..... Dated this day of 16/4/2019 2019.

cc.

DVC-Research Innovation and Outreach

Appendix 18: Research Permit from NACOSTI



NATIONAL COMMISSION FOR SCIENCE, TECHNOLOGY AND INNOVATION

Telephone:+254-20-2213471, 2241349,3310571,2219420
Fax:+254-20-318245,318249
Email: dg@nacosti.go.ke
Website : www.nacosti.go.ke
When replying please quote

NACOSTI, Upper Kabete
Off Waiyaki Way
P.O. Box 30623-00100
NAIROBI-KENYA

Ref. No. NACOSTI/P/19/16566/29967

Date: 24th May, 2019

Ernest Muthami Mutua
Dedan Kimathi University of Technology
P.O. Box 657-10100
NYERI.

RE: RESEARCH AUTHORIZATION

Following your application for authority to carry out research on ***"Use of mobile phone based intervention in optimizing medication adherence among hypertensive patients in Nyeri County, Kenya"*** I am pleased to inform you that you have been authorized to undertake research in **Nyeri County** for the period ending **23rd May, 2020.**

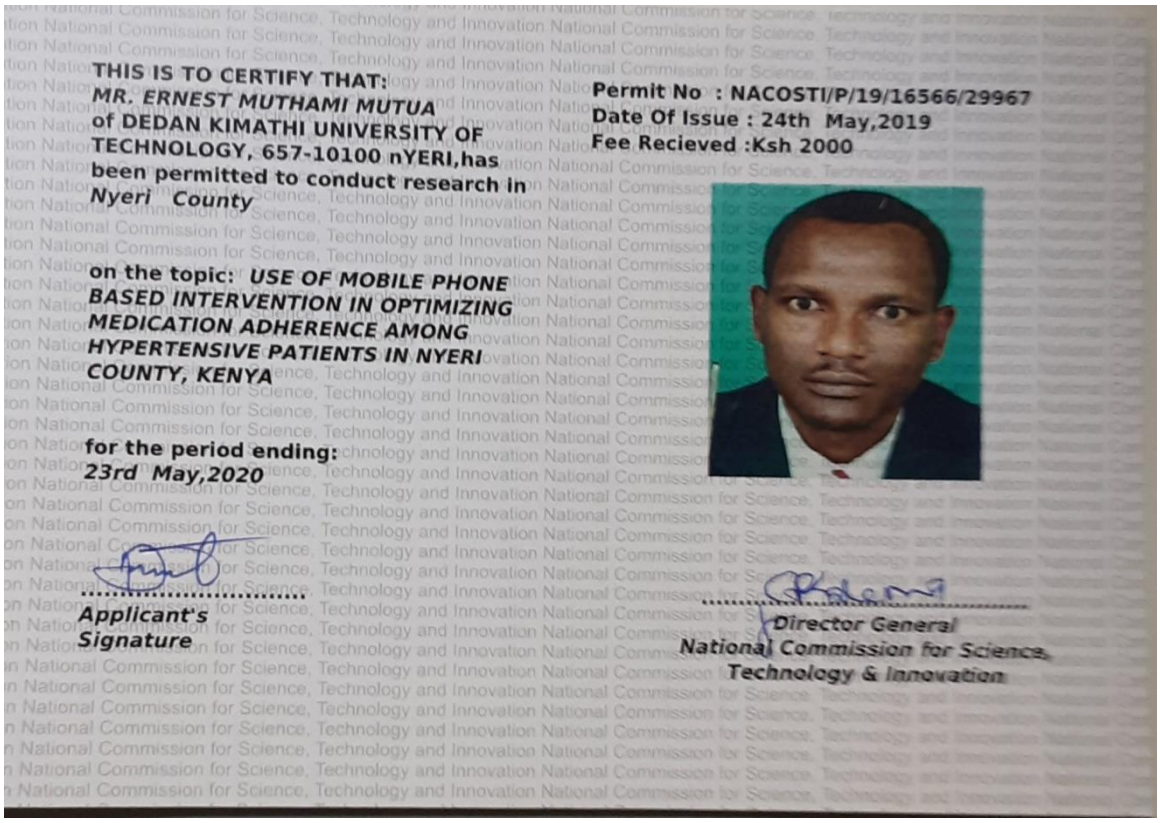
You are advised to report to **the County Commissioner, the County Director of Education and the County director of Health Services, Nyeri County** before embarking on the research project.

Kindly note that, as an applicant who has been licensed under the Science, Technology and Innovation Act, 2013 to conduct research in Kenya, you shall deposit **a copy** of the final research report to the Commission within **one year** of completion. The soft copy of the same should be submitted through the Online Research Information System.

GODFREY P. KALERWA MSc., MBA, MKIM
FOR: DIRECTOR-GENERAL/CEO

Copy to:

The County Commissioner
Nyeri County.



THIS IS TO CERTIFY THAT:
MR. ERNEST MUTHAMI MUTUA
of DEDAN KIMATHI UNIVERSITY OF TECHNOLOGY, 657-10100 nYERI,has been permitted to conduct research in *Nyeri County*

on the topic: *USE OF MOBILE PHONE BASED INTERVENTION IN OPTIMIZING MEDICATION ADHERENCE AMONG HYPERTENSIVE PATIENTS IN NYERI COUNTY, KENYA*

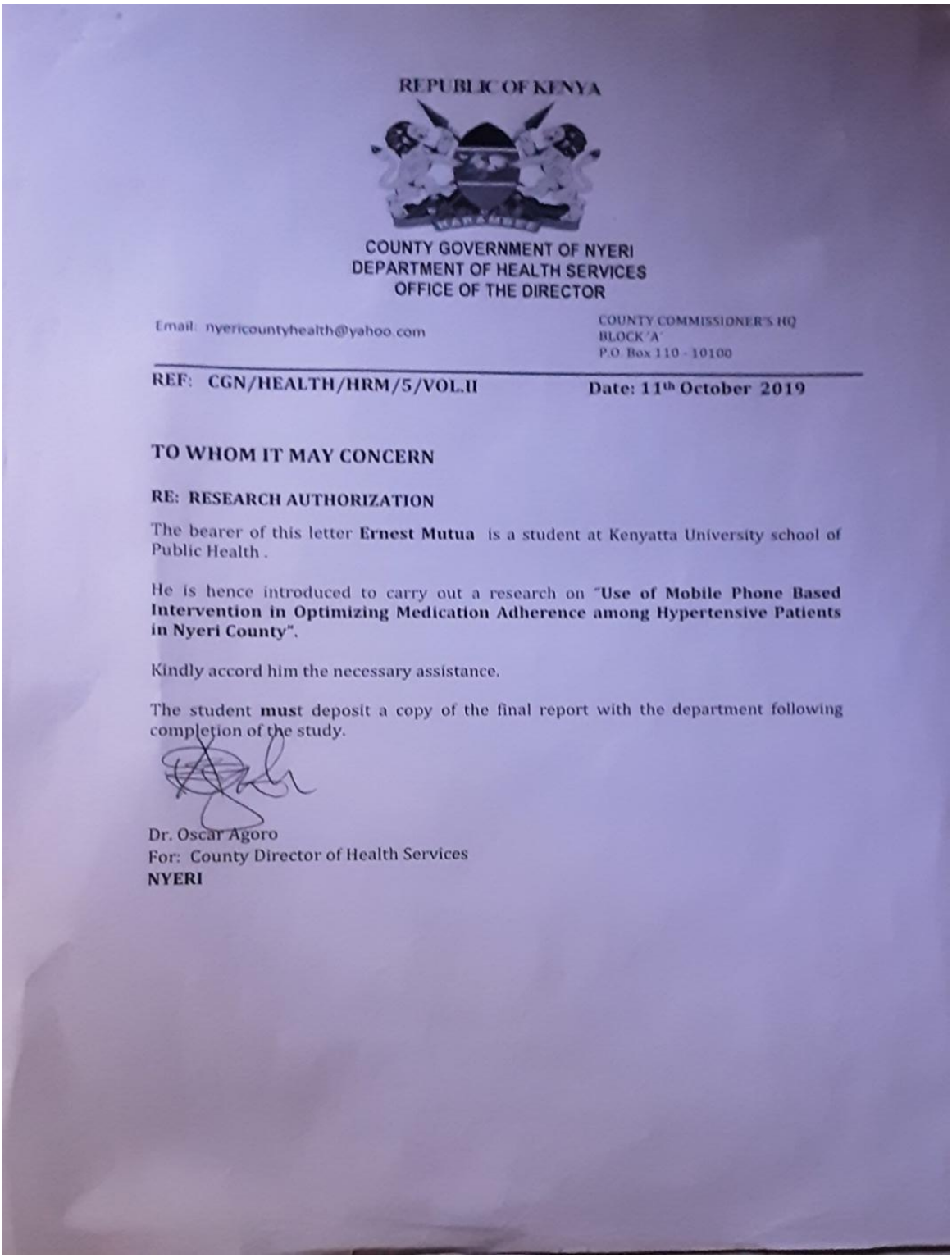
for the period ending:
23rd May,2020

.....
Applicant's Signature

Permit No : NACOSTI/P/19/16566/29967
Date Of Issue : 24th May,2019
Fee Recieved :Ksh 2000

.....
Director General
National Commission for Science, Technology & Innovation

Appendix 19: Letter of Clearance from Nyeri County Department of Health



REPUBLIC OF KENYA

COUNTY GOVERNMENT OF NYERI
DEPARTMENT OF HEALTH SERVICES
OFFICE OF THE DIRECTOR

Email: nyericountyhealth@yahoo.com

COUNTY COMMISSIONER'S HQ
BLOCK 'A'
P.O. Box 110 - 10100

REF: CGN/HEALTH/HRM/5/VOL.II Date: 11th October 2019

TO WHOM IT MAY CONCERN

RE: RESEARCH AUTHORIZATION

The bearer of this letter **Ernest Mutua** is a student at Kenyatta University school of Public Health .

He is hence introduced to carry out a research on **"Use of Mobile Phone Based Intervention in Optimizing Medication Adherence among Hypertensive Patients in Nyeri County".**

Kindly accord him the necessary assistance.

The student **must** deposit a copy of the final report with the department following completion of the study.

Dr. Oscar Agoro
For: County Director of Health Services
NYERI