Using mHealth to Optimize Glycemic Control in Adults with Type 2 Diabetes in Nakuru County: A Proof-of-Concept Randomized Controlled Trial

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Table of Contents

List of Figures

List of Tables

List of acronyms

AIDS:	Acquired Immune Deficiency Syndrome
AMREF ESRC:	African Medical Research Foundation Ethics and Scientific Research Committee
BCW:	Behavior Change Wheel
FPG:	Fasting plasma Glucose
GDPR:	General Data Protection Regulation
HbA1c:	Glycated Haemoglobin
HDL-C:	High-density lipoprotein-cholesterol
HIC	High Income Countries
HIV:	Human Immunodeficiency Virus
JKUAT:	Jomo Kenyatta University of Agriculture and Technology
KDDA:	Kenya Defeat Diabetes Association
KEMRI:	Kenya Medical and Research Institute
LMIC:	Low- and middle-income countries
MIC:	Middle-income countries
MOH:	Ministry of Health
NACOSTI:	National Council for Science Technology and Innovation
RCT:	Randomized controlled trial
TC:	Total cholesterol
TG:	Triglycerides
WHO:	World Health Organization

Abstract

Background

Approximately 552,400 (2.2%) adults aged between 20-79 years in Kenya have type 2 diabetes, 36.0% of the adults have undiagnosed diabetes. Diabetes considerably increases the risk to all-cause mortality and accompanying treatment leads to heavy economic costs. The use of mHealth in managing type 2 diabetes has been associated with increased adherence to diabetes medication, reduction in morbidity and increased self-monitoring of blood glucose in patients with type 2 diabetes.

Objectives

The objective of this study is to evaluate the efficacy of a diet-related mHealth intervention on glycated hemoglobin in adults with type 2 diabetes.

Methods

The mHealth intervention will be delivered using one-way and two-way mobile text messages that were systematically developed using the behavior change wheel to facilitate food literacy. The text messages are loss- or gain-framed to increase influences behavioral decisions. The primary outcome of this proof-of-concept randomized controlled trial will be glycated hemoglobin. Secondary outcomes include: i) anthropometric measurements (BMI, waist-hip ratio, and bioelectric Impendence analysis); ii) dietary intake of fruits, vegetables and legumes; iii) food literacy scores and iv) mHealth user satisfaction. Assessments shall be conducted at baseline, 3 months (primary endpoint) and 6 months (follow-up). To identify between-group differences, the generalized linear models will be determined using analysis of covariance through the intention-to-treat principle.

Study duration

This will be a 12-week intervention, that will be followed by a follow-up of the study cohort for another 12 weeks.

Budget

It is estimated that this study will cost approximately Kes 2,483,540.

1 Introduction/Background

Diabetes is a serious, long-term condition that develops when the body cannot produce adequate or any insulin or cannot effectively use the insulin. Type 2 Diabetes contributes to 90% of all diagnosed cases of diabetes and is attributed to ageing and the nutrition transition (1). In 2019, approximately 463 million people were estimated to have diabetes globally, and it is expected that the prevalence will rise to 578 million by 2030 (2). In the African region, an estimated19.4 million adults aged 20–79 years had diabetes in 2019, representing a regional prevalence of 3.9%. The proportion of undiagnosed diabetes is high globally, where more than one in two (59.7%) people living with diabetes are uninformed of their condition. In the African region, the prevalence of diabetes is higher in urban (5.9%) compared to that in rural areas (2.4%)(3). Further, glycemic control, which is an important treatment outcome for type 2 diabetes, remains comparatively low in LMICs. A recent cross-sectional study on health system performance for people with diabetes analyzed the cascade of care in 28 LMICs (4). This study showed that only 22.8% of persons with diabetes receiving treatment with lifestyle modification advice achieve glycemic control.

In Kenya, it is estimated that 552,400 (2.2%) adults aged between 20-79 years have diabetes. Further, more than a third (36.0%) of the adults in the same age-group are not aware that they have diabetes. Kenya also has the second highest proportion of deaths (88.4%) in Africa related to type 2 diabetes for people aged below 60 years. In 2019 alone, 8,081 deaths were attributed to diabetes. The prevalence of type 2 diabetes in Kenya is higher in urban areas (3.4%) compared to rural areas (1.9%) (5). The prevalence of diabetes is higher among persons in the highest wealth quintile (5.2%) compared to those in the lowest wealth quintile (1.0%). In Nakuru County, the prevalence of type 2 diabetes among people aged 50 years and above is 6.5% (6).

Diabetes considerably increases the risk to all-cause mortality globally. Cardiovascular disease (CVD) mortality associated with diabetes is higher in low- and middle-income countries (LMICs) compared to high income countries (HIC). A recent cohort study (7) with 143,567 adults aged 35–70 years reported higher CVD rates among people with diabetes in LMICs (LIC 10.3, MIC 9.2, per 1,000 person-years, $P < 0.001$) compared to HIC (8.3 per 1,000 person-years, $P < 0.001$). Cardiovascular mortality was also higher in LMICs (LIC 10.3, MIC 9.2 person-years, $P < 0.001$) compared to HIC (1.0 per 1,000 person-years, $P < 0.001$).

Diabetes treatment leads to heavy economic costs, with approximately USD 727 billion spent per year globally on diabetes healthcare (8). In Kenya, USD 70.5 Million was spent in expenditures related to diabetes care (9), translating to approximately USD 324 per person with diabetes per year (2). This increasing epidemic points to a dire need for global, regional, and in-country approaches to find suitable solutions to forestall further adversity.

It has been proven that multi-disciplinary, patient-centered, and well-coordinated models facilitate diabetes self-management (10). Various diabetes care guidelines recommend individualization of care to

enable attainment of treatment outcomes, reduce of hospitalizations and adverse clinical events and improving the quality of life (11–13). To implement recommendations, systemic and financial barriers need to be overcome. Hence, governments and relevant stakeholders need to invest in high-quality, team-based diabetes care to optimize modern technological advancements (14).

Technological advancement and diabetes technology may use the versatile nature of mobile phones and appliances (mHealth) to support diabetes. The recent increase in mobile phone ownership and use in LMICs (15–17) has resulted in a commensurate rise in the use of mHealth in behavior change interventions (17–22). In Kenya, the use of mHealth showed increased adherence to diabetes medication, significantly reduced in morbidity and increased self-monitoring of blood glucose in patients with type 2 diabetes (21,22). mHealth has the potential to address gaps in accessibility and coverage. mHealth is associated with positive effects on clinical outcomes, compliance and quality of life in type 2 diabetes (23–25). Despite there being many studies that have shown changes in treatment outcomes for type 2 diabetes in Kenya, there is a dearth of evidence on the use of theory-driven mHealth interventions on diabetes care.

The most common approach to diabetes care has been focusing on behavior change and lifestyle modification. However, a recent systematic review and meta-analysis (26) provided evidence that changing dietary environment had a greater reduction in HbA1c: 0.5% (5.5 mmol/mol [95% CI -0.65, -0.34]) compared to 0.32% (3.5 mmol/mol [95% CI -0.40, -0.23]) for interventions that intended to change behavior. This review (26) suggested four strategies to refine the efficacy of dietary behavior interventions in treatment of type 2 diabetes. These strategies include more robust reporting of content and frequency of behavior change techniques (BCTs), intervention fidelity (the extent to which an intervention was delivered as conceived and planned) and alignment of the intervention with behavior change theory. (27)

This study seeks to use interactive mHealth to optimize glycemic control through dietary behavior and food literacy in people with type 2 diabetes in Nakuru County, Kenya.

2 Statement of the Problem

The prevalence of type 2 diabetes in Kenya is rising and by 2045, it is projected that nearly 1.5 million people will have diabetes. The application of mHealth in diabetes care has gained prominence globally, but little is known on how this novel approach will affect treatment and management of diabetes in LMICs settings. Further, the use of the behavior change wheel model has been associated with notable improvements in various aspects of diabetes self-care. In addition, our systematic review showed that mHealth interventions lack engagement and sub-optimally apply behavior change theories.

These gaps in diabetes care in Kenya, where the increased availability and use mobile telephones creates an important opportunity for sustainable and locally suitable interventions in diabetes care. This proof-of-concept randomized controlled trial will use mHealth, one-way and interactive mobile text messages to optimize glycemic control in adults with type 2 diabetes. It is anticipated that the findings from this trial will

provide information on how mobile technology can be applied to support dietary behavior modification among adults with type 2 diabetes in a Kenya.

3 Review of Literature

This section reviews literature on use of mHealth in type 2 diabetes care, glycemic control, food literacy and using the behavior change wheel model to develop an intervention.

3.1 Evidence on the use of mHealth in management of type 2 diabetes

Diabetes management in LMICs is influenced by a complex interplay between individual factors, the socio-cultural and physical environment, the health system and other related drivers coupled with lack of health insurance and poor-income levels (28–30). To address challenges in diabetes self-care in LMICs, the principles of collaboration, education, standardization, resource optimization and technological innovation need to be considered (31). Technological innovation includes using diabetes technology and the versatile nature of mobile phones and appliances to support self-care.

According to the World Bank (32), there are 104 per 100 people mobile phone subscriptions globally. Further, over 93.2% of the world's population is now covered by a mobile broadband network (33). In Africa, there are 76 per 100 people mobile phone subscriptions with 88.4% of the population covered by mobile broadband network (33). Following the high ownerships and use of mobile technologies followed by their innovative application to address health, mHealth is a fast-growing and evolving field that provides a potential for chronic disease management.

Increased availability and use of mobile phones has facilitated the application of mHealth in behavior change interventions (17–20). mHealth is defined as medical and public health practice that is supported by mobile devices, like mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices (34). In LMICs, mHealth has been shown to address gaps in accessibility and coverage and resulted in positive effects on clinical outcomes, compliance and quality of life in type 2 diabetes (23–25). mHealth is also influencing delivery and management of health services and information (35). The increased accessibility to mHealth has expanded the possibilities of personalization and citizen-centered public health and medical care. mHealth has effectively been applied in various fields of healthcare, including maternal and child health(36), chronic disease management (37) and HIV/AIDS (38).

The potential of mHealth interventions to improve care and management of diabetes has resulted in numerous empirical studies. Two meta-analyses, which included mainly studies from HICs, suggested that mHealth interventions for diabetes have clinically meaningful changes of more than 0.5% change of HbA1c (39,40). A pooled effect on HbA1c from three studies on mobile phone–based interventions showed a larger effect of up to 20.5% (40). Further, mHealth interventions have been shown to be cost-effective (41) despite being criticized for having meager user satisfaction ratings and usability challenges (42). Most of the studies are however conducted in HICs. Additionally, mHealth has been associated with changes in clinical

outcomes, improved adherence to treatment and communication with providers, decreased travel time, easier access to expert advice and cost-effective diabetes education in LMICs (43). Further, our systematic review on interventions in LMICs showed that mHealth has the potential to change HbA1c in clinically significant margins (44). The operational and socio-cultural framework in LMIC is dissimilar from that in high income countries. Therefore, more methodologically sound interventions to determine the efficacy of well-designed interventions in these settings are required (43).

3.1.1 Use of text messaging in mHealth interventions for patients with type 2 diabetes

Text messaging is convenient, does not require internet access and is commonly used among most mobile phone users, irrespective of their socioeconomic status (45) and is not affected by racial disparities (46). Evidence shows that interventions using text messaging successfully reach most population subsets, including the high-risk and hard-to-reach (47,48). Text messaging has also improved self-care and glycemic control in racially and ethnically diverse populations with low socioeconomic status (49–51). A recent survey in Kenya on the use of smartphone and social media in emerging economies identified text messaging as the most popular social activity among phone users. The survey showed that 85% of Kenyans had sent text messages in the past 12 months (52).

However, there is a lack of evidence on how health literacy interventions using text messaging affects adults with type 2 diabetes (53). Nelson, *et al.,* 2016 (54) examined the association between health literacy status and engagement using text messaging, and suggested that user experience is important in the development of engaging mHealth interventions.

Studies in LMICs have shown that using text messaging is beneficial to treatment and have full patient satisfaction. An Egyptian study (55) suggested an up to 1.0% HbA1c reduction, considerable improvements in adherence to medication, self-efficacy and resulted in increased knowledge and participant satisfaction. Another study in Iraq showed a 0.7% HbA1c reduction after a 6 month SMS intervention, accompanied by a correlated improvement in knowledge score and satisfaction ratings (56).

3.1.2 Mobile phone applications in patients with type 2 diabetes

Mobile applications (apps) are commonly referred to as a type of application software designed to run on a mobile device, such as a smartphone or Tablet computer. The prominence of health-related smartphone apps started in 2010, and studies have illustrated the potential of smartphone apps in complementing diabetes care (57). Mobile health apps have the possibility to support patients in managing diabetes through monitoring of blood glucose, diet, and exercise as well as to increase adherence to diabetes management and self-monitoring. Evidence from meta-analyses suggest that mobile apps can support improvement of blood glucose control and strengthen the self-care perceptions in people with diabetes by increasing health knowledge (58,59). A recent systematic review and meta-analysis shows that SMS-based

mhealth interventions produced the highest effects on treatment when compared with smartphone apps-based services (60).

3.2 Evidence on using glycated hemoglobin (HbA1c) in measurement of glycemic control

Glycated hemoglobin (HbA1c) is the average plasma glucose over the previous eight to twelve weeks (61). This test can be conducted at any time of the day and does not require any specific prior preparation, such as fasting. This flexibility makes HbA1C a more preferred and recommended diagnostic test for measuring glycemic control in people with diabetes (62–64). The recommended cut-off point for diagnosing diabetes using HbA1c is 6.5% (48mmol/mol). However, a value >6.5% does not necessarily imply diagnosis of diabetes while levels between 5.7 and less than 6.5%, infer a pre-diabetes range.

Using HbA1c is advantageous because it avoids the day-to-day variability of glucose values, and the need for the patient to fast prior to the test. However, differences in precision of HbA1c measurement between laboratories and global inconsistency remain problematic concerns for this test (62). Additionally, HbA1C is influenced by erythropoiesis, altered haemoglobin, glycation, erythrocyte destruction and assays (65).

Despite the expectation that low HbA1C reduces all-cause mortality, some studies have shown increased risk of mortality and cardiac events, depicting a U-shaped correlation (66,67). The reason for the higher mortality risk is however not clearly known but may be explained by hypoglycemia and a possible direct adverse effect of administered pharmacological glucose-lowering agents. Further, other studies have revealed that the there is an increased risk of mortality associated with low HbA1c values (68–70). High levels of HbA1C increases the risk to cardiovascular conditions, diabetes complications and other debilitating health outcomes as compared to normal ranges of HbA1C. Hence, various guidelines (71–74) recommend reducing HbA1c levels to less than 7% and emphasize the value of achieving the low HbA1C through individualized treatment approaches based on specific patient characteristics (75,76).

3.3 Evidence on the role of food literacy on type 2 diabetes

Vidgen *et al.* (77) define food literacy as 'a collection of inter-related knowledge, skills and behaviors required to plan, manage, select, prepare and eat food to meet needs and determine intake'. In this definition, food literacy is composed of 4 components: (i) Planning and management; ii) Selection; iii) preparation and iv) eating. Recently, Fisher *et al.,* (78) redefined food literacy in the South African context as 'Food literacy refers to an individual's knowledge, skills and behavior as demonstrated through the sourcing, consumption as well as the nutritional, economic, safety and social aspects of food'. The two definitions agree on the broader significance of knowledge, skills, and behavior. However, the new South African definition emphasizes on sourcing of food, nutritional value, safety, economic and social aspects related to food consumption. It has also been advanced that food literacy is influenced by interdependent intrinsic attributes (79). In this perspective, intrinsic factors include food skill, knowledge, and self-efficacy while extrinsic attributes are ecological or socio-cultural drivers. Using a combination of the described components (77) and attributes (79) food literacy can be defined as 'the interrelated combination of

knowledge, skills and self-efficacy on food planning, food selection, food preparation, eating and evaluating information about food with the ultimate goal of developing a lifelong healthy, sustainable and gastronomic relationship with food' (80).

Food literacy has the potential to connect food and nutrition-related knowledge, cooking skills, and capability to promote and develop relevant knowledge to facilitate dietary behavior change (81). In Australia, food literacy interventions have been shown to provide individuals with skills that contribute to health (77,81). Similarly, an Irish study showed that lower diabetes nutrition knowledge was linked to lower intakes of fruits and vegetables and consumption of foods with higher dietary glycemic index (82). A positive correlation between health literacy and diabetes knowledge has also been inferred in patients with type 2 diabetes, as described in a recent systematic review (83).

There is a dearth of information on food literacy of people with type 2 diabetes in Kenya. However, one study on nutrition knowledge in people with type 2 diabetes revealed that 69.3% had low nutrition knowledge and 81.4% of the people did not know the meaning of a balanced diet (84).

3.4 Development of an intervention using the behavior change wheel model

Behavior change interventions are defined as organized sets of activities that are designed to change specific behavior patterns (85). Generally, these patterns are measured based on prevalence or incidence of the behaviors in specific populations. Human behavior change is complex given that it is determined by the intricate interactions between the individuals' environment and a diverse set of social drivers (86). There is increasing recognition that the design of behavior change interventions should be based on relevant theories (87–89). The value of using behavior change theories and behavior change techniques (BCTs) in mHealth interventions is known (90,91). However, their application in LMICs is sub-optimal (92). Recently, the behavior change wheel (BCW) (86) has been applied in the design and implementation mHealth interventions (93–95). BCW allows users to design and decide on interventions and policies based on an analysis of the specific behavior. It also takes into consideration the processes that need to be altered to effect the behavior change, and provides the interventions and policies needed to change the processes (86).

The BCW outlines three stages of designing interventions as illustrated in Figure 1 below.

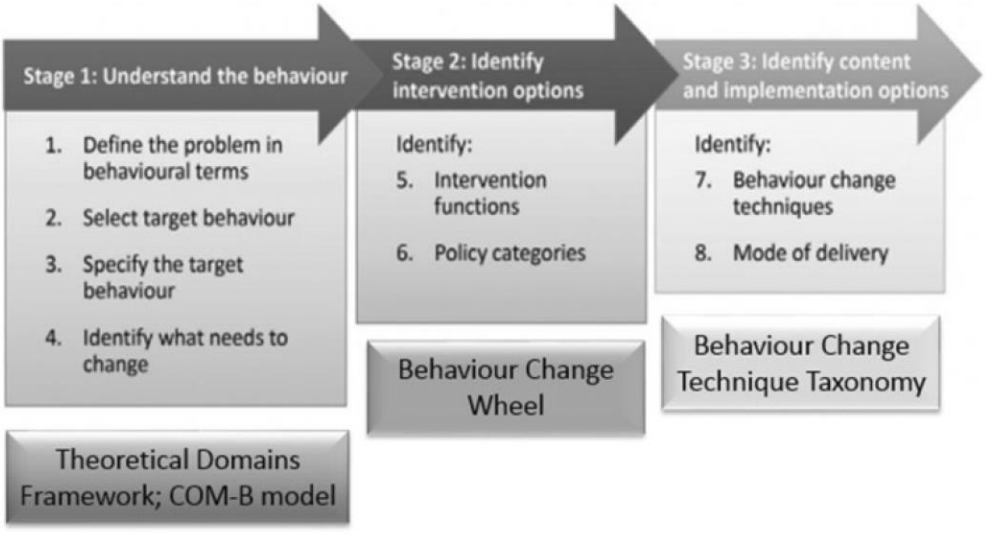

Figure 1. The Behavior Change Intervention design process

Source: Adapted from The Behavior Change Wheel, A guide to Designing Interventions (p 25) by Michie, S., *et al.* 2014.

3.5 Research Objectives

The objective of this study is to evaluate the efficacy of a diet-related mHealth intervention on glycated hemoglobin among adults with type 2 diabetes.

By using one-way and interactive mobile telephone messages, this intervention seeks to achieve the following specific objectives:

1. Reduce glycated hemoglobin by at least 0.3% after 12 weeks
2. Increase food literacy scores as measured by the self-perceived food literacy scale

4 Conceptual Framework and Operationalization

The theoretical framework (Figure 2) of dietary behavior and food literacy is founded on the four components of food literacy in Vidgen *et al.* (77) and the attributes of food literacy described by Perry *et al.,* (79). The four components of food literacy include planning, selection, preparation and eating, while the attributes are skills, knowledge, and self-efficacy. Vidgen definition. (77) has been criticized for its emphasis on knowledge and excludes functional skills (96). Our operational definition therefore amalgamates a wider scope of definition of food literacy. Based on findings from our qualitative study conducted in the same population, it was found that two components of food literacy presented as the highest-ranking barriers to health dietary intake. We therefore developed the conceptual framework based on selection and eating of healthy dietary diet. BCW is applied to systematically identify the theoretical domains framework, intervention functions and behavior change techniques that were used to develop text messages for the intervention. It is anticipated that the text messages will influence changes selection and eating of healthy diets that will result in a reduction in HbA1C.

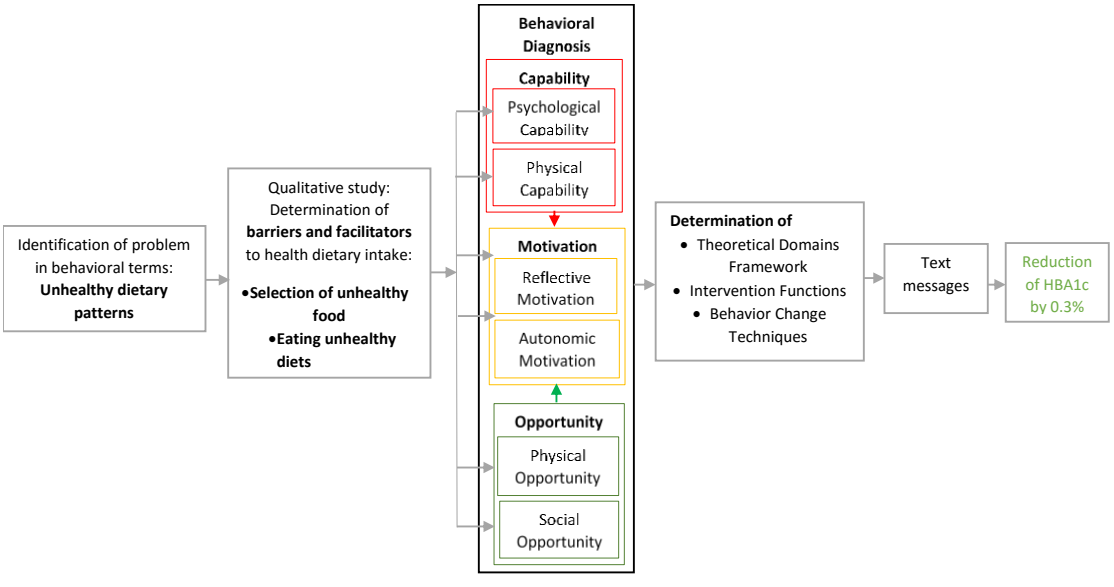

Figure 2. Conceptual Framework for dietary behavior outcomes and food literacy concepts

4.1 Operational definition of independent and dependent variables

4.1.1 Definition of independent variables

i. Food literacy: the interrelated combination of knowledge, skills and self-efficacy on food planning, selecting foods, food preparation, eating and evaluating information about food with the ultimate goal of developing a lifelong healthy, sustainable and gastronomic relationship with food (80).

ii. Attribute of food literacy: quality or feature considered as a characteristic or integral part of food literacy (79,97)

iii. Psychological capability: The mental capacity, knowledge or psychological skill to engage in the necessary thought (85)

iv. Physical capability: The capacity, physical skill, strength, or stamina to perform an activity (85)

v. Physical opportunity: The opportunity offered by the environment (85)

vi. Social Opportunity: The cultural milieu, social cues and interpersonal influences that direct the way we think about things (85)

vii. Reflective Motivation: Processes such as evaluating and planning (85)

viii. Automatic motivation: The emotions, reactions, desires and impulses arising from associative learning and/or innate dispositions (85)

4.1.2 Definition of dependent variables

Glycated hemoglobin (HbA1c) is the average plasma glucose over the previous eight to twelve weeks (61).

5 Hypotheses/research questions

We hypothesize that using mHealth influences food literacy and dietary behavior hence reducing HbA1c by at least 0.3% in 12 weeks among adults with type 2 diabetes.

6 Study design and sampling strategy

6.1 Study design

This will be a proof-of-concept randomized controlled trial (RCT) using mobile text messaging to optimize glycemic control in adults with type 2 diabetes.

6.2 Participants

6.2.1 Setting of the study

This study will be conducted in Nakuru County, located 157km North-West of Nairobi, Kenya (Appendix 1). Nakuru County covers an area of 7,495 km^2 and has 11 administrative Sub-Counties including Nakuru Town East, Nakuru Town West, Naivasha, Molo, Gilgil, Njoro, Kuresoi North, Kuresoi South, Rongai, Nakuru North and Subukia (98). The county is estimated to have a population of nearly 2 million people (99) and an estimated prevalence of 2.4% of type 2 diabetes among adults aged ≥50 years (6).

6.2.2 Inclusion and exclusion Criteria

Participants will be eligible for inclusion into the study if they meet the following criteria:

a. adults over the age of 18 years;
b. diagnosed the type 2 diabetes within the previous 1 year and obtaining care at a participating level 4 hospital;
c. able to read English or Swahili Language (self-reported).
d. currently own and able to read and send mobile text messages using any phone;

Participants will be excluded if they:

a) are on dialysis;
b) are pregnant;

c) are unable to use mobile phone because of mental or visual impairment or any other reason.

6.3 Sample size

Hypothesis testing was not the objective of this study. However, for an effect size of 0.60, at a power of 0.80 and at an alpha level of 0.05, a sample size of 25 in each group has been used to results in a 1% reduction of HbA1c levels at post-test compared with pre-test (100). We therefore determined a sample size of 60 a-priori (n=30 intervention, n=30 control arm) to assess feasibility of text messaging in optimizing glycemic control. It is anticipated that this proof-of-concept study will obtain parameters that will be used in determining a robust power calculation for a fully powered efficacy trial, as it has been applied elsewhere in Bucci *et al.* (101).

6.4 Sampling design

Nakuru county has 18 level 4 hospital(102). Purposive sampling will be used to select two hospitals, one in a rural setting, and another in an urban setting. Multistage random sampling with then be applied to randomly assign 15 participants in either the intervention or control arms using simple random sampling in each of the selected hospitals.

6.5 Recruitment

The officers-in-charge of the non-communicable disease clinics shall be enlisted to help in the recruitment of participants. The officers will receive the recruitment procedure guidelines prior to the onset of the study to ensure a standard approach in all the hospitals. During the clinic visits, the participants will be asked to participate in the study. Possible study participants will be given details on the study and asked to acknowledge their willingness to participate within 7 days. The recruitment is planned to take place between 15th July to 15th August 2021.

Due the COVID-19 disease the following precautionary measures shall be ensured by the research team, participants and hospital staff during recruitment, training and all activities in this study:

1. The study shall provide personal protective equipment (PPE) for all study participants and researchers.
2. Regular and thorough washing of hands with soap and water, or alcohol-based hand sanitizer provided by the research.
3. Maintaining a distance of at least 1 meter (5 feet) between yourself and anyone (who is coughing or sneezing), avoiding handshakes or hugging.
4. Persons with a cough or sneezing should stay home or keep a social distance but avoid mixing with others in a crowd.

5. Maintain good respiratory hygiene by covering your mouth and nose while coughing and sneezing with a handkerchief, tissue, or into flexed elbow.
6. Stay at home if you feel unwell with symptoms like fever, cough and difficulty in breathing.
7. All study participants should at all times wear a face mask to reduce the chances of transmission of the virus.
8. Any cases regarding the disease will be reported using the call line facility number 719. Correct messages to be relayed to the participants (if need be) will be received from *719#
9. Surfaces used during the research activities (e.g. desks, tables) and objects will be wiped with disinfectant regularly.
10. Surfaces used during the research activities (e.g. desks, tables) and objects will be wiped with a disinfectant regularly.

6.6 Randomization

We will apply simple random sampling through a computer-generated list of random numbers. The hospital diabetes registers from the two selected hospitals will be used to select patients on regular diabetes care from the hospital patient records. The patients will then be assigned numbers and randomly selected.

6.7 Blinding

Blinding of the participants, care providers or the research team is not possible because the intervention requires identification of participants to receive text messages.

6.8 Interventions

6.8.1 Intervention group

The intervention group will receive a total of 43 text messages as tabulated in Table 1 below. Text messages were developed using the BCW through a systematic process linked to specific behavior change techniques (Table 2). The text messages will provide practical information or guidance to influence selection and eating healthy diet for type 2 diabetes care. The text messages were either loss- or gain-framed to increase influence on behavioral decisions (103). Additionally, the participants will receive a text message to rate their ability on selection of food and eating of healthy diet based on the messages received in the month. The combination of the one-way and two-way messages in this group are designed to increase engagement of the participants.

Table 1. Text Messages Schedule

Message type	Message format	Frequency	Total number of messages
Introductory message	One-way	Once	1
Clinic Appointment	One-way	1 message per month	3
Selection of healthy food	One-way	3 messages per week	18
Eating healthy diet	One-way	3 messages per week	18
Evaluation message	Interactive	1 message per month	3

6.8.2 Control group

The control group will continue receiving standard care in the hospitals. The control group shall receive a reminder text messages one day before the routine clinic appointment. The clinic appointment dates shall be derived from the hospital where the participant receives routine diabetes care.

Figure 3 describes the study timeline and workflow. At the beginning of the intervention, both the control and intervention groups will receive introductory text messages. Text messages shall consist of personalized salutation (using the preferred name of the participant) sent to the officially registered mobile numbers. The messages shall be sent between 10am and 3pm through the Africa's Talking ® Application Programming Interface (API).

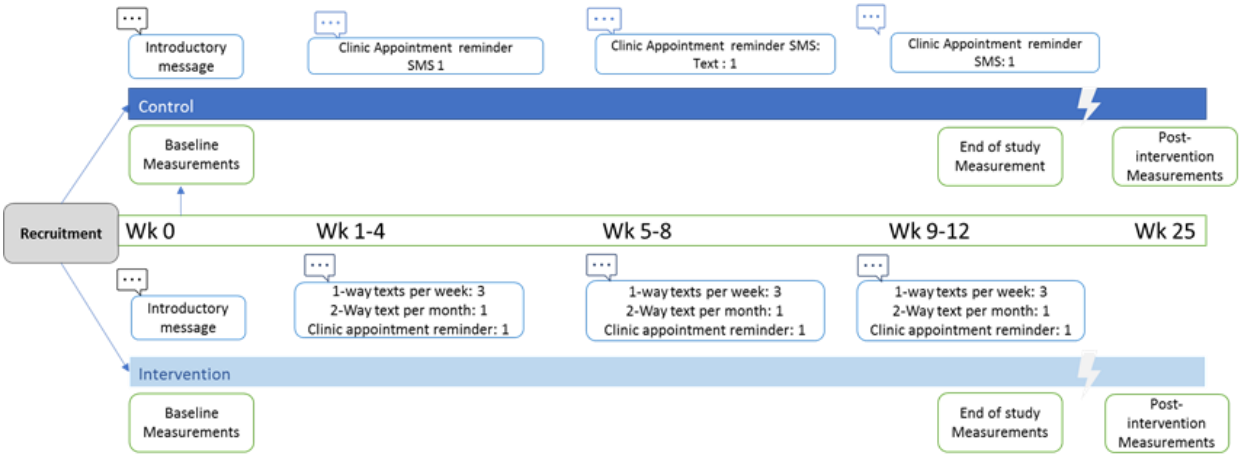

Figure 3. Study timeline

Table 2. Text messages for specific target behaviors

COM-B Components	What needs to happen for the target behavior to occur?	Behavior Change Technique	Text No	Text Messages
Physical capability	Be able to select healthy food	Instructions on how to perform behavior	S 1	To meet nutrient needs within calorie limits, choose a variety of nutrient-dense foods across and within all food groups in recommended amounts. Energy dense foods include vegetables, fruits, whole grains, beans, nuts and seeds, and lean protein — when prepared with little or no saturated fats, added sugars and sodium
			S 2	There are 5 food groups: (1)Vegetables and legumes or beans (2)Fruit; (3)Lean meats and poultry, fish, eggs, nuts and seeds, legumes or beans;(4) Grain (cereal) foods, mostly wholegrain or high cereal fiber varieties (5) Milk, yoghurt, cheese or alternatives, mostly reduced fat.
			S 3	Reduce foods and beverages that are high in added sugars to better control your blood sugar. To avoid added sugars, check for words like brown sugar, corn sweetener, corn syrup, dextrose, fructose, and high-fructose corn syrup. These are added sugars
			S 4	Reduce or avoid foods and beverages that are high in saturated fat like whole milk, cream, butter, cheese, meat, palm oil and coconut oil. Instead, select low-fat milk and use healthier plant-based oils.
			S 5	Instead of selecting canned fruit or bottled juices, buy fresh juice or fruits as they are energy dense and have fiber that helps in blood sugar control. Fresh fruits are also cheaper.
	Be able to eat healthy food diet		E1	To ensure you eat a healthy diet, try to eat the following food servings most days of the week: **(1) Vegetables and legume beans:** Like 5-6 medium cups of managu, or mixed vegetables, or 2 tomatoes. **(2) Fruits:** Like 2 medium size apples, bananas, oranges or pear. (**3)Lean meats and poultry, fish, eggs, nuts and seeds, legumes or beans:** Like 200g raw meat or fish, or 2 eggs, or 60g of nuts or 300g beans ; (**4) Whole meal grain (cereal) foods: Like** 60–90 g of Ugali, bread, chapati **(5) Milk, yoghurt, cheese or alternatives: like** 500 ml milk or yoghurt
			E 2	Most processed carbohydrate foods release glucose more quickly than whole grain carbohydrates. Eat whole grain carbohydrates which produce a slower rise in blood glucose levels, which are called low-glycemic index (GI) foods and result in better blood glucose control.
			E 3	Low GI foods include some posho milled unga, high-fiber breads and whole meal cereals githeri, most fruits, legumes, and low-fat dairy products
			E 4	Eating vegetables before a carbohydrate rich meal has been shown to have beneficial effects on blood sugar levels. This practice slows down the speed at which carbs are absorbed into the bloodstream and may benefit both short- and long-term blood sugar control.

			E 5	Eat fruits instead of making fruit juice. Fruits contain fiber and various plant compounds. Sugar from fruits is generally digested very slowly and do not cause increases in blood sugar levels.
			E 4	Limit pork, lamb, beef meats: instead, eat plant-based proteins like beans, green peas, green grams or animal proteins like eggs or fish. Pork, lamb, beef meats contain saturated fats
			E 6	Limit lard/bacon /chicken fat/butter, instead, vary with liquid vegetable-based oils: Use olive oil or vegetable oil for cooking. Limit lard, bacon, chicken fat and butter contain saturated fats
			E 7	Eat regular meals and spread out your servings of energy giving foods evenly throughout the day. This helps you can maintain energy levels without causing large rises in blood glucose levels.
Psychological capability	Know healthy food	Information about health consequences	S 6	The amount of carbohydrate in your meal has the greatest effect on blood glucose levels. Avoid big servings of carbohydrates in your meal and ensure most of your energy giving foods are composed of whole meal or high fiber. Make vegetables and fruits take the larger portion of your plate.
			S 7	There are two main types of fat: saturated and unsaturated. Too much saturated fat in foods like fatty meat, sausages and butter can increase the amount of cholesterol in the blood, which increases your risk of developing heart disease.
			S 8	Instead of selecting foods with saturated fats, select foods with unsaturated fats like nuts, seeds, seafood, and avocados.
			S 9	Some food items like sauces have hidden sugar and salt, therefore it is wise to avoid tomato sauces, fat-free salad dressings, and condiments. Instead of sauces. To improve the taste of your food, select preferred spices, herbs, onions, or other low-energy flavorings
	Advanced planning skills to ensure selection of food healthy food		S 10	Select whole or minimally processed foods, which help to control your blood glucose
			S 9	Make an eating plan each week – this is the key to fast and easy meal preparation. This will also ensure that you plan for healthy diets and better controlled blood glucose.
			S 11	Plan to have meals with plenty of vegetables and fruit. Your goal is to fill half your plate with vegetables and fruit at every meal. Choose colored fruits like oranges, mangoes, loquats, plums and vegetables like managu, carrots and tomatoes.
	Know the composition of the plate model		E 8	Start with a 9-inch dinner plate Fill **half** with non-starchy vegetables, such as managu, *Sukuma wiki*, green beans, broccoli, cauliflower, cabbage, and carrots. Fill **one quarter** with a lean protein, such as chicken, fish, legumes or beans, or eggs. Fill **one quarter with whole meal carbohydrate foods:** grains, starchy vegetables (such as potatoes and peas), rice, pasta, beans, fruit, and yogurt. A cup of milk also counts as a carb food.
Social Opportunity	Change cultural habits on portion size	-Goal setting (behavioral) -Restructuring the physical environment	S 12	Controlled portion sizes of food are important to reducing calorific intake. To control your portion sizes, plan to use a smaller plate size when serving meals.
			S 13	Your health is a personal responsibility. When eating, try to avoid places that may entice you to eat excessive food. Eat most of your meals at home for better control of healthy food and your blood sugar

Reflective motivation	Intend to select healthy diet	-Information about health consequences -prompts/cues	S 14	Make your shopping list ahead of time and do not go shopping while hungry. This helps you to buy healthier items but also save money and select healthier foods.
			S 15	Intend to purchase less saturated and unhealthy fats by using oils like canola, corn, olive, peanut, safflower, soybean, and sunflower oils. Unsaturated oils that are healthy and are also naturally present in nuts, seeds, seafood, and avocados.
			S 16	Intend to select healthy dietary pattern by selecting foods and beverages that have low or no added sugars, saturated fat, and/or sodium. Check food labels to check the nutrient content of the food items.
			S 17	Instead of purchasing processed grade 1 flour or unga, use posho mill unga. It contains fiber and other plant extracts that are important to the body and blood sugar control.
	Intend to prioritize eating healthy diet		E 9	Small changes to more nutrient-dense, single food and beverage choices combine to become a nutrient dense meal, and can lead to a whole day made up of nutrient-dense meals and snacks, increasing you blood sugar control
			E 10	Place fresh and locally available low-carbohydrates fruits on the table or where they are easy to reach to increase intake of fruits. This enables you to eat healthy and avoid unhealthy snacking.
			E 11	To reduce salt intake, ensure that salt in added to food when cooking. Avoid having saltshakers on the table when eating
			E 12	A supportive family enables you to eat healthy meals. Enlist your family members to support you to encourage your intake of healthy meals by planning meals and eating together.
			E 13	Portion sizes of food affect the calories consumed. Plan to control your portion sizes by using smaller plates and ensuring that you apply the plate model in serving your various foods
			E 14	Water is important to prevent dehydration and aid in the digestion of food and absorption of nutrients. To increase water intake, flavor your water with fruits like lemon or orange.
Automatic motivation	Establish routines and habits to select healthy diet	Instructions on how to perform behavior	S 18	Keep a food diary for a few days to evaluate what you eat every day. Note how you were feeling when you ate – hungry, not hungry, tired, or stressed? Create a list of "cues" by reviewing your food diary to become more aware when you're "triggered" to eat for reasons other than hunger. Is there anything else you can do to avoid the cue or situation? If you cannot avoid it, do something differently that would be healthier. Replace unhealthy habits with new, healthy ones
		Restructuring the physical environment Prompts/Cues	S 18	Replace white rice with whole grains foods or brown rice. This ensures that better blood sugar control.
			E 15	Eat smaller meals more often. Eat at least three meals a day with snacks in between. When you wait too long to eat you are more likely to make unhealthy food choices.

	Establish routines and habits to serve and eat healthy diet		E 16	Make a routine of eating healthy snacks like groundnut or almonds, yogurt, or yogurt with berries, hard-boiled eggs, avocado, or fruit slices. These snacks help you to maintain you blood sugar and reduce extra energy intakes.
			E 17	Eating at home, or carrying safe food when traveling ensures that you eat healthy diets that make you control our blood sugar
			E 18	Alcohol consumption can worsen diabetes-related medical complications, such as disturbances in fat metabolism, nerve damage, and eye disease. Avoid of limit alcohol to have optimal blood sugar control
Two-way messages			Month 1	Looking at the messages you have received this month, rate your confidence in selecting of healthy diets 1 2 3 4 5
			Month 2	Looking at the messages you have received this month, rate your ability to eat healthy dietary choices for diabetes care 1 2 3 4 5
			Month 3	Looking at the messages you have received this month, rate your general knowledge relating to selection and eating of health diet 1 2 3 4 5

6.9 Outcomes

6.9.1 Primary outcome measures

The primary outcome measure is HbA1c which shall be measured at baseline and at the end of the intervention. HbA1c will be measured using a high-performance liquid chromatography technique using Variant II (Bio-Rad, Montreal, Quebec, Canada). FPG will be analysed by the glucose oxidase method using a Hitachi 7600 (Hitachi, Hitachi, Japan).

6.9.2 Secondary Outcome measures

Secondary outcome measures will include biochemical, anthropometric and behaviour change measurements shall be measured at baseline and endline (end of week 12). Additionally, user-satisfaction shall be assessed at 12 weeks and 24 weeks post-intervention.

Biochemical measurements will include fasting plasma Glucose (FPG), total cholesterol (TC), triglycerides (TG), and high-density lipoprotein-cholesterol (HDL-C). FPG will be analysed by the glucose oxidase method using a Hitachi 7600, while TC, TG, HDL-C will be measured using the automatic blood analyser (Hitachi 736-40). Lab testing and analysis will be conducted at the Lancet laboratories, Kenya using standard procedures.

Anthropometric measurements will include weight, height, waist and hip circumferences that shall be measured by trained research assistants, and shall follow the CDC Anthropometry Procedures Manual (104). Additionally, bioelectrical impedance analysis shall be taken to determine body fat using the

Behaviour change shall be measured by changes in dietary intake of legumes, fruits and vegetables and through the mHealth Satisfaction Questionnaire (Appendix 6). The mHealth Satisfaction Questionnaire will be adopted from the questionnaire for assessing user satisfaction with mobile health apps (105).

7 Data Collection

7.1 Quantitative Instruments

Various tools will be used to collect data. The socio-demographic and health questionnaire (Appendix 3), the food frequency questionnaire (Appendix 4) and the self-perceived food literacy questionnaire (Appendix 5) will be administered on all participants after enrolment. The socio-demographic and health questionnaire and the food frequency questionnaires have been piloted and used in studies in Kenya, while the self-perceived food literacy questionnaire shall be piloted during the study. These tools will be administered by trained research personnel in either Swahili or English, depending on the preference of the participant.

7.1.1 Socio-demographic and health history questionnaire

This study will utilize the electronic socio-demographic and health history questionnaire (Appendix 4) that was previously used in a sister study conducted in Makueni County, Kenya (Protocol number AMREF P424 2018). The questionnaire was developed based on the World Health Organization STEPS Instrument and Support Materials (106) and piloted in Makueni County, Kenya.

7.1.2 Self-perceived food literacy questionnaire

The self-perceived food literacy questionnaire is based on the tool used to assess the food literacy among people with chronic diseases in Netherlands (107). This tool was developed through an expert-based and theory-driven process and shall be piloted and adjusted before being used in the Kenyan settings. The responses options are a 5-point Likert scale where 1= 'not at all/never' to 5='yes/always' (Appendix 4).

7.1.3 Anthropometric measurements

Anthropometric measurements will be taken during the filling of the socio-demographic and Health history questionnaire. These measurements will include height, weight waist and hip circumference. Height and weight shall be used to calculate the body mass index (BMI).

7.1.4 Body composition

Body composition of all participants shall be taken at baseline and at the end of the intervention. The measurements shall be conducted by trained research assistants using the *Bodystat* 500® Body Composition Monitor.

7.1.5 Blood samples

Two trained phlebotomists, each serving one hospital, will draw 5 ml venous blood using the closed vacuum extraction tubes with single-use needle and needle holder and following the WHO and Kenya Medical and Research Institute (KEMRI) guidelines(108). Laboratory requisition forms indicating the participant identification code shall be written for all the collected samples. The samples will be immediately stored in insulated coolers containing ice/cold packs at around 4°C. At the end of sample collection, the phlebotomists will centrifuge the blood samples and serum transferred into sterile cryo-vials in the two level 4 hospital laboratories. Two centrifuges shall be provided by the study, assigned to the two study phlebotomists. Thereafter the samples will be frozen at -20 degrees centigrade in study nitrogen tanks and transported to Lancet Laboratories® in Nairobi for analysis.

Phlebotomists will ensure hand hygiene by using pair of well-fitting clean disposable latex-free gloves, alcohol rubs, water and soap before after each blood draw to reduce risks of cross-contamination. Sufficient single-use disposable needless and sampling tubes will also be ensured for each blood sampling.

The study shall provide all required laboratory disposal equipment and materials.

Disposal of all lab waste will adhere to Laboratory Biosafety and Bisecurity Policy Guidelines (109). In brief the following measures shall be ensured in disposal of infectious wastes:

i. Red infectious/biohazard waste disposal containers shall be located in each area of the laboratory where infectious waste may accumulate.
ii. Containers shall be lined with disposable bright orange/red biohazard bags before placing infectious waste into them to prevent leakage.
iii. Infectious waste containers shall not be filled more than three-quarters full.
iv. Biohazard bags shall be removed from the work area after each day's use.
v. Bags and containers shall be transport to the biohazard holding room as per the facility procedures.

7.1.6 Interactive text messaging

At the end of every 30 days of the study, participants will be asked to evaluate the usability of the text messages in past previous month using Likert scale rating. The response will determine the type of messages the participant will receive subsequent month.

7.2 Training of research assistants and piloting

Training of research assistants and enumerators will take 3 days. On day 1, the research assistants will be introduced to the research methods in a step-by-step approach as shown below. This phase of training will be conducted either online or face-to-face to allow for flexibility during the COVID crisis.

Step 1. Informed consent procedure, research ethics and regulatory requirements and documentation.

Step 2. Participant recruitment and retention strategies

Step 3. Review of the data collection tools, including the socio-demographic and health history questionnaire, food frequency questionnaire and the self-perceived food literacy questionnaire. This step is meant to give the research assistants and enumerators a broad understanding of the expected each tool. All questions in the three tools shall be read and discussed to provide an opportunity for clarification on possible responses.

Step 4. Video illustrations of study-related anthropometric assessments: height, weight, waist and hip circumferences and body composition.

On day 2, the research assistants will be provided with hands-on training on procedures that shall be applied in this study. This phase shall apply didactic approach, face-face demonstrations, and role plays. The trainers

will use actual data collection tools, PowerPoint slides and videos during these structured sessions. The following steps shall be followed in this phase of training:

Steps 1: Role playing of the interviewer-administered data collection tools.

Step 2: Demonstration and breakout sessions for role playing of anthropometric assessments.

On day 3, the socio-demographic and health history questionnaire and the self-perceived food literacy scale will be piloted in hospitals that will not be included in the study. The pilot will include a sample size of 6 respondents, representing 10% of the of the sample projected for the trial, as suggested by Connelly *et al.*, (110)

7.3 Management of data quality during fieldwork

To ensure accurate and reliable data collection, the following measures shall be applied:

i. Timely provision of data collection tools and equipment to the enumerators and research assistant
ii. Early logistical arrangements, coordinated by the PI and Co-PI in collaboration with the hospital in-charges
iii. Coordinating with hospital in-charges regarding arrival and data collection points of enumerators
iv. Identifying sampled respondents, coordinated by the hospital in-charges
v. Preparation for collection, with brief overview of steps by the Co-PI and research assistant.

Additionally, data quality during field work shall be ensured by the following activities planned by the Principal Investigator (PI) MM, in collaboration with the Co-Principal Investigators (CO-PIs):

i. Prepare, conduct, and administer the research budget, and trainings in compliance with applicable laws, regulations and institutional policy governing the conduct of the study.
ii. Ensure that procedures in the study are consistent with sound research design and do not unnecessarily expose participants to risk or harm.
iii. Define and communicate roles and responsibilities for each research team member.
iv. Regularly meet with the CO-PIs and research team to keep them informed of the status of project activities.
v. Ensure the integrity and safeguarding of research data records and scientific data.
vi. Ensure the completion, accuracy and timeliness of research data and reports.

JKUAT shall provide permission to conduct the study and provide overall supervision of the study through the Project Lead (FK) Legume Centre of Excellence for Food and Nutrition Security (LCEFONS).

KU Leuven shall provide supervision and administration of the study's research budget, and trainings in compliance with applicable laws, regulations and institutional policy governing the conduct of the study of the study through the Co-PIs (CM and RV).

7.4 Ethical issues

This study will be conducted in respect to the principles contained in the Declaration of Helsinki (111). A written informed consent will be obtained from all participants prior to their enrolment into the study (Appendix 1). The informed consent will allow the participant enough time to decide whether to be in the research study and to make that decision without any pressure from the researchers. Participants will also have the right to refuse to be in the study at all, and to stop participating at any time after study begins.

Study personnel shall ensure strategies to protect privacy interests relating to contact with potential participants, and access to private information at all times during the study. All study personnel shall sign and adhere to the Data Confidentiality Agreement for Study Staff (Appendix 6).

To ensure confidentiality, that an information disclosed by the participants shall not be divulged to others without permission in ways that are inconsistent with the understanding of the informed consent form. During consenting, subjects shall be informed of the precautions that will be taken to protect the confidentiality of the data and be informed of the parties who will or may have access.

The community engagement strategy shall ensure that the study will be conducted in a way that is respectful to individuals and communities to maximize social value. Additionally, internationally recognized standards of good practice with responsiveness to the local context (112) shall be adhered to.

The data from the study will be stored in a secure server where only authorized individuals will have access to the data. The parties will retain the data for 10 years after study completion, according to the General Data Protection Regulation (GDPR) (113). However, neither party will destroy information without first informing the other parties. In case of future testing, permission to conduct further studies shall be sort from the participants.

This study will seek the following approvals, permissions, and registration:

- Letter of support from Jomo Kenyatta University of Agriculture and Technology;
- Ethical approval from the African Medical Research Foundation-Ethics & Scientific Review Committee (AMREF-ESRC);
- Research permit from the National Council for Science Technology and Innovation (NACOSTI);
- Registration of clinical studies with human subjects that assess biomedical and/or health outcomes at clinicaltrial.gov (114).
- Study permit for permission to conduct the study through the Department of Health in Nakuru County.

8 Data Processing and Analysis

8.1 Data coding, entry, and editing; transcription of qualitative data generated

The data will be collected by use of electronic forms. Data shall be collected and stored in a secure cloud server, hosted at the Jomo Kenyatta University of Agriculture and Technology (JKUAT).

8.2 Plan for analysis of quantitative data

Quantitative data will be analyzed by the intention to treat principle (115). Various patient characteristics and primary outcome measures, including anthropometric and biochemical measurements (HbA1c, FBG, lipid profiles) at baseline will be summarized using descriptive statistics. The descriptive statistics will include means and standard deviations for continuous variables and proportions for categorical variables.

HbA1c levels will be compared at 3-months between the two arms using an ANCOVA which will control for baseline HbA1c levels. The intervention and the control groups will be followed-up for six months. One-way and interactive text messaging data will be analyzed descriptively.

A subgroup analyses per hospital and participant socio-demographics including age, sex, education, and income levels will be conducted. All statistical analyses will be performed using R version 4.0.3 (116).

9 Plan for communicating findings of the study

9.1 Dissemination strategy

Findings from the study shall be disseminated through print and electronic media to relevant stakeholders. Foreseen stakeholders include the Kenyan Ministry of Health, the county governments, NACOSTI and AMREF Ethics & Scientific Review Committee (ESRC) and the Jomo Kenyatta University of Agriculture and Technology website. The research findings will also be disseminated through a peer reviewed research publication.

9.2 Outline for research report

The research report that shall be disseminated to various stakeholders will be composed of five sections: introduction, key findings, conclusion, and recommendations for future actions. The findings from this study shall also be published in peer reviewed scientific paper, and shall follow the CONSORT guidelines(117).

9.3 Involvement of stakeholders in the study

The county government has been made aware of the study in earlier contacts and correspondences in our earlier study (AMREF-ESRC P752/2020). Further, findings from this study will be provided to participants through online and physical meetings where applicable. The Ministry of Health national technical working group on nutrition and the County Government of Nakuru will be provided with a research report. A

dissemination meeting shall be held in collaboration with the county government and other relevant stakeholders such as community leaders, hospital staff and other organizations supporting diabetes care.

9.4 Likely policy implications that might arise from the study

This being a pilot, the study seeks to generate information on the feasibility of using mHealth to optimize glycemic control and dietary behavior. The findings of the study may also be used by researchers to design larger studies on mHealth in LMICs. The findings may be of value to the county governments and the Kenyan Ministry of Health in development of policies and guidelines on type 2 diabetes and the patient organizations, including the Kenya Defeat Diabetes Association. Study Limitations and Risks

9.5 Limitations of the study design and methods of data analysis

This is a proof-of-concept study, which is therefore limited by the sample size and restricted generalizability.

9.6 Major assumptions in the study

The main assumption in this study is that participants will be willing to take actions aimed at improving their glycemic control. Secondly, it is assumed that the participants will be willing to receive, read and apply the messages disseminated through their mobile phones.

10 Management and Organization of the Study

The management and organization of this study is a collaborative organization between JKUAT and KU Leuven.

10.1 Team members, their roles, and management procedures in the study

The team members and roles in this study are listed in the table below:

Table 3. Study Team Members and Roles

Name	Institution	Role
Moses Mokaya	JKUAT and KU Leuven	Principal Investigator Study coordinator, correspondence with MOH and hospital in-charges Oversight of text message delivery Data analysis and reporting
Dr. Florence Kyallo	JKUAT	Co- Principal Investigator
Prof. Christophe Matthys	KU Leuven	Co- Principal Investigator
Prof. Roman Vangoitsenhoven	KU Leuven	Co- Principal Investigator
Dr. Janai Ondieki	JKUAT	Co- Principal Investigator Study physician and Co-PI
Research (To be determined)	JKUAT	Support in research coordination, data collection and logistics management
Enumerators (Trained Nutritionists o)-Two per hospital	JKUAT	Recruitment, Consenting, Questionnaire administration, measurement of anthropometrics

10.2 Other resources and facilities that will be availed for the study

The resources that will be availed for the study have been listed in the budget in Table 3. below.

Additionally, a vehicle will be availed during the study for transportation of study personnel and samples.

10.3 Schedule of activities

The study timelines are listed in Table 3 below

It is planned that the study will begin on 15 July 2021 to

Table 4. Schedule of Activities

	Wk 0	Wk 1	Wk 2	Wk 3	Wk 4	Wk 5	Wk 6	Wk 7	Wk 8	Wk 9	Wk 10	Wk 11	Wk 12	Wk 25
Planned Activity	23-Aug	30-Aug	06-Sep	13-Sep	20-Sep	27-Sep	04-Oct	11-Oct	18-Oct	25-Oct	01-Nov	08-Nov	15-Nov	14-Feb
Recruitment and allocation														
Baseline data collection														
Introdiction call and text messages														
Intervention month 1														
Intervention month 2														
Intervention month 3														
Post-Intervention follow-up														

10.4 Budget

The total budget for the entire study is estimated to cost Kes 2,550,320 as tabulated below

Table 5. Budget

Ethics Review Fees and Research Permit				
Item	Units	Unit Cost	Frequency	Total Cost (Ksh)
AMREF Ethics review	1	5000	1	5,000
NACOSTI Research Permit	1	2000	1	2,000
Sub total				**7,000**
Mobilization and planning				
Item	Units	Unit Cost	Days	Total Cost
Community Mobilizer	6	2,540	1	15,240
Airtime for mobilization	6	500	4	12,000
Sub total				**27,240**
Lab test Equipment				
Item	Units	Unit Cost	Frequency	Total Cost
Plain Tubes for Serum Zinc Collection	2	1,200	1	2,400
Vacutainer needles (100pcs) Gauge 21	2	1,400	2	5,600
Alcohol swabs (100pcs)	1	420	2	800
Micro pore Tape	1	400	1	400
Disposable Rubber Gloves (Dust free 100pcs)	1	1,000	2	2,000
Test Strips for Cholesterol Metre (25pcs)	5	2,500	2	25,000
Test Strips for Glucometer (50pcs)	3	1,600	2	9,600
Biohazard Safety Box	1	300	1	300
Red Disposable bags (Big)	5	50	1	250
Red Disposable bags (small))	10	30	1	300
Hand Sanitizers (500ml)	5	500	1	2,500
Mask (50pcs)	5	800	1	4,000
Cryol Vial (100pcs)	3	1,000	1	3,000
Sub total				56,150
Equipment for Handling, Transfer and Storage of Blood Samples				
Item	Units	Unit Cost	Frequency	Cost
Refill of Nitrogen Tank with liquid nitrogen 47lit	47	480	1	22,560
Sub total				**22,560**
Stationery Costs				
Item	Units	Unit Cost	Frequency	Cost
Printing paper	5	500	2	5,000
Pens	15	15	2	450
Sub total				**5,450**
Lab test costs				
Item	Pts	Unit Cost	Frequency	Cost
HbA1C	60	2949	3	530,820
Lipid Profile	60	2949	3	530,820
Total Cholesterol, Serum	60	949	3	170,820
Sub total				**1,232,460**
mHealth Costs				

Item	Pts	Unit Cost	Frequency	Cost
Setting up Charges	-	20,000	1	20,000
Maintenance Costs	-	20,000	1	20,000
Bulk SMS Services: Intervention Arm	30	5	48	7,200
Bulk SMS Services: Control Arm	30	5	4	600
Audio Calls: Intervention	30	5	12	18,000
Sub total				65,800
Study monitoring				
Item	Pax	Unit Cost	Frequency	Cost
Per Diem (Principal Investigator)	1	7,640	20	152,800
Per Diem (PhD researcher)	1	7,640	30	229,200
Per Diem (Driver)	1	5,135	30	154,050
Sub total				536,050
Personnel				
Item	Pax	Stipend	Days	Cost
Phlebotomist	2	7,640	14	213,920
Enumerators	4	2,540	14	142,240
Enumerator's transport	6	1,000	2	12,000
Research Assistant	1	795	90	71,550
Community Mobilization	2	2,540	14	71,120
Sub total				510,830
Transport				
Item	Cars	Unit Cost	Frequency	Cost
Fuel Costs	1	10,000	2	20,000
Sub total				20,000
			Grand Total	2,483,540

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Appendix 2 Food Literacy Questionnaire

1. Planning and management

14	*How do you normally store your fruits and vegetables (multiple choices are possible)*				
	1: In a fridge	2: On a floor in the house	3: In a basket	4: on the shelves	5: Others specify ……

What is your opinion on the following?

Assessment question		Likert scale				
1	What I eat has an impact on my health and wellbeing	1: Strongly Disagree	2: Somewhat disagree	3: Somewhat agree	4: Strongly Agree	
2	How often do you think about health when deciding on what to eat	1: Never	2: Rarely	3: Sometimes	4: Always	
3	Which of following food groups do you consider as a typical balanced meal	1: Matooke, Rice, Chicken, One banana	2: Matooke, Rice, Beans, One banana	3: Matooke, Rice, Greens (amaranth/ managu), One banana	4: Matooke, Beans or chicken, Greens (amaranth/ managu), One banana	5: Not sure
4	How often do you plan meals ahead of time?	1: Never	2: Rarely		3: Sometimes	4: Always
5	Do you normally have plan a weekly menu?	1: Never	2: Rarely		3: Sometimes	4: Always
6	How often do you plan the meals to include all food groups?	1: Never	2: Rarely		3: Sometimes	4: Always
7	How easy is it for you to plan a meal including at least one food from each of the food groups on a limited budget	1: Very difficult	2: Somehow difficult		3: Somehow easy	4: Always easy
8	How often do you think about vegetables when deciding what to eat?	1: Never	2: Rarely		3: Sometimes	4: Always
9	How often do you think about fruits when deciding what to eat?	1: Never	2: Rarely		3: Sometimes	4: Always

2. Questions about selection

10	How often do you make a food shopping list before going to shop?	1: Never	2: Rarely	3: Sometimes	4: Always	
11	How often do you purchase vegetables even if you have limited money?	1: Never	2: Rarely	3: Sometimes	4: Always	
12	How often do you purchase fruits, even if you have limited money?	1: Never	2: Rarely	3: Sometimes	4: Always	
13	*On average how long do you stock up on the following food items*					
13a	Leafy vegetables	1: Do not stock (buy for immediate consumption)	2: Daily	3: two days	4: three days	5: four to five days	6: weekly
13b	Other vegetables (carrots, cucumbers, avocado, tomatoes, eggplants etc)	1: Do not stock (buy for immediate consumption)	2: Daily	3: two days	4: three days	5: four-five days	6: weekly
13c	Fruits	1: Do not stock (buy for immediate consumption)	2: Daily	3: two days	4: three days	5: four–five days	6: weekly

3. Questions about preparation

15	How often do you cook meals at home?	1: Never	2: Rarely	3: Sometimes	4: Always
16	How often do you prepare vegetables at each main meal (e.g. pasted vegetables? a side dish)	1: Never	2: Rarely	3: Sometimes	4: Always
17	Vegetable preparation is too much work?	1: Strongly agree	2: Somehow agree	3.Somehow disagree	4: Strongly disagree
18	How confident do you feel about cooking a variety of healthy and tasty vegetables?	1: Not confident	2: Low	3: Moderate	4: High
19	How would you rate your ability to cook vegetables in at least three different ways? e.g. steaming, stir frying, pasting or in different dishes	1: Not confident	2: Low	3: Moderate	4: High
20	How often do you try out new vegetable recipes?	1: Never	2: Rarely	3: Sometimes	4: Always
21	Rate your confidence in changing recipes (written or unwritten) to make them healthier.	1: Not confident	2: Low	3: Moderate	4: High
22	How confident are you about the hygiene of home prepared vegetables?	1: Not confident	2: Low	3: Moderate	4: High
23	How confident are you that vegetables prepared at home don't contain pesticide residues	1: Not confident	2: Low	3: Moderate	4: High
24	How confident are you about the hygiene of home prepared fruits?	1: Not confident	2: Low	3: Moderate	4: High
25	How confident are you that fruits prepared at home don't contain pesticide residues	1: Not confident	2: Low	3: Moderate	4: High

4. Eating behaviours

26	How many portions of vegetables is ministry of health and world health organisation is recommending people to eat? (a portion = 3 heaped table spoons or 1 handful)	1: two or more portions a day	2: one portion a day	3: five portions a week	4: three portions a week	5: one portion a week	6: Not sure
27	How many portions of fruits ministry of health and world health organisation is recommending people to eat? (1 portion of fruit is equal to 1 medium piece of banana, orange, mango or a slice of watermelon or pineapple)	1: two or more portions a day	2: one portion a day	3: five portions a week	4: three portions a week	5: one portion a week	6: Not sure

28: Please indicate how often you consume at least one portion of fruits

1 portion of fruit is equal to 1 banana , orange, mango or a slice of watermelon or pineapple	 What is a portion – 1 banana mango							
1: Once in a month	2: one time a week	3: two times a week	4: three times a week	5: four times a week	6: five times a week	7: six times a week	8: one time a day	9: two or more times a day

29: Please indicate how often you consume at least one portion of leafy vegetables

Four heaped tablespoons (one handful) of cooked green leafy veggies like cabbage, Sukuma wiki,, sagaa, managu, spinach,	 What is a portion – 4 heaped table spoons or 1 handful							
1: Once in a month	2: one time a week	3: two times a week	4: three times a week	5: four times a week	6: five times a week	7: six times a week	8: one time a day	9: two or more times a day

30: Please indicate how often you consume at least one portion of vegetables other than leafy vegetables

Three heaped tablespoons (one handful) of vegetables like sliced carrots, cucumber, green pepper, eggplant, mixed vegetables	 What is a portion – 3 heaped table spoons or 1 handful							
1: Once in a month	2: one time a week	3: two times a week	4: three times a week	5: four times a week	6: five times a week	7: six times a week	8: one time a day	9: two or more times a day

31	*How easy is it for you to eat fruits and vegetables when you find yourself in the following situations*				
31a	When at work	1: Very difficult	2: Somewhat difficult	3: Somewhat easy	4: Always easy
31b	When traveling	1: Very difficult	2: Somewhat difficult	3: Somewhat easy	4: Always easy
31c	When you experience time pressure	1: Very difficult	2: Somewhat difficult	3: Somewhat easy	4: Always easy
32	How often do you pack fruits when going to work?	1: Never	2: Rarely	3: Sometimes	4: Always
33	How often do you pack vegetables when going to work?	1: Never	2: Rarely	3: Sometimes	4: Always
34	How often do you eat vegetables as snacks (between meals)? e.g. avocado, carrots, tomatoes, cucumbers	1: Never	2: Rarely	3: Sometimes	4: Always
35	How often do you eat fruits as a snack (in between meals)?	1: Never	2: Rarely	3: Sometimes	4: Always

5. Nutrition information

36	When you have questions on what food to eat for better health, do you know where to find this information?	1: Never	2: Rarely	3: Sometimes	4: Always
37	There is a lot of information available on healthy eating today. How well do you manage to choose the information relevant to you?	1: Very difficult	2: Somewhat difficult	3: Somewhat easy	4: Always easy
38	*In general, how often do you use (listen and value) the sources of nutritional information below?*				
38a	Nutrition advice from family members	1: Never	2: Rarely	3: Sometimes	4: Always
38b	Nutrition advice from friends and peers	1: Never	2: Rarely	3: Sometimes	4: Always
38c	TV or radio program on nutrition	1: Never	2: Rarely	3: Sometimes	4: Always
38d	Self -proclaimed nutrition experts on streets	1: Never	2: Rarely	3: Sometimes	4: Always
38e	Health workers (doctors)	1: Never	2: Rarely	3: Sometimes	4: Always
38f	Nutritionists	1: Never	2: Rarely	3: Sometimes	4: Always
38g	Social media (WhatsApp, face book, you tube)	1: Never	2: Rarely	3: Sometimes	4: Always
39	How easy is it for you to judge if healthy eating information shared on various platforms can be trusted?	1: Very difficult	2: Somewhat difficult	3: Somewhat easy	4: Always easy

Appendix 3: Informed Consent Form

Study Title	Using mHealth to Optimize Glycemic Control in Adults with Type 2 Diabetes in Nakuru County: A Proof-of-Concept Randomized Controlled Trial
Investigator(s)	Moses Mokaya Jomo Kenyatta University of Agriculture and Technology (JKUAT) +254 721 299 189 Dr. Florence Kyallo Legume Center of Excellence for Food and Nutrition Security Jomo Kenyatta University of Agriculture and Technology (JKUAT) +254 722 693 523 Prof. Christophe Matthys Katholieke Universiteit Leuven 3000 Leuven, Belgium +32 16 34 2655 Prof. Dr. Roman Vangoitsenhoven Katholieke Universiteit Leuven +32 16193235 Dr. Janai Ondieki Jomo Kenyatta University of Agriculture and Technology +254 724 925 705
Study Sponsor(s)	VLIR UOS
Collaborators	County Government of Nakuru

Part 1. Information Sheet

You are being invited to participate in a study being conducted as a collaboration between JKUAT and KU Leuven, Belgium. This study is funded by VLIR-UOS and executed in collaboration with the County Government of Nakuru through the Ministry of Health.
As part of the study, to implement an mhealth intervention to enhance dietary behavior and food literacy for people living with Type 2 Diabetes Mellitus. You are one of the many people being asked to participate in this intervention.

What shall the study entail?

- Participants in all groups will receive text messages with different content to support their diabetes care but sent at varying frequencies.
- At the beginning and the end of 12 weeks, 3 electronic questionnaires (in a tablet), each lasting between 10-30 minutes shall be administered to you.
- Various measurements shall be taken at the beginning of the study, and at the end of 12 weeks. They include weight, height, waist and hip circumference and body

composition analysis. A government approved laboratory specialist (phlebotomist) shall draw 5ml of blood from your arm. This will be used to compare how the study affect your glycated hemoglobin (long term measure of blood glucose control) your fasting blood glucose and blood cholesterol, at the beginning and at the end of the study.

- At the end of 6 months, you will be contacted and asked questions on your progress.

Why is this Study important?

You may personally benefit from participating in this research because its findings will be used to improve the management of type 2 diabetes mellitus in adults.

Participation is your choice

Your participation in this study is entirely voluntary and it is not an expectation of your doctors, the study staff or the Ministry of Health that you must participate in this study. Your decision on whether to participate will not affect the care you receive from your doctors and will not affect your participation in any other studies by Jomo Kenyatta University of Agriculture and technology and KU Leuven.
Whether or not you decide to join the study, you will receive the best available health Education information on ways to better manage Type 2 Diabetes Mellitus in adults.

What are the risks?

You will be receiving 3 one-way text messages per week, one message in which you will be asked to respond, and one 1 voice call per month. The messages will give you practical information on dietary behavior and food literacy for people with type 2 diabetes. There is no foreseen risk of being involved in this study are always free to not answer a question if you do not want to.
How will you be protected from the risk to contracting COVID 19 during interaction with the research team?
Considering that the COVID-19 disease has now been classified as a pandemic we are taking the following precautionary measures during research activities:

1. The study shall provide personal protective equipment (PPE) for all study participants and researchers.
2. Regular and thorough washing of hands with soap and water, or alcohol-based hand sanitizer provided by the research.
3. Maintaining a distance of at least 1 meter (5 feet) between yourself and anyone (who is coughing or sneezing), avoiding handshakes or hugging.
4. Persons with a cough or sneezing should stay home or keep a social distance but avoid mixing with others in a crowd.
5. Maintain good respiratory hygiene by covering your mouth and nose while coughing and sneezing with a handkerchief, tissue, or into flexed elbow.
6. Stay at home if you feel unwell with symptoms like fever, cough and difficulty in breathing.

7. All study participants should at all times wear a face mask to reduce the chances of transmission of the virus.

8. Any cases regarding the disease will be reported using the call line facility number 719. Correct messages to be relayed to the participants (if need be) will be received from *719#

9. Surfaces used during the research activities (e.g. desks, tables) and objects will be wiped with disinfectant regularly.

What are the Benefits?

There will be no direct benefit to you, but your participation is likely to help us find out more about how to improve the management of type 2 diabetes.

What procedures shall the study involve?

If you choose to take part in this study, you will continue receiving care and treatment in your hospital as usual.

How will we protect your Information and Confidentiality?

All information shared during the study will be confidential to the extent permitted by law. The session will be tape recorded and converted into written format. Your participation means that you agree to allow the information to be used for scientific purposes, but your name will not be identified in any way in reports or publications.

Can I Refuse to Participate or Withdraw from the Study?

You are free to withdraw your consent and to discontinue your participation in this study at any time without prejudice against future medical care or study participation at JKUAT and KU Leuven. Participating in this study will have not affect your participation to the current or future studies at JKUAT and KU Leuven or at MOH facilities. If you wish to withdraw for the study, your records will not be used in any part of the study and shall be destroyed.

What will happen with the results?

The knowledge that we get from this research will be shared with you and your community before it is made widely available to the public. Each participant will receive a summary of the results. There will also be small meetings in the community, and these will be announced. Following the meetings, we will publish the results so that other interested people may learn from the research.

What is the costs for Participation in Research?

There are no costs to you for taking part in this discussion group.

Who can I contact?

If you have any questions, you can ask anyone from our team now or later. If you have questions later, you may contact [Dr. Florence Kyallo, P.O. Box 62000 – 00200, Nairobi +254 722 693 523 E-mail: fkyallo@jkuat.ac.ke]. If you have questions about your rights as a study subject, you may contact:

The Research Officer
AMREF Health Africa in Kenya, Wilson Airport, Lang'ata Road
Office Tel: +254 20 6994000
Mobile No: 0795746777, Fax: +254 20 606340
P.O Box 30125-00100
Nairobi, Kenya

Legal Rights

By signing this consent form, you are not waiving any legal rights.
Do you have any questions at this time?

Part II: Certificate of Consent

I have read this information, or it has been read to me in a language that you can speak, and its contents explained to you. All my questions have been satisfactorily answered.

Print Name of Participant	[at least forename and surname]
Signature or thumb of Participant	
DD/MM/YYYY	

If visually impaired, physically impaired, mentally impaired or illiterate

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print Name of Participant	[at least forename and surname]
Thumb/Foot print of Participant	
Signature of Witness	[A literate witness must sign and should be selected by the participant and MUST have no connection to the research team.
DD/MM/YYYY	

Appendix 4. Socio-demographic and Disease History Questionnaire for Type 2 Diabetes Patients

Identification

Sub-county:
Questionnaire number:
Name of Interviewer:
Respondent Code Identifier: Sex: M__/F__
Respondent's date of birth:
Date of Interview:

Section 1: Demographic and Socio-Economic Characteristics

1	Where do you live? Location:_____ Village: _____	
2	Highest level of education? l=Not attended school; 2=Completed primary; 3= Completed secondary; 4= Completed tertiary level education	
3	Current employment status? l= Employed Doing housework at home Student Retired/long-term disabled Unemployed	
4	Marital status 1=Married; 2=Divorced/Separated; 3= Widowed; 4= Living together/Traditional marriage; 5=Other, specify: _____	
5	Household income per month in Ksh. (Including wages, rent, sales of vegetable, etc.) 1=Less than 10,000; 2= 10,000-40,000; 3=40,001-70,000; 4=70,001-100,000; 5=More than 100,000	
6	How many persons, including yourself, live in your household? _____	

Section 2: Disease History and Management

1	How long have you had diabetes? ____Years ____Months	
2	Have any member of your family (first relatives) being diagnosed of diabetes (Type-1 or Type -2)? 1=Yes; 2=No	
3	How often do you visit the hospital? 1=Weekly; 2=Once in two weeks; 3=Once a month; 4= Other, specify: _____	
4	Are you hypertensive? 1=Yes; 2=No	
5	Have you taken medication for high blood pressure on a regular basis? 1=Yes; 2= No	
6	On average how often do you check your blood sugar? 1= Once a month; 2=At least once a week; 3=1 time per day; 4=Other (specify)	
7	Which of the following describes your treatment regimen 1= insulin and oral medication only; 2= diet only; 3= insulin and diet; 4= insulin, oral medication and diet	
8	How well do you think you manage your diabetes with your eating habits? 1=Poor; 2=Fair; 3=Good; 4=Very good; 5=Excellent	

Section 3: Personal Habits and Physical Activity (Based on the STEPS Instrument (106)

Physical Activity		
I am going to ask you about the time you spend doing different types of physical activity in a typical week. Please answer these questions even if you do not consider yourself to be a physically active person. Think first about the time you spend doing work. Think of work as the things that you have to do such as paid or unpaid work, study/training, household chores, harvesting food/crops, fishing or hunting for food, seeking employment. [Insert other examples if needed]. In answering the following questions 'vigorous-intensity activities' are activities that require hard physical effort and cause large increases in breathing or heart rate, 'moderate-intensity activities' are activities that require moderate physical effort and cause small increases in breathing or heart rate.		
Question	Response	Code
Work		
Does your work involve vigorous-intensity activity that causes large increases in breathing or heart rate like [carrying or lifting heavy loads, digging or construction work] for at least 10 minutes continuously? [INSERT EXAMPLES] (USE SHOWCARD)	Yes 1 No 2 If No, go to P 4	P1
In a typical week, on how many days do you do vigorous intensity activities as part of your work?	Number of days ⌊_⌋	P2
How much time do you spend doing vigorous-intensity activities at work on a typical day?	⌊_⌋⌊_⌋: ⌊_⌋⌊_⌋ Hours : minutes hrs mins	P3 (a-b)
Does your work involve moderate-intensity activity, that causes small increases in breathing or heart rate such as brisk walking [or carrying light loads] for at least 10 minutes continuously? [INSERT EXAMPLES] (USE SHOWCARD)	Yes 1 No 2 If No, go to P 7	P4
In a typical week, on how many days do you do moderate intensity activities as part of your work?	Number of days ⌊_⌋	P5
How much time do you spend doing moderate-intensity activities at work on a typical day?	⌊_⌋⌊_⌋: ⌊_⌋⌊_⌋ Hours : minutes hrs mins	P6 (a-b)
Travel to and from places		
The next questions exclude the physical activities at work that you have already mentioned		
Now I would like to ask you about the usual way you travel to and from places. For example to work, for shopping, to market, to places of worship. [Insert other examples if needed]		
Do you walk or use a bicycle (pedal cycle) for at least 10 minutes continuously to get to and from places?	Yes 1 No 2 If No, go to P 10	P7
In a typical week, on how many days do you walk or bicycle for at least 10 minutes continuously to get to and from places?	Number of days ⌊_⌋	P8

How much time do you spend walking or bicycling for travel on a typical day?	Hours : minutes ⌊_⌋⌊_⌋ : ⌊_⌋⌊_⌋ hrs mins	P9 (a-b)

Question	Response	Code
Recreational activities		
The next questions exclude the work and transport activities that you have already mentioned. Now I would like to ask you about sports, fitness and recreational activities (leisure), [Insert relevant terms].		
Do you do any vigorous-intensity sports, fitness or recreational (leisure) activities that cause large increases in breathing or heart rate like [running or football] for at least 10 minutes continuously? [INSERT EXAMPLES] (USE SHOWCARD)	Yes 1 No 2 If No, go to P 13	P10
In a typical week, on how many days do you do vigorous intensity sports, fitness or recreational (leisure) activities?	Number of days ⌊_⌋	P11
How much time do you spend doing vigorous-intensity sports, fitness or recreational activities on a typical day?	Hours : minutes ⌊_⌋⌊_⌋ : ⌊_⌋⌊_⌋ hrs mins	P12 (a-b)
Do you do any moderate-intensity sports, fitness or recreational (leisure) activities that cause a small increase in breathing or heart rate such as brisk walking, [cycling, swimming, volleyball] for at least 10 minutes continuously? [INSERT EXAMPLES] (USE SHOWCARD)	Yes 1 No 2 If No, go to P16	P13
In a typical week, on how many days do you do moderate intensity sports, fitness or recreational (leisure) activities?	Number of days ⌊_⌋	P14
How much time do you spend doing moderate-intensity sports, fitness or recreational (leisure) activities on a typical day?	Hours : minutes ⌊_⌋⌊_⌋ : ⌊_⌋⌊_⌋ hrs mins	P15 (a-b)
Sedentary behaviour		
The following question is about sitting or reclining at work, t home, getting to and from places, or with friends including: sitting at a a time spen desk, sitting with friends, traveling in car, bus, train, reading, playing cards or watching television, but do not include eping. [INSERT EXAMPLES] (USE SHOWCARD) time spent sl		
How much time do you usually spend sitting or reclining on a typical day?	Hours : minutes ⌊_⌋⌊_⌋ : ⌊_⌋⌊_⌋ hrs mins	P16 (a-b)

Section 4: Food Consumption

24-Hour Recall Questionnaire

Please write down all foods and beverages consumed for the previous 24-hour time (one day) period starting at 12:00 am and ending at 11:59 pm.

List the approximate Time the meal was consumed, Place where it was consumed (home, work, name of restaurant, church, etc.), and the type of eating occasion or Meal (breakfast, lunch, dinner, snack, or other). List each Food/Beverage Item you consumed, including foods eaten between meals and all drinks, even if it is a non-caloric item like water, coffee, or tea. Specify Details/Ingredients/Preparation of each food or beverage consumed. Record the Amount of each food or beverage consumed using weight (grams, kilograms) and volume (millilitres, litres). Cups, tablespoons, and teaspoons measures can also be used. Size (small, medium, large, length, width, height) measures the physical dimensions or proportion of a food.

Date of interview:

Date of Record:

Meal & Time	Place	Food/Beverage Item	Details/Ingredients/Preparation	Amount
Breakfast				
Midmorning snack				
Lunch				
Afternoon snack				
Dinner				
Night snack				

Would you consider the above two intake records of foods and beverages today a typical day's eating pattern?

1= Yes; 2=No

If no, explain why not typical?

Section 5: Anthropometric Measurements

S/N	Measure	1st reading	2nd reading	Average
1	Weight (kg)			
2	Height (m)			
3	Triceps skin fold thickness (mm)			
4	Waist circumference (cm)			
5	Hip circumference (cm)			
6	Body composition measurement			