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EFFECTS OF LIFESTYLE EDUCATION PROGRAMS ON DIABETES CONTROL AMONG DIABETIC PATIENTS AT KIGALI UNIVERSITY TEACHING HOSPITAL, RWANDA

A study project submitted in partial fulfillment of requirements for the award of a degree of Master of Medicine in INTERNAL MEDICINE

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Kigali, March 2014

DEDICATION

This work is dedicated to:

- *Irene, my wife and friend, for her love and continuous moral support;*
- *Laurie and Maelys, my daughters, source of my happiness.*

ACKNOWLEDGEMENTS

This work could not be realized without tremendous support and commitment from many people.

First and foremost I would like to thank Dr. Charlotte Bavuma, the principal supervisor of this work. Without her support it would have been impossible to complete this work. Her continuous guidance and criticism have been the cornerstones of the work accomplished so far.

I would also like to thank Dr. Tim Walker, co-supervisor, for pushing us to evaluate this study from a public health perspective. His remarks have resulted in a better rounded and globally relevant work.

I would also like to express my heartfelt thanks to the following people: Dr. Brian Robinson, Dr. Marie Florence Uzabakiriho, Dr. Vincent Karamuka, Dr. Cyprian Ntirenganya, Dr. Patrick Kavabushi, Uwiragiye Joseph, Mukantagorama Donatille, Bisimwa Jeanne, Uwintwali Marie Henriette, Umulisa Henriette, and Niyomwungeri Scholastique for having voluntarily and pricelessly taken part in the study as educators and data collectors despite their busy schedules. Without their commitment, we could not have moved this research project to completion.

I would also like to thank the participants of the study, for this noble work is primarily based on the information received from them.

I would also like to thank Professor Andre Sofair, Professor Silvio Inzucchi, Dr. Rudasingwa Gategе Joseph, Dr. Abel Kagame and late Dr. Henri Gift for their guidance on the study design and for having encouraged me to carry out this study in Rwanda.

Special aknowledgement goes to Dr Zhenya Krapivinsky for having proof-read and provided invaluable comments to this work.

A word of recognition and thanks also goes towards the management of Sanofi Aventis and KUTH research department for having funded this research.

I am very grateful to the School of Medicine at the University of Rwanda for training me and to the Government of Rwanda and the Rwandan Ministry of Health for funding my postgraduate studies.

Last but not least at all, I humbly owe much respect to all the faculty of Internal Medicine, my fellow postgraduates and all the hospital staff who have encouraged and supported me over the past four years. You all have made my postgraduate journey a joy and have tremendously contributed to both my personal growth and my growth as a mature physician.

Etienne Amendezo

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ACRONYMS

ADA: American Diabetes Association

AHA : Africa Humanitarian Action

HCR: High Commission for Refugees

ANOVA: Analysis of variance

BMI: Body Mass Index

BP: Blood Pressure

CHUK: Centre Hospitalier Universitaire de Kigali

CKDF: Chronic Kidney Disease

CRF: Case Report Form

CVD: Cardiovascular disease

DKA: Diabetic ketoacidosis

DM : Diabetes Mellitus

EASD: European Association for the Study of Diabetes

ESRD: End-stage renal disease

GIP: Gastric inhibitory peptide

GLP-1: Glucagon-like peptide-1

HbA1c: Glycosylated hemoglobin

HHS: Hyperglycemic hyperosmolar syndrome

HIV/AIDS: Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome

HRH: Human Resources for Health

IDF: International Diabetes Federation

IFG: Impaired Fasting Glucose

IGT: Impaired Glucose Tolerance

ITT: Intention to treat

KUTH: Kigali University Teaching Hospital

LDL: Low density Lipoproteins

MODY: Maturity Onset Diabetes of the Young

MoH: Ministry of Health

NCDs: Non-communicable diseases

RCT: Randomized Controlled Trial

RSSB/RAMA: Rwanda Social Security Board

FARG: Fonds D'assistance Aux Rescapés du Genocide

SSA: Sub-Saharan Africa

T2DM: Type 2 diabetes mellitus

UKPDS: United Kingdom Prospective Diabetes Study

US: United States

WHO: World Health Organization

ABSTRACT

Background:

The increasing burden of non-communicable diseases (NCDs) such as type 2 diabetes mellitus is a serious global health problem. In Sub-Saharan Africa it is especially problematic as it places further economic strains on public health systems already exhausted by high rates of infectious and malnutrition-related diseases. Focusing on the individual determinants of diabetes is necessary to shift risk levels downwards and mitigate this growing health system challenge.

In Rwanda, like in many other developing countries, accessibility to standardized diabetic health care is still limited. Evidence to show whether lifestyle intervention programs are beneficial for diabetic patients in resource-limited countries is unclear and remains an open question.

We carried out the present study to assess the effects of an intensive lifestyle education program on diabetes control among patients attending an outpatient referral clinic in Kigali, Rwanda.

Methods:

The study is a randomized controlled trial evaluating the impact of an intensive lifestyle modification education program on diabetes control compared to standard of care treatment in Kigali, Rwanda. The study participants are adults, age 21 years or greater who have been diagnosed with diabetes mellitus who receive routine outpatient care at one of two internal medicine outpatient clinics at the Central Hospital of Kigali (CHUK). The participants were randomly assigned to an intervention group (standard of care plus monthly lifestyle counseling & education sessions lasting from 45 to 60 minutes) or to a control group (standard of care for diabetes in our setting which consists of monthly or bi-monthly medical follow up and individual counseling on dietary habits and lifestyle change delivered by attending physicians and/or nutritionists as per needed). The lifestyle education program for the intervention group was administered by a team of physicians, nurses, nutritionists and counselors who received special training for the purpose of this study.

The primary outcome is between-groups difference in glycosylated hemoglobin (HbA1c). Secondary outcomes are within-group differences from baseline to six months in HbA1c, between-groups and endpoint-versus-baseline differences in blood pressure, weight, body mass index (BMI), lipid profiles and fasting plasma glucose. The follow up time for this study is one year, but the presented results relate a six-month interim analysis of the data.

Results:

The study included 251 diabetic patients. However, the presented results have been obtained from a six-month interim analysis, which included 186 subjects (91 in interventional group and 95 in the control group) who had completed six-month follow up period, representing 70% of total subjects included in the study.

Of the 91 subjects allocated to the intervention group, 81 (89%) attended to at least three group education sessions. Forty six (50.5%) attended all the six pre-envisaged sessions.

At baseline, the mean age was 51.5 years; females represented 69.4%; 64.4% had at least a secondary school education level; the mean duration of diabetes was 7.3 years, at least 50.5% had both diabetes and hypertension; and 26.9% were obese (BMI>29.9 kg/m^2)

The median glycosylated hemoglobin levels differed significantly between baseline and six-month follow up visit within both interventional and control groups. After six months follow up, the mean HbA1c levels reduced by 1.52 (95% CI: 1.05 to 1.98); p<0.001) in the interventional group; and by 0.91 (95% CI: 0.45 to 1.36); p: 0.003) in the control group. Although a trend towards greater HbA1c reduction was observed in the intervention group at six months, the difference in HbA1c reduction between the intervention and control groups was not significant (p = 0.064).

The overall number of subjects achieving glycemic target goal (HbA1c<7%) increased from 16% at baseline to 35% at six-months with greater changes being observed in the intervention group (from 5% at baseline to 20.3% at six-month visit) compared to the control group (from 11% at baseline to 14.7% at six month visit).

The six-month median fasting glucose levels, systolic blood pressure and diastolic blood pressure also differed significantly from baseline in the interventional group (p<0.001, 0.006, 0.002 respectively) but not in the control group (p: 0.411, 0.80, 0.42 respectively). Between groups median differences were statistically significant for diastolic blood pressure (p=0.047) but not for median fasting glucose levels (p=0.062) or systolic blood pressure (p=0.09), although a trend towards greater improvement in the lifestyle intervention group were seen for all three parameters.

There were no significant improvements in weight within/across and between the two study groups. However, the median weight for people in the control group increased of 0.74 kg while those in the intervention had a median loss of 0.19 kg, suggesting that the intervention may, at least, have potential to prevent weight gain.

Conclusions:

Our study demonstrates that implementing an intensive lifestyle education program for diabetes control is feasible in a resource limited setting and is beneficial to diabetic patients. Although no statistically significant difference in glycemic control was observed among patients randomized to a lifestyle education program compared to individual diabetic counseling at six months, a trend towards great benefit with the lifestyle education program have been observed and could become amplified when at 1-year of follow up. Overall this study demonstrated that both forms of diabetes risk modification education strategies may be effective in Rwanda and other similar settings.

Group-based diabetes education strategies are attractive in resource-constrained settings as they might have potential to allow for better use of the few available health professionals and have the ability to reach a greater number of patients. Further research looking at long-term effectiveness and sustainability of such programs in Sub-Saharan Africa are urgently needed. (ClinicalTrials.gov Identifier: NCT02032108).

PROBLEM STATEMENT AND CONTEXTUAL FRAMEWORK

The increasing burden of non-communicable diseases (NCDs) represents a serious health and socioeconomic problem worldwide (1)(2)(3)(4). In developing countries, NCDs are expected to increase tremendously in terms of both prevalence and associated morality during the first third of the 21st century (2)(5). Among NCDs, Diabetes Mellitus (DM) deserves special attention dues to its high global prevalence and costly complications (5)(6)(7).

In Sub-Saharan Africa (SSA), the ever increasing prevalence of NCDs such as DM, Cardiovascular disease (CVD), Cancer and Chronic Respiratory Disease adds undue strain to health systems already burdened by high rates of infectious diseases (HIV/AIDS, malaria, tuberculosis) and malnutrition-related health problems (1)(3)(6)(8). The rising prevalence of NCDs not only impacts the health systems but also has negative connotations for individuals' families and communities. Diabetes for example in SSA kills persons in their most economically productive years, 20-39 years old, which has long standing repercussions for their families and communities at large (8)(9).

According to many authors, rapid uncontrolled urbanization, aging populations, obesity and other changes in lifestyle including dietary habits, smoking and physical inactivity all contribute to the general rise of DM worldwide, but among developing countries and SSA inhabitants in a special way (1)(2)(3)(6)(8).

In Rwanda, like in many developing countries, access to comprehensive diabetic care is still limited (1)(10)(11). Due to resource and work force constraints routine screening for diabetic complications is limited and patients frequently develop devastating sequellae such as kidney failure and cardiovascular complications. This in turn worsens the quality of life of diabetic patients and increases diabetes related mortality (1)(7)(11) (12).

A recent cross-sectional study of diabetic patients at Kigali University Teaching Hospital (KUTH) demonstrated that diabetic patients in Rwanda are younger and develop disease complications earlier than persons with diabetes from the US and Europe. More than a half of subjects in the KUTH study had at least one diabetic complication despite a relatively short mean disease duration (13).

According to previous research carried out in developed countries, lifestyle modification can have a significant effect on both the development of diabetes and on progression of established

disease (14)(15)(16)(17). Furthermore such interventions have been described to improve both glycemic control and mitigate cardio-vascular risk factors in diabetics (1).

Direct evidence showing that lifestyle interventions are beneficial for diabetic patients living in resource-limited countries is unclear and remains an open question; particularly because, though in these countries, access to a healthy diet is often anecdotally claimed to be the major barrier to implementation of therapeutic lifestyle based initiatives (18), we hypothesize that knowledge gaps are more important barriers than access to healthier diets and other lifestyle habits.

In Rwanda, we have observed that many patients have little knowledge of appropriate lifestyle changes necessary to control diabetes. In addition to poor understanding of lifestyle changes, patients often hold incorrect beliefs about diabetes and frequently use traditional medicines. Together these misconceptions may lead to poor adherence to medications and to early onset of complications.

According to existing literature (1)(19)(20), lifestyle modifications and dietary interventions should be part of the core therapies for all diabetic patients, particularly so for type 2 DM. Such interventions have been described to benefit not only glycemic control but also other CVD risk factors (1).

Poor patient understanding of diabetes and its management can in part be attributed to the limited number of health workers trained in diabetes care compared to the ever-increasing number of diabetic patients in our settings.

For instance, while the World Health Organization (WHO) estimates that Europe has 32 doctors and 79 nurses or midwives for 10,000 people; in Africa, there are only two doctors and 11 nurses or midwives for every 10,000 people (11). In Rwanda, the doctor-patient ratio is 1 to 33,000 people and a physician on average sees 30 to 50 patients per day in consultation (21). Yet in most places, such lack of human resources becomes worse when the increasing burden of NCDs is combined with the burden of other health conditions including communicable diseases, physical and psychological injuries as well as nutrition related problems. Thus, DM, which needs long-term care, information and support for patients, is often still not seen as a priority (11).

Research conducted in developed countries has compared group intensive lifestyle education programs with routine individual counseling/standard of care, but, their results have been conflicting (14)(22)(23)(24)(25)(26)(17).

A trial by Bo S., et al. (2007) evaluating intensive lifestyle intervention showed significant improvement in dietary and exercise patterns as well as reduction in hyperglycemia in patients receiving lifestyle intervention counseling (14). Weinger K., et al. (2011), reported that a structured, cognitive group behavioral program had a greater impact in controlling DM than other lifestyle education methods among people with poorly controlled diabetes (25). However a systematic review by Schellenberg et al. (2013) only showed beneficial effects of lifestyle interventions on a pre-diabetic population, but failed to show significant benefit for people already diagnosed with diabetes in terms of disease control, prevention of diabetic complications and mortality (26). Such controversy in the existing literature demands further research in this area.

During the present study, what matters is not only the type of information received by diabetic patients, but also how information is delivered.
We particularly hypothesize that, in our setting, the type of individual counseling that diabetic patients receive is not as exhaustive as it would be in a standard/ideal situation, or as a mean to deliver quality diabetes lifestyle education, and therefore, propose to carry out this study to assess the efficacy of intensive lifestyle education programs delivered through group diabetic counseling, comparing it to the current standard of diabetic care practice in Rwanda.

Objectives

Overall objective

To assess the effects of a lifestyle education program on diabetes control in patients followed up at Kigali University Teaching Hospital (KUTH), Rwanda.

Specific objectives

1. To evaluate the feasibility of a group lifestyle education program at KUTH
2. To examine the effects of a group lifestyle counseling program on glycemic control among diabetic patients followed up at KUTH
3. To examine the effects of a group lifestyle counseling programs on the weight, cholesterol level and blood pressure in diabetic patients at KUTH
4. To generate recommendations for the role of lifestyle education programs in chronic diabetic care in a resource-limited setting.

LITERATURE REVIEW

The International Diabetes Federation (IDF) defines DM as a chronic disease associated with the failure of pancreas to make insulin, or the body to use insulin that is produced (27).

According to the American Diabetes Association (ADA), « insulin is the main hormonal regulator of metabolism. Its most prominent effects are the stimulation of glucose uptake by peripheral tissues (mainly skeletal muscle) and the suppression of endogenous glucose production (mostly by the liver). This anabolic hormone also suppresses lipolysis in adipocytes and proteolysis in muscle » (28).

Motala A. et al. (2010) describes DM as a worldwide pandemic (11). WHO and the International Diabetes Federation (IDF) estimate that 347 million people have diabetes worldwide (WHO 2013). It is estimated that 550 million people will be living with diabetes by 2030. More than 80% of these 550 million people will be living in low- and middle-income countries (7)(29)(27).

The number of people living with diabetes in SSA, where previously this condition was considered rare, is now estimated at 12.1 million people (8)(33), representing a prevalence of 3.0%-14.5% (8)(11). Experts predict that SSA will have the highest growth in the number of people with diabetes compared to any other region in the world, reaching 23.9 million by 2030 (11). Rapid urbanization, ageing population, and many other factors, have been described as potentially contributing to the steady rise in diabetes prevalence among SSA and other developing countries' inhabitants (Table1) (1)(2)(8).

Table 1. Risk factors for diabetes mellitus in SSA

Table 1 shows a list of potential factors that contribute to the rise of diabetes in SSA as described by Tuei et al. 2010 (1).

Modifiable risk factors
Obesity
Anthropometric parameters (Body Mass Index, waist circumference, waist-to-hip ratio, abdominal fat)
Nutrition/lifestyle changes
Fetal undernourishment

Stunting
Cultural preference of an excess body weight
Transitions
Nutrition (dietary changes)
Lifestyle (physical inactivity, smoking*, alcohol use*)
Socio-economic/demographic (urbanization, mechanization, higher levels of incomes and education)
Non-modifiable risk factors
Ageing
Gender*
Ethnicity (Indigenous blacks < Caucasian < Indian)
Family history of diabetes (Offsprings and first degree relatives of patients with type 2 diabetes mellitus
Genetic predispositions
Other risk factors
Gestational diabetes*
Tuberculosis*
Antiretroviral therapy*

**Not well studied in Africa*

In addition to risk factors cited by Tuei the following have been described by other authors as risk factors for diabetes mellitus (32)(34)(36):

- Previously identified with Impaired Fasting Glucose (IFG), Impaired Glucose Tolerance (IGT), or a glycosylated hemoglobin (HbA1c) of 5.7–6.4%
- History of gestational diabetes or macrosomia (delivery of baby >4 kg)
- Hypertension
- Dyslipidemia
- Polycystic ovary syndrome or acanthosis nigricans
- History of cardiovascular disease

Mortality related to diabetes is high worldwide. Diabetes is the fifth leading cause of death worldwide and responsible for almost four million deaths in 2010 (representing 6.8% of deaths worldwide) (36). In Africa, the mortality associated with diabetes is expected to be even higher, although data on exact rates is lacking (11).

The ADA (37) classifies diabetes into four types :

i. Type 1 Diabetes Mellitus

ii. Type 2 Diabetes Mellitus

iii. Gestational diabetes

iv. Other

- Genetic defects in beta cell function (Maturity Onset Diabetes of the Young syndromes)
- Genetic defects in insulin action
- Diseases of the exocrine pancreas (pancreatitis, pancreatic cancer, cystic fibrosis, hemochromatosis)
- Endocrinopathies (Cushing Syndrome, acromegaly, glucagonoma, pheochromocytoma)
- Drug- or chemically induced (corticosteroids, niacin, diazoxide)
- Infections (Cytomegalovirus, congenital rubella)
- Rare forms of immune-mediated diabetes
- Other genetic syndromes associated with Diabetes (Down, Turner, Klinefelter, Prader-Willi, Laurence-Moon-Biedl syndromes; myotonic dystrophy ; Huntington chorea) (36)(37).

In Africa, some specific subtypes of diabetes have been described. The best known one is ketosis-prone atypical diabetes which represents up to 15% of diabetic patients in Africa (8). The pathogenesis of ketosis-prone atypical diabetes and other special forms of diabetes such as malnutrition related diabetes are not yet fully understood (8).

Table 2 summarizes the diagnostic criteria for DM and for pre-diabetic states. The latter, which include the IFG and the IGT, describe situations of abnormally elevated blood glucose levels while not meeting the definition of diabetes.

Pre-diabetic patients are especially important targets of public health interventions due to their increased risks to developing diabetes and cardiovascular diseases and potential for risk modification (35).

Table 2. **Diagnostic criteria for DM and Pre-diabetic states**

Diagnosis	**Fasting Plasma Glucose**	**Random Plasma Glucose**	**2-Hour Plasma Glucose**
Normal glucose homeostasis	<100 mg/dL (5.6 mmol/L)	—	<140 mg/dL (7.8 mmol/L)

Impaired glucose ("pre-diabetes")	100-125 mg/dL (5.6-6.9 mmol/L) (IFG)	—	140-199 mg/dL (7.8-11.0 mmol/L) (IGT)
Diabetes	≥126 mg/dL (7.0 mmol/L) Or HbA1c>6.5%	≥200 mg/dL (11.1 mmol/L) (with symptoms of diabetes*)	≥200 mg/dL (11.1 mmol/L)

(36)(37)

Diabetic complications are generally grouped into two categories: acute complications and chronic complications.

Acute complications include Diabetic ketoacidosis (DKA), hyperglycemic hyperosmolar syndrome (HHS) and hypoglycemia.

DKA indicates profound insulin deficiency which is manifested by hyperglycemia, ketosis and dehydration (36).

Patients with HHS present with hyperosmolarity, severe hyperglycemia, dehydration and altered mental status (36).

Hypoglycemia in diabetics signals excess insulin supply. It usually occurs in patients taking insulin or insulin secretagogues (36).

Chronic complications of DM are subdivided into microvascular complications, macrovascular complications and other complications.

Microvascular disease in diabetes mellitus includes diabetic nephropathy, diabetic retinopathy and diabetic neuropathy.

Macrovascular complications of diabetes mellitus include ischemic heart diseases, stroke, and peripheral artery disease (36). Of note, Diabetes is the leading cause of end-stage renal disease (ESRD), non-traumatic lower extremity amputations, and adult blindness (26)(36).

Other complications associated with diabetes include immune system alterations resulting in a high incidence of infections and poor healing of wounds. Diabetes also is a risk factor for steatohepatitis, obstructive sleep apnea, venous thrombosis, bone fractures, dementia, depression and cancer (32)(36)(38).

In SSA the incidence of microvascular complications is higher than the incidence of macrovascular complications probably due to frequently comorbid hypertension (8).

Appropriate blood glucose control mitigates the incidence of complications and mortality rate among diabetic patients (39)(40).

Regardless of the type of DM, the ADA recommends periodic HbA1c measurement as the most reliable assessment of overall glycemic status (41).

In developing countries, however, access to HbA1c measurements is limited and diabetic care teams must rely on single point in time blood glucose levels to monitor diabetic patients (10).

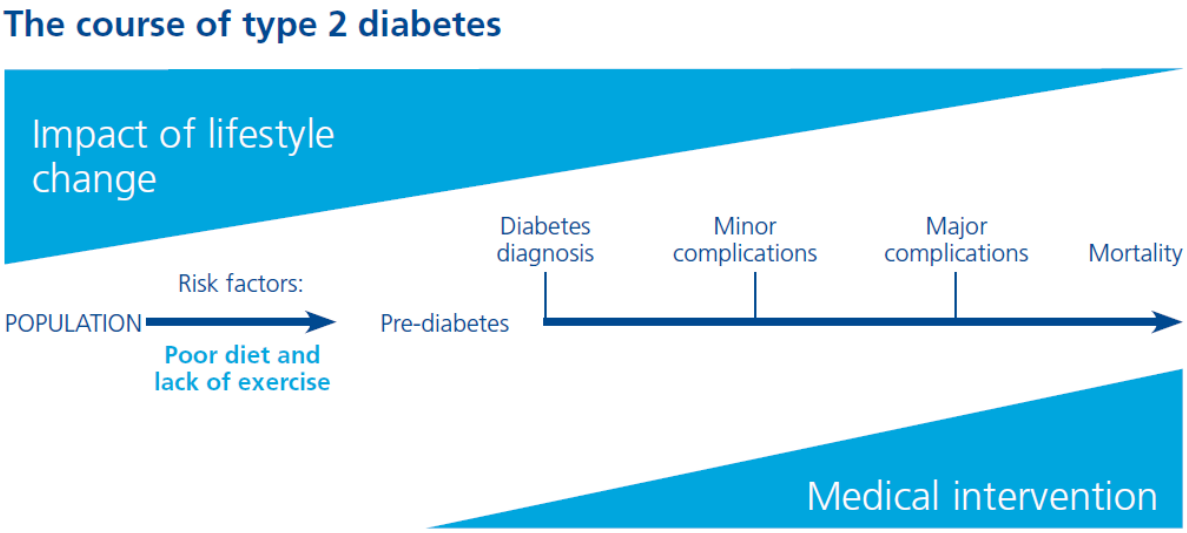
Lifestyle and dietary modifications are a core component of diabetic care (1)(37). Validated core therapies for diabetes besides lifestyle intervention include metformin, sulfonylureas insulin, α-glucosidase inhibitors, thiazolidinediones, glinides, dipeptidyl-peptidase-4 inhibitors, glucagon-like peptide-1, and amylin agonists (1)(36)(37)(42). Metformin, sulfonylureas and insulin are the most available in SSA , the remainder being rarely found, mostly due to their inaccessibility due to related high costs (1).

The ADA and European Association for the Study of Diabetes (EASD) consensus statement advises initiation of metformin monotherapy in conjunction with diet and exercise in newly diagnosed diabetic patients. Because type 2 diabetes mellitus is a progressive disease, drugs with different mechanisms of action are typically added to metformin when therapy beyond lifestyle changes is required. Early initiation of insulin therapy may be appropriate in many patients if glycemic control is not achieved after a trial of two to three oral agents at a time (37).

The benefits of lifestyle interventions on diabetes control have been widely documented. Patient education and self-management are critically important components of diabetic care and involving patients in their own care is one of the best strategies to attain optimal glycemic control (27). The ADA stresses that health care professionals should educate patients about the role of diet, exercise in diabetic treatment (37). Lifestyle interventions have been shown to delay the onset of diabetes as well as delaying the onset of diabetic related complications(11).

Figure 1 shows the overall contribution of lifestyle interventions in the prevention of diabetes and/or its complications among type 2 diabetic patients.

Figure 1. Overall contribution of lifestyle in the prevention and treatment of diabetes type 2



Source: Motala, A. and Ramaiya, K., 2010 (11)

According to Shrivastava et al., 2013, seven essential self-care behaviors in people with diabetes have been described as predictive of good diabetic outcomes. These are healthy eating, being physically active, monitoring of blood sugar, compliance with medications, good problem-solving skills, healthy coping skills and risk-reduction behaviors (27). Research evidence has confirmed that all the above mentioned interventions are positively correlated with good glycemic control, reduction of diabetic complications and improvement in quality of life (27).

Although the benefits of lifestyle modification on diabetes is well established, doctors and patients still struggle with achieving optimal glycemic control. The National Health and Nutrition Examination Survey in the US show that 45% of patients with diabetes do not achieve glycemic targets of HbA1c lower than 7% (25). One of the important reasons for poor glycemic control is patients' difficulties with implementing lifestyle modifications recommended by their physicians. This is particularly a problem in SSA where patients' face to face time with clinicians is often limited (25).

According to Weinger, K. et al., (2011), one way to conceptualize these interventions is to conduct interactive patient education sessions that allow the educator to tailor information, assess comprehension, clarify difficult concepts and use motivational interviewing techniques and action plans (25). Whether interactive patient education sessions are best done in a group setting or one on one is not yet clearly understood (25).

The present study seeks to assess the effects of group interactive lifestyle education sessions on glycemic control in diabetic patients. Our hypothesis is that interactive group counseling will have a greater impact on glycemic control in diabetic patients when compared to the standard of care in Rwanda which is physician initiated individual counseling. To our knowledge it is the first time such a study is attempted in a resource-limited setting.

MATERIALS AND METHODS

Design

The study is a randomized controlled trial evaluating the impact of an intensive lifestyle modification program on diabetes control compared to standard of care treatment in Kigali, Rwanda. The study participants are adults, age 21 years or greater who have been diagnosed with diabetes mellitus who receive routine outpatient care at one of two internal medicine outpatient clinics at the Central Hospital of Kigali (CHUK).

The participants were randomly assigned to an intervention group (standard of care plus monthly lifestyle counseling & education sessions lasting from 45 to 60 minutes) or to a control group (standard of care for diabetes in our setting which consists of monthly or bi-monthly medical follow up and individual counseling on dietary habits and lifestyle change delivered by attending physicians and/or nutritionists as per needed).

The lifestyle education program for the intervention group was administered by a team of physicians, nurses, nutritionists and counselors who received special training for the purpose of this study.

In order to maximize the retention of participants to the study, patients were called on a regular basis to remind them about getting laboratory tests and attending follow up appointments.

An interim analysis has been performed after six months of intervention. The present thesis work describes the results of the interim analysis as study subjects follow up is still ongoing. (The planned date of study completion is December 2014).

Study subjects

The study participants are adults, age 21 years or greater who have been diagnosed with diabetes mellitus who receive routine outpatient care at one of two internal medicine outpatient clinics at the Central Hospital of Kigali (CHUK). Diabetes care at KUTH is routinely provided by a physician/specialist doctor, an endocrinologist or a postgraduate in Internal medicine.

The study inclusion criteria are: diagnosis of diabetes at least three months prior to study entry; current treatment with either insulin, an oral hypoglycemic drug or both; ability to travel to KUTH for follow up. The study exclusion criteria are: advanced diabetic complications (advanced nephropathy with advanced Chronic Kidney Disease (CKD) class III or higher, proliferative retinopathy and blindness, recent history of myocardial infarction, severe heart failure, peripheral artery disease, stroke, severe diabetic foot disease; pregnancy; severe

psychiatric disorder; any other severe illness that would impede the patient's functional capacity.

Randomization

An excel computer randomization model was used to allocate study subjects to receive either lifestyle intervention (interventional group) or the standard of care (control group).

Lifestyle Intervention Group

Study participants randomized to receive interactive group lifestyle education sessions received one group lifestyle educational session every month for one year. The group education sessions focused on: diabetic meal composition; methods to decrease salt, sugar and unsaturated fat intake; methods to increase fruit and vegetable intake; regular physical activity; smoking cessation; alcohol abuse; medication adherence; adherence to routine medical follow up; diabetic complications; self management of hypo and hyperglycemia and stress reduction. (*A list of education topics covered is found in the appendix section*).

A standardized lifestyle education tool was developed by a team of endocrinologists and internists from KUTH and the Human Resources for Health (HRH) Rwanda. The tool was adapted from the IDF, ADA and European guidelines for lifestyle modifications in diabetes and from prior research protocols evaluating similar interventions ((1)(11)(27)(42)(28)(20))).

Education & counseling sessions were provided by a team of doctors, nutritionists, nurses and counselors who received training for the purpose of the study prior study beginning. One group counseling session on average lasted between 45 to 60 minutes. In addition, participants allocated to the intervention group received diabetic education brochures containing information on lifestyle change for diabetes control. The brochures were designed, adapted to local context and translated into local language for the purpose of this study (a *copy of the diabetes education pamphlet/brochure is found in the appendix section*).

To standardize teaching materials and methods, facilitators attended three training sessions prior to study initiation. The principal investigators additionally held monthly meetings with the team of educators and data collectors to provide feedback on the study process and ensure quality control in intervention administration.

Control group

Participants in the control group received the usual care delivered by attending physicians at KUTH. This included monthly medical follow up visits and individual counseling on dietary habits and lifestyle changes delivered by attending physicians and/or nutritionists.

Study outcomes

The primary outcome in our study was the between-groups difference in HbA1c. Secondary outcomes were differences from baseline in HbA1c after one year follow up, between-groups and baseline-to-six-month differences in blood pressure, BMI, lipid profile, fasting blood glucose, creatinine and urine albumin/creatinine ratio. Data was additionally collected on demographics, date of diagnosis, anthropometry, socioeconomic status and personal & familial medical history using a pre-defined questionnaire at enrollment visit (a copy of the *Case Report Form (CRF) is found in the appendix*).

Clinical (anthropometrics, waist circumference, blood pressure, heart rate) and laboratory (HbA1c, fasting blood glucose, lipid profile, serum creatinine, urine albumin/creatinine ratio) data were collected at enrollment, 6 months and one year. HbA1c was measured at enrollment and at every 3 months. The above data was collected by KUTH technicians who were blinded to the participants' group assignments.

Statistical analysis

The study was designed to have a statistical power of 80% power to detect a reduction in HbA1C $\geq$ 0.40 in the intervention group compared to the control group during a median follow up of one year with a two-sided significance level of $P < 0.05$. The HbA1c reduction of 0.40 is based on prior research of similar interventions (25)(24)(44)). Given the specified statistical power the study was designed to obtain 217 primary endpoints (sample size calculated using Epiinfo) . The final sample size was 250 persons to allow for a small drop-out rate.

Demographic, clinical and laboratory variables were summarized using percentages (categorical variables) and measures of location (means/medians) and dispersion (continuous variables).

The analysis was performed on an intention-to-treat basis with the inclusion of all patients who underwent randomization. Mean (or median if population not normally distributed) values of outcome measures in the intervention and control groups were compared using the Student's t-/Wilcoxon test with a two-sided significance of 5%. Wilcoxon rank-sum (Mann-Whitney) test was used to evaluate between groups (intervention and control) differences while Wilcoxon

signed rank test was used to compare baseline versus endpoint (six-month follow up) measurements in primary and secondary study outcomes.

Median HbA1c improvements were obtained by computing the median differences between HbA1c measurements at baseline and at six-month follow up visits. The obtained measures were used to assess between group differences and to evaluate their association in regard to the intervention before and after adjusting for the confounding variables.

Linear regression model was used to assess differences between two non-parametric continuous variables while ANOVA was used when continuous variables were compared with categorical ones. In the analyses we controlled for age, sex, education level, study site, years with diabetes diagnosis, size of household, hypertension, other comorbid conditions, insurance type, weight, ongoing medications, number of group educational sessions attended and lipid profiles.

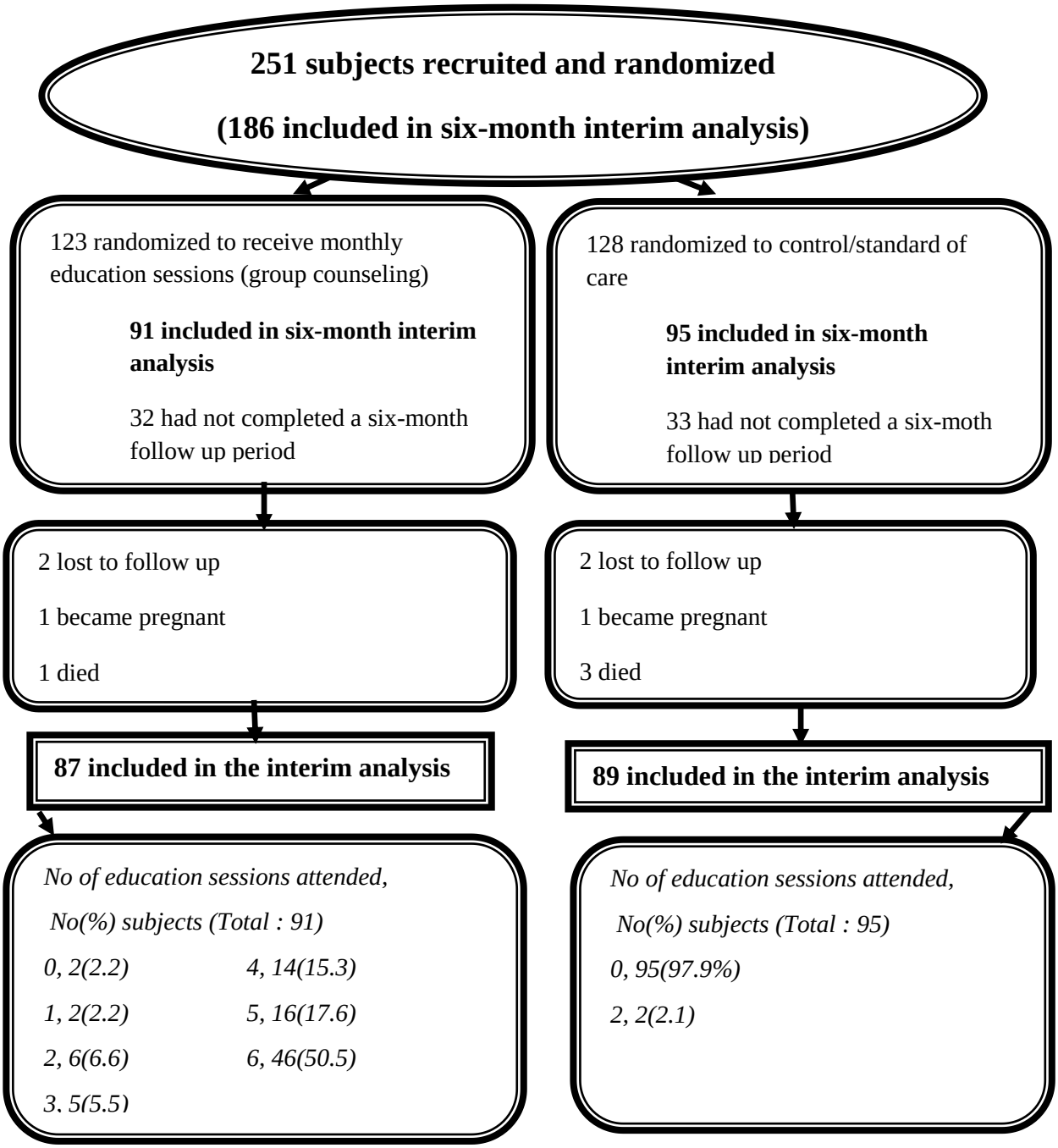
Statistical analysis was performed using STATA software version 11 (StataCorp. Texas, USA) and SPSS software version 21 (IBM Corp. 2012).

Ethics

The study was approved by the research ethics committee at the University of Rwanda's School of Medicine and Kigali University Teaching Hospital. Each participant included in the study gave a written informed consent before enrollment (*Copies of the consent forms are found in the appendix section*).

Participants were not paid for their participation in the study and were not reimbursed for travel expenses. Group education sessions were schedule on routine clinic days in order to minimize extra visits. HbA1c and urine albumin/creatinine ratio labs were provided to the participants at no additional cost.

Figure 2.Trial flow chart



RESULTS

Study participants

From March 2013 to November 2013, 251 diabetic patients who were eligible and willing to take part in the study were enrolled. In February 2014, 186 participants (91 in interventional group and 95 in the control group) had completed six-months of follow up and were included in the interim analysis. Data were not available for 10 participants (four lost to follow up, four died and two became pregnant) (Figure 2). For the present six-month interim analysis 176 (87 from interventional group and 89 from control group) out of 251 participants have been considered for outcome measures assessment. They represent 70.1% of the total sample (Figure2).

Of the 91 participants randomized to receive monthly group education sessions (intervention group), 81 (89%) attended three educational sessions and 46 (50.5%) attended all the six sessions. Two (2.1%) participants randomized to the control group mistakenly participated in the first two diabetic education sessions before they were identified and redirected. The two participants were analyzed in the control group in accordance with the ITT analysis. (Figure 2).

Demographic Data

The mean age of study participants was 51.5 (+/-10.6) years; the majority (69.4%) were women; 64.4% had secondary school education; the mean duration of diabetes was 7.3 (=/-6.6) years; 51.1% had a family history of diabetes and 46.7% of women had a personal history of fetal macrosomia.

50.5% of participants had hypertension; 49.5% reported being sedentary or doing minimal physical activity; 31.8% were current or past tobacco smokers and 68.3% were current or past alcohol consumers.

57% of subjects used a low class insurance type (community insurance a.k.a. mutuelle de santé), most of them being followed up in the Polyclinique study site ($p<0.001$). The average household size of participants was 6.1 persons per house. The baseline characteristics were not significantly different between the two study groups (Table 3).

Table 3. Demographic data of participants included in the six-month interim analysis

	All (n=186)	**Intervention (n=91)**	**Control (n=95)**	**P-value**
Mean Age (years)	51.5 (+/- 10.6)	52.1 (+/- 10.8)	50.9 (+/- 10.4)	0.40
Sex (% females)	69.4	68.1	70.5	0.72

Study site (% Polyclinique)	59.7	61.5	57.9	0.61
Education (%)				0.58
None	4.3	2.2	6.3	
Primary school	31.2	29.7	32.6	
Secondary & technical school	41.3	45.1	37.9	
University	23.1	23.1	23.2	
Duration of diabetes (years)	7.3 (+/-6.6)	6.9 (+/- 5.8)	7.7 (+/- 7.3)	0.26
0 – 5 yrs	50.0	49.5	50.5	
6 – 10 yrs	21.0	24.2	17.9	
11 – 15 yrs	18.3	19.8	16.8	
More than 15 yrs	10.8	6.6	14.7	
Household size	6.1 (5.7-6.5)	5.7 (5.2-6.2)	6.5 (6.0-7.0)	0.12
Insurance type (%)				0.89
Community insurance	57.0	54.9	58.9	
RSSB/RAMA	29.6	30.8	28.4	
CORAR	2.2	3.3	1.1	
MEDIPLAN	5.4	5.5	5.3	
AHA/HCR	1.6	2.2	1.1	
FARG	3.2	2.2	4.2	
Other	1.1	1.1	1.1	
Family history of diabetes (% positive)	51.1	51.6	50.5	0.49
Personal history of fetal macrosomia (% positive)*	46.7	53.4	40.6	0.15
Physical activity (%)				0.25
None	10.8	8.8	12.6	
Walking	72.0	73.6	70.5	
Farming/Digging	3.8	6.6	1.1	
Fitness/Gym-tonic	8.6	7.7	9.5	
Swimming	0.5	0.0	1.1	
Other sports (football, volleyball, etc.)	3.8	2.2	5.3	
Other	0.5	1.1	0.0	
Overall level of activity (%)				0.81
Sedentary	15.6	13.2	17.9	
Mild activity	33.9	36.3	31.6	
Moderate activity	46.2	46.2	46.3	
Severe activity	4.3	4.4	4.2	
Comorbid conditions (%)				0.49
None	29.0	25.3	32.6	
Arterial hypertension	**50.5**	**51.6**	**49.5**	
HIV infection	6.5	8.8	4.2	
Asthma	3.8	3.3	4.2	
Chronic gastritis/Peptic Ulcer Disease	3.2	4.4	2.1	
Viral hepatitis B or C	1.1	0.0	2.1	
Chronic use of steroids	0.5	1.1	0.0	

Long term use of traditional herbs	0.5	0.0	1.1	
Other	4.8	5.5	4.2	
History of tobacco smoking (%)	31.8	34.1	29.5	0.41
History of alcohol consumption (%)	68.3	65.9	70.6	0.17

**Percentages were computed out of 122 female participants who responded to the question*

Baseline clinical and laboratory characteristics

The median baseline HbA1c for all study participants was 9.04%. The median urine albumin /creatinine ratio was 27.2 µg/mg with 16.2% of subjects having abnormally elevated levels (Table 4). The median blood pressure was 136.1/79.8 mmHg, Weight: 75.8 Kg. The median BMI was 27.8 with 72.6% of participants overweight (BMI>24.99 kg/m^2) and 26.9% obese. 38.7 % of participants were treated with metformin and a sulfonylurea while 22% were on insulin monotherapy. The baseline clinical and laboratory characteristics did not significantly differ between the two groups. (Table 4).

Table 4. Baseline clinical and laboratory characteristics

	All (n=186)	**Intervention (n=91)**	**Control (n=95)**	**P-value**
HbA1c (%)	**9.04 (8.6-9.3)**	**9.21 (8.7-9.7)**	**8.87 (8.3-9.3)**	**0.16**
Systolic BP (mmHg)	136.1 (133.1-139.1)	134.7 (130.9-138.5)	137.4 (132.8-142.0)	0.81
Diastolic BP (mmHg)	79.8 (78.3-81.3)	79.6 (77.5-81.7)	80.0 (77.9-82.2)	0.56
Weight (kg)	75.8 (73.8-77.8)	76.0 (73.1-78.8)	75.7 (72.8-78.6)	0.88
Height (cm)	165.3 (164.0-166.5)	165.7 (163.9-167.4)	164.8 (163.1-166.6)	0.42
BMI (kg/m^2)#	27.8 (27.0-28.5)	27.7 (26.7-28.7)	27.9 (26.8-29.0)	0.81
<19*	2.2	2.2	2.1	
19-24.99*	25.3	25.3	25.3	
25-29.99*	45.7	47.3	44.2	
>/=30*	**26.9**	**25.3**	**28.4**	
Waist circumference (cm)	96.3 (94.4-98.2)	96.6 (94.2-99.1)	96.0 (93.2-98.9)	0.37
Total Cholesterol (mmol/l)	4.2 (4.04-4.30)	4.3 (4.0-4.6)	4.1 (3.8-4.4)	0.30
Triglycerides (mmol/l)	1.8 (1.7-2.0)	1.8 (1.6-2.1)	1.8 (1.6-2.0)	0.41
Serum Creatinine (µmol/l)	80.0 (76.8-84.2)	80.0 (74.7-82.5)	80.0 (73.5-86.5)	0.91
Urine albumin/creatinine ratio	27.2 (16.7-37.8)	23.5 (12.7-34.2)	31.1 (12.7-49.4)	0.22
No microalbuminuria (<30 µg/mg) **	83.8	85.1	82.6	
Microalbuminuria (>30 µg/mg)**	16.2	14.9	17.4	
Diabetic medications*				0.85
Insulin only	22.0	18.7	25.3	
Metformin only	14.0	15.5	12.6	
Sulfonylurea only	9.8	8.8	10.6	

Insulin+metformin	11.4	11.0	11.6
Insulin+Sulfonylurea	2.7	3.3	2.1
Metform+Sulfonylurea	38.7	40.7	36.8
Other	1.6	2.2	1.1

**Percent*

 # calculated in medians (95% Confidence Intervals) as weight in kilograms divided by height in meters squared.

***Percent out of 173 subjects on whom the test was performed*

Primary and secondary outcomes

Table 5. Changes in clinical and laboratory outcomes at six months

	Intervention (n=87)				**Control (n=89)**				**Mean Diff. P-value ***
	Baseline Median (95%CI)	6 month Median (95%CI)	Diff.	P-value	Baseline Median (95%CI)	6 month Median (95%CI)	Diff.	P-value	
HbA1c	9.21 (8.7-9.7)	7.65 (7.3-8.01)	1.52	<0.001	8.87 (8.36-9.39)	7.89 (7.56-8.22)	0.91	0.003	0.064
Fasting Glucose (mmol/L)	8.59 (7.78-9.39)	7.10 (6.57-7.62)	1.29	<0.001	8.08 (7.4-8.7)	7.69 (7.23-8.16)	0.32	0.411	0.062
Systolic BP (mmHg)	134.7 (130.9-138.5)	130.2 (127.1-133.4)	4.91	0.006	137.4 (132.8-142.0)	135.5 (131.7-139.4)	0.48	0.80	0.090
Diastolic BP(mmHg)	**79.6 (77.5-81.7)**	**75.3 (73.2-77.4)**	**4.48**	**0.002**	**80.0 (77.9-82.2)**	**78.7 (76.7-80.7)**	**0.90**	**0.42**	**0.047**
Weight (kg)	76.0 (73.1-78.8)	75.9 (72.9-78.9)	-0.19	0.60	75.5 (72.8-78.6)	76.8 (73.8-79.8)	0.74	0.7	0.063

Primary Outcome

The median glycosylated hemoglobin significantly decreased in both the intervention (from 9.21% at baseline to 7.65% at six-months) and the control group (from 8.87% at baseline to 7.89% at six months). Although there was a trend towards greater degree of HbA1c reduction in the intervention group compared to the control group, the between group difference in HbA1c at six months was not statistically significant (p = 0.064) (Table 5, Figure 3).

Secondary Outcomes

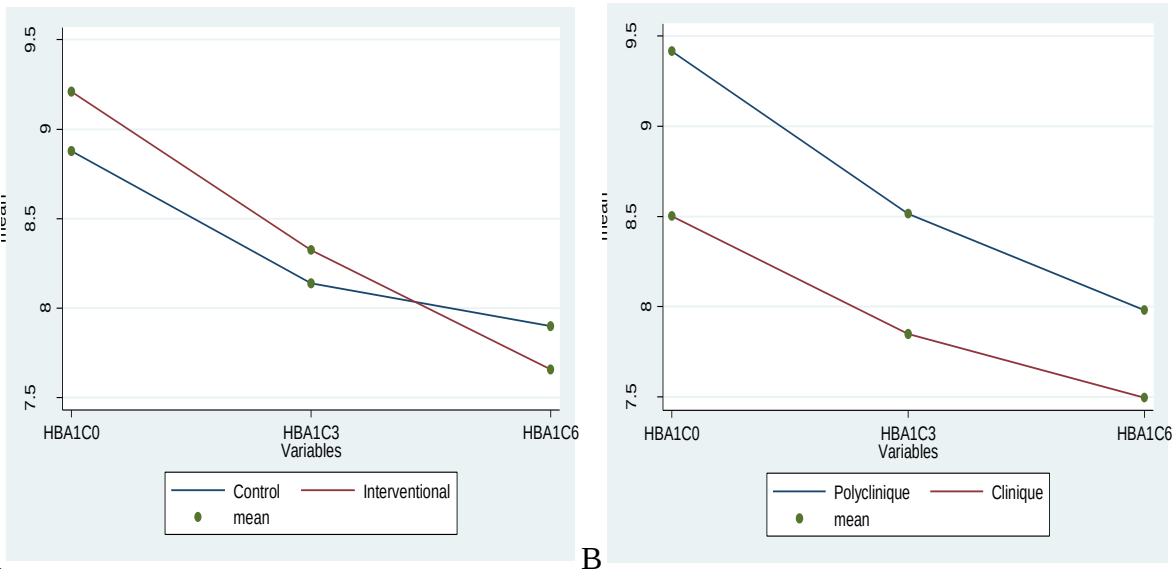
The median HbA1c levels reduced by 1.52 (95% CI: 1.05 to 1.98); p<0.001) in the intervention group; and by 0.91 (95% CI: 0.45 to 1.36); p= 0.003) in the control group (Table 5, Figure 3).

The median fasting blood glucose, systolic blood pressure and diastolic blood pressure all significantly decreased in the intervention group over the 6-month study period ($p<0.001$, 0.006, 0.002 respectively). Participants in the control group saw a modest decrease in fasting glucose, systolic and diastolic blood pressures but these results were not statistically significant ($p=0.411$, 0.80, 0.42 for median difference in fasting glucose, systolic blood pressure and diastolic blood pressure from baseline to 6 months in the control group) (Table 5, Figure 4).

There was a statistically significant difference in diastolic blood pressure reduction in the lifestyle education group compared to the control group at six months ($p=0.047$). Although a trend towards greater reduction in fasting glucose and systolic blood pressure were observed in the intervention group when compared to the control group at six months, it was not statistically significant (Table 5, Figure 4). The mean six-month fasting glucose was 7.10 mmol/L in the intervention group and 7.69 mmol/L in the control group ($p= 0.062$). The mean systolic blood pressure at six months was 130.2mmHg in the intervention group and 135.5mmHg in the control group ($p=0.090$) (Table 5).

There were no significant improvements in weight within or between the two study groups. However, the median weight for people in the control group increased by 0.74 kg while those in the intervention group had decreased 0.19 kg (Table 5).

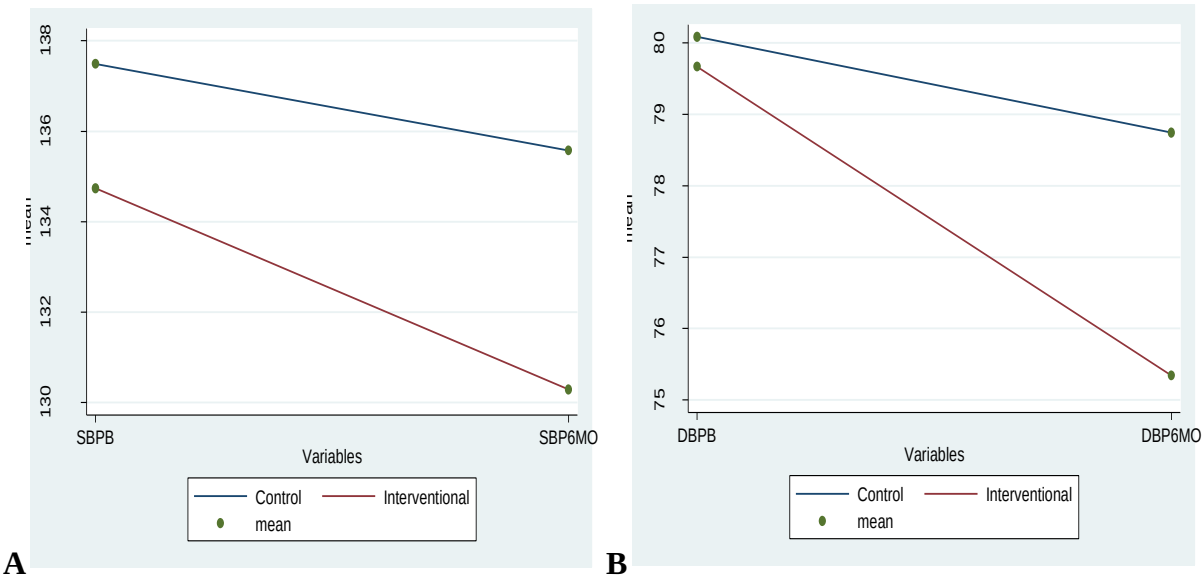
Figure 3. HbA1c levels by study group (A) and by study site (B)



A B

Figure 3 shows the mean HbA1c at baseline (HBA1C0), three months (HBA1C3) and six months (HBA1C6). Graph A shows the HbA1c reduction in the intervention and control groups over the 6 month study period. Graph B shows the combined (intervention and control) HbA1C reduction at each of the two study sites.

Figure 4. Mean Systolic (A) and Diastolic (B) blood pressures at baseline and six months.



A **B**

Figure 4 (A) shows the decline in systolic blood pressures of the intervention and control groups over six months. Figure 4 (B) shows the decline in the diastolic blood pressures of the intervention and control groups over six months. The intervention group saw a statistically greater decrease in diastolic blood pressure at six months compared to the control group.

Using a linear regression model, we adjusted for potential factors that would otherwise contribute to changes in outcome measures. Confounders controlled for in the regression model were: age, sex, education level, study site, years since diagnosis of diabetes, household size, hypertension, insurance type, weight, ongoing medications, number of group educational sessions attended and baseline lipid levels.

The degree of HbA1c improvement at six-months was positively correlated with the baseline HbA1c and negatively correlated with baseline triglyceride levels. Participants with a high baseline HbA1c had a greater absolute reduction in HbA1c at six months (95%CI 0.60-0.78; $p<0.001$). Participants with low/normal triglycerides at baseline had a greater absolute reduction in HbA1c at six months ($p=0.05$).

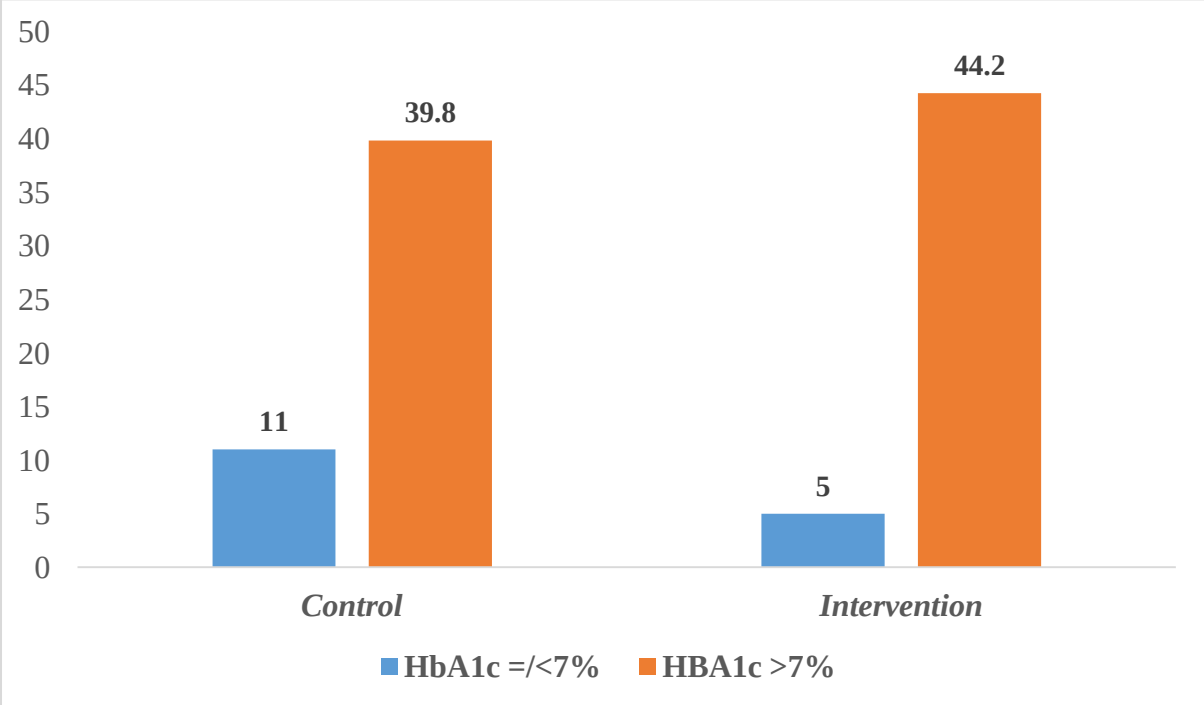
Greater HbA1c reduction at six months was observed in participants treated with insulin monotherapy, insulin + metformin and those on metformin + sulfonylurea compared to participants treated with metformin monotherapy, sulfonylurea monotherapy or insulin + sulfonylurea ($p=0.04$).

Age, sex, diabetes duration, baseline total cholesterol, weight, BMI, level of physical activity, comorbid conditions, study site, education level, insurance type, household size, and number of group educational sessions attended did not show a significant influence on HbA1c levels at six months.

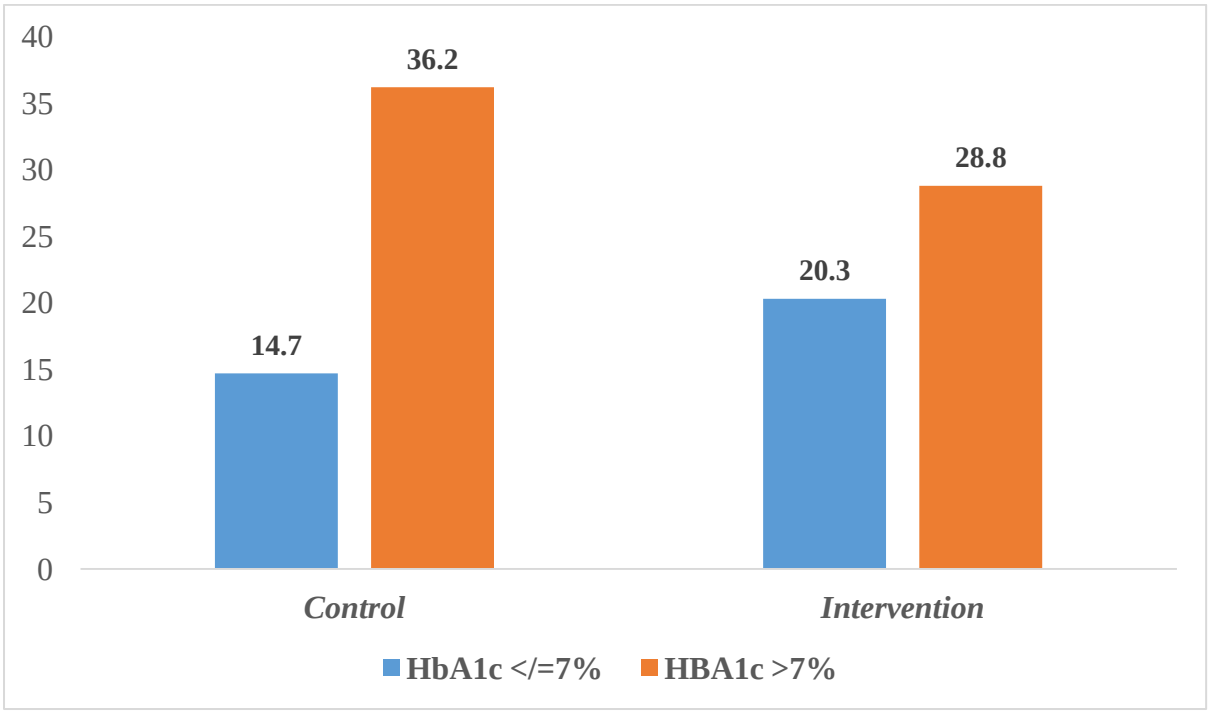
There was an overall increase in the number of study subjects who met the target HbA1c (<7%) at six months in both the control and intervention groups (HbA1c goal was achieved in 16% of all study participants at baseline and in 35% at six months). A greater proportion of subjects in the intervention group achieved HbA1c<7% at six months (from 5% at baseline to 20.3% at six months) compared to the control group (from 11% at baseline to 14.7% at six-months). However, although there was a trend, statistical significance for such a difference was not observed (p=0.08) (Figure 5)

Figure 5. Participants achieving target HbA1c <7 at enrollment (A) and six-months (B)

(A) Percent of participants with HbA1C < 7% at study enrollment



(B) Percent of participants with HbA1c < 7% at six months



DISCUSSION

This randomized controlled prospective intervention trial evaluated the impact of a group lifestyle modification program on glycemic control of diabetic patients in Rwanda. The presented results were obtained from a six-month interim analysis that included 186 participants, representing 70% of total subjects included in the study. The final results from 1-year follow up will be available in December 2014.

Baseline data show that prior to study initiation the overall degree of glycemic control in Rwandan diabetics was poor (overall only 16% of all study participants had a baseline HbA1c <7). Similar figures have been reported from Kenya by Matheka et al. at Kenyan National Referral Hospital (10). The figures indicate that diabetic care in East Africa is still far behind developed countries where at least 55% of diabetic patients are reported to have a HbA1C < 7% (2011 United States National Health and Nutrition Examination Survey) (35).

The number of diabetic patients in Rwanda with poor glycemic control coincides with the previously reported high prevalence of diabetic complications in Rwanda (13). These figures are alarming and could have devastating human and economic toll if the trends are not reversed in the near future. Sustainable lifestyle modifications in diet and physical activity are the initial, and often the primary, component in the management of diabetes and the metabolic syndrome and have the potential to reverse the increasing incidence of diabetes and its complications in Rwanda.

Our study demonstrates that effective diabetic care in Rwanda is possible. Group lifestyle modification programs, similar to programs already used in developed countries, can have dramatic impact on diabetes control in Africa. Overall, at six-month follow up, the number of subjects achieving HbA1c goal of < 7% had increased to 35%, which is greater than two times the baseline rates. Significant six-month improvements in HbA1c and fasting blood glucose were seen for both the intervention and control groups. Figure 3 shows the trend in HbA1c reduction in both study groups. The degree of HbA1c reduction was significant at three months for both the intervention and control groups and was sustained throughout the six-month follow up.

The striking decrease in HbA1c by 1.5% in the intervention group and 0.9% in the control group has important clinical implications for diabetic patients in Rwanda. Prior studies have demonstrated that each 1% reduction in HbA_{1c} over 10 years is associated with a risk reduction of 21% in diabetes related deaths, 14% in myocardial infarctions, and 37% in microvascular

complications (46). Thus it is likely that a 0.9-1.5% reduction in HbA1c observed in our study is clinically significant.

Although not statistically significant, greater absolute reduction in HbA1c and fasting blood glucose were observed in the lifestyle intervention group compared to the control group. Likewise, although not statistically significant, a great proportion of participants in the lifestyle modification arm achieved a target HbA1c<7 after six months of study participation compared to the control arm. These results are very encouraging and indicate that an improvement in diabetic care is not only possible in Rwanda but can be achieved over a relatively short period of time.

Although the present study does demonstrate some superiority of group lifestyle education programs over individual physician or nutritionist directed counseling in managing diabetes in Rwanda, both approaches improved glycemic control and minimized cardiovascular risk factors. This has been previously reported in other studies. Rickheim et. al. for example in his 2002 study reported on the benefit of both group and individual counseling on glycemic control but demonstrated greater HbA1c reduction with group counseling compared to individual counseling (22). Figure 3 shows that the bulk of hyperglycemia reduction in the control group occurred in the first three months of the study, while the intervention group continued to improve in their glycemic parameters throughout the six month period. This highlights the possibility that a group lifestyle intervention program may have more sustainable long-term effects on individuals' behaviors and thus may be more efficacious in chronic management of diabetes in Rwanda. The one-year outcomes of the present study may be able to shed further light on this topic.

Other trials comparing group and individual behavior modification programs for diabetes control have reported on significantly better outcomes with group counseling which we did not observe in this study. Xavier et al. in the Look AHEAD Trial observed significant reduction in HbA1c and cardiovascular risk factors (blood pressure, cholesterol, triglycerides, weight) among participants in a group lifestyle modification program compared to individual counseling over one year follow up (45). Trento et al. similarly reported that hyperglycemia, hypertension and dyslipidemia were all better controlled with group educational programs than individualized counseling.

The homogeneous effect of both the group lifestyle education program and physician-directed individual counseling on diabetes control in the present study can at least in part be attributed to the fact that this is the first intervention of its kind in Rwanda. The novel training that diabetic care providers involved in the study received prior to study initiation likely increased provider knowledge on the role of diet and exercise in diabetic management in both arms of the study

and can partly explain the modest difference in outcomes of the two study arms. In addition new Continuous Professional Development Program in Rwanda affords all providers to receive extended diabetes education on a regular basis and may account for overall improvement in diabetic counseling both in the individual and group setting.

The novelty of conducting such a study in Rwanda may have primed the participants to take an unprecedented interest in their own disease management and this as well can explain the similar outcomes between the intervention and control groups in the present study. Lastly, the similar glycemic outcomes in the study and control groups may have been affected by crossover. Patients often share a waiting area medical consultations and as a lot of participants were very enthusiastic about the new study they probably constantly shared information between each other leading to control group contamination.
On the other hand the homogeneous effect of the two groups in our present study may point to the fact that a variety of educational approaches may be effective in improving glycemic control in African patients.

In the present study we observed that triglyceride levels at baseline were negatively correlated with HbA1c reduction. These results imply that hypertriglyceridemia has deleterious effects on glycemic control. This has been previously reported by Erickson et. al. who observed that elevated triglycerides were associated with insulin insensitivity (16). The relationship between diabetes control and hyperlipidemia should be further explored in future research conducted in Rwanda.

Although not the main objective of the study, we observed better glycemic control with some diabetic regimens (insulin, insulin + metformin, metformin + sulfonylurea) than others (metformin, insulin + sulfonylurea, sulfonylurea alone). Better improvements mostly with insulin containing regimens may be explained by the previously reported higher prevalence of Beta-cell dysfunction and insulin deficiency in diabetic people living in SSA (1)(8)(11). However, further research designed to elucidate which regimens are more efficacious to control diabetes among african patients is needed.

Our results of improved blood pressure in diabetic patients with group lifestyle modification methods are in line with prior studies published on this topic (14), On the other hand, our finding that group counseling failed to result in significant weight loss is different from previously published trials(14)(45). Nonetheless, the intervention seems to protect subjects from

weight gain (people in the control group rather gained some more weight throughout six month follow up whereas those in the intervention lost weight).

An unexpected finding in our analysis was that HbA1c decline was not correlated with the number of educational sessions attended by participants. One possible explanation for this observation is that subjects randomized to the intervention group, besides attending monthly education sessions and receiving monthly phone calls from the educational team, received a diabetic education brochure that contained most of the topics covered during group education sessions. (A *copy of the diabetic education brochure can be found in the appendix*). This again highlights the possibility that numerous diabetes educational approaches may be highly effective in improving glycemic control among diabetic patients in Rwanda and other similar settings.

We intentionally conducted the study at two socioeconomically different clinics in Kigali in order to ensure that the benefits in diabetic control could be attributed to the diabetic education sessions and not be a reflection of intensive HbA1c monitoring dictated by the study protocol. HbA1c monitoring was not routinely performed for most participants attending 'Polyclinique'. Most participants attending Polyclinique have community insurances that do not reimburse for HbA1c testing. HbA1C monitoring on a three month basis was however widely available to participants at the 'Clinique' site. On average the participants attending 'Clinique' are wealthier and can afford routine HbA1c testing.

Similar improvements in glycemic control and blood pressure reduction was observed across the two study sites (Figure 3, Graph B). This finding supports the conclusion that the improvement in hyperglycemia and cardiovascular risk factors in our study can be attributed to the diabetic education efforts and not to the increased monitoring of diabetic outcomes that resulted as an effect of the study.

Lifestyle modification programs in SSA have been previously evaluated for their role in diabetes prevention (11). To our knowledge, however, the current study is the only one that has looked at the role of lifestyle modification programs on glycemic control in established diabetics in SSA. The observed effects of diabetic education on glycemic control; the high rates of participant retention in the intervention group (89% attended a minimum of three group educational sessions which is similar to previously reported data (16)(25)(44)) as well the tremendous enthusiasm towards lifestyle modification approach to diabetic management expressed by both patients and providers illuminates the great potential of such programs in routine diabetic care in Rwanda.

More importantly, the team of educators was mostly composed of primary care health professionals, thereby signaling the feasibility of such an intervention program and its applicability in other similar settings and even in lower level health facilities. This may be particularly relevant for other African countries where the majority of NCD care is provided at the primary level healthcare facilities.

Indeed, this goes in line with previous studies showing that lifestyle intervention programs conducted by primary care teams have beneficial effects on glycemic control, other CV risk factors as well as overall well-being of diabetic patients (16)(24)(44).

Study strengths and limitations

The principal strengths of the present study are its randomized, prospective design and the fact that it addresses lifestyle education programs for diabetes care in Rwanda - a country where such interventions had not been previously evaluated. The present study provides initial clues that behavior modification programs may be useful in the public health management of non-communicable disease in SSA.

The study has some limitations. Although treatment group assignment was randomized, loss-to-follow-up was limited, and intention-to treat analyses were adhered to ; nor were the participants nor the providers blinded to the study arm assignment. Similarly the patients and providers were not blinded to results of the primary and secondary outcomes (for example every patient had to bring the HbA1c test result to his provider in order to get follow up) and this potentially introduced bias into the results.

Two doctors attending to diabetic patients also played a major role as group educators, which could have led to information bias and led to control group contamination. To correct for this, the study was organized in such a way that the physician attending to patients in Polyclinique (one site) could only participate in sessions delivered at Clinique and never at Polyclinique and vice versa.

While it is universally described that type 2 diabetes patients are potentially the ones to show great improvements on lifestyle intervention programs, our study included both type one and type two diabetics. We are aware that this could have introduced some bias but our study was not large enough to allow differentiation of the two groups.

The study was designed to evaluate dyslipidemia at baseline and six-months, but due to reagents stock outs, only baseline lipid profiles were measured. This limited our ability to assess the effect of the lifestyle modification program on dyslipidemia among our study participants.

Funding sources

This study received funding from Sanofi Aventis and KUTH's Department of Research. Sanofi provided funds for HbA1c and urine albumin/creatinine testing while KUTH paid for development of study materials. Neither institution has been involved in the analysis of study data or the interpretation of the study results.

CONCLUSIONS AND RECOMMENDATIONS

A six month interim analysis of the presented prospective randomized control trial shows that lifestyle intervention programs for diabetes management in Rwanda is feasible and effective.

The number of subjects achieving proper glycemic control (HbA1c<7%) increased tremendously for all the study participants (from 16% at baseline to 35% at six-months).
A trend towards better glycemic control and greater reduction in cardiovascular risk factors was observed among participants partaking in group lifestyle education sessions, although absolute difference in HbA1c levels at six months of study was not statistically different between the intervention and control groups. Nonetheless, our results suggest that participating in a lifestyle group education programs provides beneficial effects on glycemic control among diabetic patients in Rwanda. Whether such improvements can be sustained for a long-term period will be subject of a further analysis at the end of study follow up.

The present study demonstrated that lifestyle modification programs are feasible in a resource limited setting such as Rwanda. All of the study relevant education was successfully administered by primary care health workers. Majority of participants showed great enthusiasm towards continued engagement in the study despite the additional time burdens associated with participation. These optimistic outcomes suggest that similar interventions may be effectively implemented in other SSA countries with similar and even lower level health facilities.

Based on the above findings, we have formulated the following recommendations:

- Both group and individualized diabetes education resulted in a dramatic improvement of glycemic control. Irrespective of the method of education delivery, diabetes care providers in Rwanda should incorporate lifestyle modification education and self-management education into routine and primary diabetic care algorithms
- Group diabetes education is an attractive option when compared to individual counseling in Rwanda and other resource limited settings because at the very least it results in glycemic control not inferior to individual counseling and has the potential to reach more people while utilizing less healthcare workers.
- Further research to deeply explore which approach (es) use(s) less time while being efficacious is, however, recommended.
- The implementation of the described diabetic management methods will be limited in Rwanda unless widespread access to HbA1c monitoring is made available to the public. The Ministry of Health (MoH) in Rwanda and affiliated policy makers should look for

sustainable solutions to address the frequent stock outs of HbA1c testing reagents as well as the prohibitive cost associated with HbA1c testing under the Rwandan community insurance. Widespread availability of HbA1c testing will tremendously facilitate diabetic monitoring, provide invaluable feedback to patients and providers and ultimately curb the rising rates of early onset diabetic complications observed in Rwanda.

- Further research is necessary to investigate the optimal diabetic medications in African populations. In addition, improved education of primary care doctors in the use of add on medication for the treatment of diabetes would be beneficial.
- Further research is necessary to evaluate the role of lifestyle intervention programs in the management of diabetes-associated diseases such as hypertension, dyslipidemia, and obesity.

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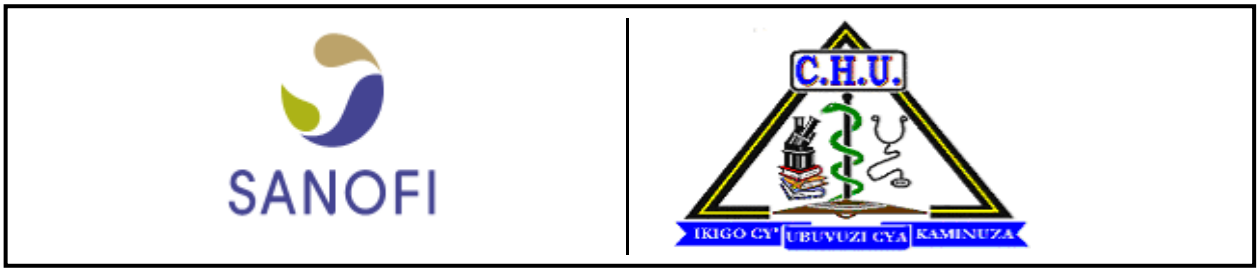
APPENDIX

Appendix 1. Case Report Form

CASE REPORT FORM

Investigator Name:	
Investigator Site:	



TRIAL FLOW CHART

Visit	**1**			**2**			**3**			**4**		
Day	**0**			**90**			**180**			**270**		
Months	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	
Assessments												
Written informed consent from subjects	X											
Demographic data	X											
Socio-economic status	X											
Medical and treatment history (incl Diabetic)	X											
Dietary/lifestyle habits	X			X			X			X		
Inclusion/Exclusion criteria/ Eligibility assessment	X											
45mins -1hr lifestyle counseling session	X	X	X	X	X	X	X	X	X	X	X	
Physical Examination	X			X			X			X		
Vital signs	X	X	X	X	X	X	X	X	X	X	X	
Clinical laboratory tests: Fasting Blood Glucose, HbA1c, Serum Creatinine Serum Urea	X			X			X			X		
Lipid profile (Total Cholesterol, HDL,LDL), Triglycerides Urinary Microalbumin Urine alb/creat ratio	x						x					
Concomitant medication	X			X			X			X		
Adverse Event recording	X	X	X	X	X	X	X	X	X	X	X	

GENERAL INSTRUCTIONS FOR COMPLETION OF CASE REPORT FORM

1. **TEXT:** Please print all written entries in BLOCK CAPITAL LETTERS and avoid writing outside the space provided.
   English should be used and abbreviations should be avoided.
   Always use a black ballpoint pen.
   Do not use single or double quotation marks.
   When an answer fits into the 'Other' category of a list, complete the 'specify' field.

2. **ANSWERS/TICK BOXES:** Please make sure that you answer all relevant questions.

   Closed boxes are used for ticking (✓): ☐ ☑

   Open boxes are for entering digits or characters: **|__|__|** e.g. **| 0 | 1 |** **| A | J |**

   If an assessment is **Not applicable, Not done,** or the results are **Not known**, a single horizontal line should be drawn through all the fields (only if an appropriate check box has not been provided to indicate this).

3. **ERRORS:** Cross out the error with a single horizontal line and write the correction next to it. **Initial and date** the correction. Do not use correction fluid, pencil or red ink. Make sure the error, although crossed out, remains legible. The process for the correction of subsequent discrepancies involves the use of specific terms, i.e., Data Clarification Forms (DCF).

4. **SIGNATURES AND DATES:** Sign and date CRF pages, where requested.

5. **SUBJECT IDENTIFICATION:** Each subject is identified by: **Subject Identification Number:** Each subject will be screened and numbered according to study procedures.

6. **NUMERIC FIELDS:** Where the answer to a question is a number, please put only one digit in each box, with a leading zero when necessary. Boxes must be completed from right to left, e.g., 12 written as 0012 e.g. Number of days: **| 0 | 4 | 9 |.** Record all values in the units indicated on the CRF.

7. **DATES:** Record the **actual date of the visit**. The order of entry in the date format is Day, Month, Year (07/JAN/2011). Day and year are to be expressed numerically; month is to be expressed alphabetically (the first three letters of the month) in block capital letters.

   Correct entry for complete date: **| 0 | 1 |/ | J | A | N |/| 2 | 0 || 1 | 1 |**

   In the absence of an exact date for events and therapies that precede the subject's inclusion into the study, incomplete dates should be recorded as follows:

   Correct entry for incomplete date: **| N | K |/ |__| N | K |/| 1 | 9 || 8 | 1 |**, providing at least a year.

8. **CRF COMPLETION COLLATION:** If the CRF is not completed at the time of visit, record the date of the visit, not the date of CRF completion. Check that all visits are in chronological order. Ensure that all appropriate pages are present in the CRF and are in proper sequence.

Protocol No.: LIFESTYLE	VISIT 1 (DAY 0) Center Nbr: |__|__|__| Site number: |__|__| Subject Number: |__|__|__| Page 1 of 8
	Date of Visit: |__|__|/|__|__|__|/|__|__|__|__| DD MON YYYY

INFORMED CONSENT

- **No study related activities may take place before the patient has signed the Informed Consent form.**

Date informed consent was obtained: \|__\|__\|/\|__\|__\|__\|/\|__\|__\|__\|__\|
DD MON YYYY

DEMOGRAPHICS

Age : \|__\|__\|__\| years

Gender: (please ☑ one):

- ☐ 1-Male
- ☐ 2-Female

Profession (please ☑ one):

- ☐ 1- Unemployed
- ☐ 2- Full-time
- ☐ 3- Part-time job
- ☐ 4- Self-employment
- ☐ 5- Housewife
- ☐ 6- Retired
- 7. Student
- 8. Farmer (teanant)
- 9.Other (specify)

Residence (please ☑ one):

- ☐ 1-Urban (Kigali town)
- ☐ 2-Semi-urban (eg. Huye, Ruhengeri,…)
- ☐ 3-Rural (rural areas)

Education (please ☑ one):

- ☐ 1- None
- ☐ 2- Primary School
- ☐ 3- Secondary School
- ☐ 4-Technicon/College
- ☐ 5-University and beyond

Number of people living in the same house ☐☐

Insurance type: (please ☑ one):

- ☐ 1-Mutuelle communautaire
- ☐ 2- RAMA
- ☐ 3. MMI
- ☐ 4. CORAR
- ☐ 5. Mediplan (SORAS)
- ☐ 6. Other (Specify)

Family history of diabetes (please ☑ one):

- ☐ 1-Yes (if Yes, go to next question)
- ☐ 2- No
- ☐ 3. Not known

If positive history of diabetes, specify:

- ☐ 1. Mother
- ☐ 2. Father
- ☐ 3. Brothers/sisters
- ☐ 4. Extended family

Marital status (please ☑ one):
☐ 1. Married
☐ 2. Divorced
☐ 3. Widow
☐ 4. Religious
☐ 5. Single
☐ 6. Other (Specify)

History of fetal macrosomia (any of the children):

Child's birth weight:
☐1. ≥ 4 kg
☐ 2. < 4 kg

☐5. Other (specify)

Relevant previous medical history:
☐ 1. Hypertension
☐ 2. Asthma
☐ 3. Chronic use of steroids
☐ 4. Use of traditional herbs/drugs
☐ 5. HIV infection
☐ 6. Viral hepatitis (☐B ☐ C)
☐ 7. Other not listed (Specify)

Do you have access to clean water (please ☑ one):
☐ Yes
☐ No

Do you have access to electricity (please ☑ one):
☐ Yes
☐ No

TYPE II DIABETES

Date of Diagnosis: \|__\|__\|__\|__\|
YYYY

DIETERY / LIFESTYLE HABITS

Average number of meals per day \|__\|__\|

Source of meals (please ☑ one):
☐ 1. Bought in market

Who prepares the food at home?

☐ Self (lui-meme)
☐ Spouse
☐ House maid
☐ Other (Specify)

☐ 2. Own ground/field

☐ 3. Both market &own ground

☐ 4. Other (Specify)

How many times do you eat green fruits/vegetables per week: |__|__|

How often do you eat in a restaurant per week: |__|__|

How often do you add salt in your meal at the table: |__|__|

What kind of physical exercise do you do (Please ☑ all that apply):
☐ Walking
☐ Farming/digging
☐ Fitness (gym-tonic)
☐ Swimming
☐ Sport (foot, volley…)
☐ Other (specify)

Average number of days you actively walk for at least 30 min per week |__|

Average number of days of physical exercise per week: |__|

Overall level of activity (including work, sports etc)	☐ 1- Sedentary ☐ 2. Mild activity	☐ 3- Moderate Activity ☐ 4. Strenuous activity	
Tobacco use	☐ 1- Ever	☐ 2- Never	☐ 3. Current (specify chewing or smoking)
Alcohol use	☐ 1- Ever	☐ 2- Never	☐ 3. Current (Specify volumes)

PHYSICAL EXAMINATION / VITAL SIGNS					
Height cm	**Weight** kg	**BMI**	**Heart Rate** bpm	**Waist circumference cm**	**Blood Pressure** Systolic/ Diastolic mmHg
|__|__|__| , |__|	|__|__|__| , |__|	|__|__|__|	|__|__|__|	|__|__|__|	|__|__|__| / |__|__|__|
•	• **Should be measured on the non-dominant arm after 5 minutes of supine rest**				

DIABETES COMPLICATIONS PROFILE

Nephropathy ☐ 1- Yes ☐ 2- No ☐ 3. Not known

Protocol No.: LIFESTYLE	VISIT 1 (DAY 0) Center Nbr: |__|__|__| Site number: |__|__| Subject Number: |__|__|__|	Page 2 of 8
	Date of Visit: |__|__|/|__|__|__|/|__|__|__|__| DD MON YYYY	

Retinopathy ☐ 1- Yes	☐ 2- No	☐ 3. Not known	(To be assessed by ophtalmologist)
Neuropathy ☐ 1- Yes	☐ 2- No	☐ 3. Not known	(To be assessed using monofilaments)
Diabetic peripheral vascular disease ☐ 1. Yes	☐ 2. No	☐ 3. Not known	
Ischemic heart disease ☐ 1. Yes	☐ 2. No	☐3. Not known	
Previous TIA/Stroke ☐ 1. Yes	☐ 2. No	☐3. Not known	

LABORATORY EVALUATIONS				
FBG	**HbA1c**	**Total Cholesterol**	**HDL**	**LDL**
|__|__|__|	|__|__|__|	|__|__|__|	|__|__|__|	|__|__|__|
Triglycerides	**Creatinine**	**Serum Urea**	**MicroAlbumin**	**GFR**
|__|__|__|	|__|__|__|	|__|__|__|	|__|__|__|	|__|__|__|
Urine albumin/creat ratio	**GFR (Cocroft-Gault)**			
|__|__|/|__|__|	|__|__.|__|			

RANDOMISATION		
Group randomised to:	☐ 1- Group A (lifestyle)	☐ 2- Group B (control)

INCLUSION / EXCLUSION CRITERIA REVIEW		
Did the subject meet all eligibility criteria (inclusion and exclusion)?	☐ 1-Yes	☐ 2-No
Is the subject eligible to continue?	☐ 1-Yes	☐ 2-No

If 'NO' was answered to one or both of the above, please specify reason(s) below:

_____

_____

_____

- **If "Is the subject eligible to continue?" is answered "No", please withdraw the patient from the study**

DIETERY / LIFESTYLE HABITS

Average number of meals per day |__|__|

Source of meals (please ☑ one):
☐ 1. Bought in market

☐ 2. Own ground/field

☐ 3. Both market &own ground

☐ 4. Other (Specify)

Who prepares the food at home?

☐ Self (lui-meme)
☐ Spouse
☐ House maid
☐ Other (Specify)

How many times do you eat green fruits/vegetables per week: |__|__|

How often do you eat in a restaurant per week: |__|__|

How often do you add salt in your meal at the table: |__|__|

What kind of physical exercise do you do (Please ☑ all that apply):
☐ Walking
☐ Farming/digging
☐ Fitness (gym-tonic)
☐ Swimming
☐ Sport (foot, volley…)
☐ Other (specify)

Average number of days you actively walk for at least 30 min per week |__|

Average number of days of physical exercise per week: |__|

Overall level of activity (including work, sports etc)	☐ 1- Sedentary ☐ 2. Mild activity	☐ 3- Moderate Activity ☐ 4. Strenuous activity	
Tobacco use	☐ 1- Ever	☐ 2- Never	☐ 3. Current (specify chewing or smoking)
Alcohol use	☐ 1- Ever	☐ 2- Never	☐ 3. Current (Specify volumes)

PHYSICAL EXAMINATION / VITAL SIGNS

Weight kg	Heart Rate bpm	Blood Pressure Systolic/ Diastolic mmHg

|__|__|__| , |__|	|__|__|__|	|__|__|__| / |__|__|__|

- **Should be measured on the non-dominant arm after 5 minutes of supine rest**

LABORATORY EVALUATIONS				
FBG	**HbA1c**	**Total Cholesterol**	**HDL**	**LDL**
|__|__|__|	|__|__|__|	|__|__|__|	|__|__|__|	|__|__|__|
Triglycerides	**Creatinine**	**Serum Urea**	**MicroAlbumin**	
|__|__|__|	|__|__|__|	|__|__|__|	|__|__|__|	

CONCOMITANT MEDICATION
Please specify on the Concomitant Medication form if the subject takes any new medication

ADVERSE EVENTS
Please specify on the Adverse Events form if the subject is experiencing any adverse events.

DIETERY / LIFESTYLE HABITS

Average number of meals per day |__|__|

Source of meals (please ☑ one):
☐ 1. Bought in market

☐ 2. Own ground/field

☐ 3. Both market &own ground

☐ 4. Other (Specify)

Who prepares the food at home?

☐ Self (lui-meme)
☐ Spouse
☐ House maid
☐ Other (Specify)

How many times do you eat green fruits/vegetables per week: |__|__|

How often do you eat in a restaurant per week: |__|__|

How often do you add salt in your meal at the table: |__|__|

What kind of physical exercise do you do (Please ☑ all that apply):
☐ Walking
☐ Farming/digging
☐ Fitness (gym-tonic)
☐ Swimming
☐ Sport (foot, volley…)
☐ Other (specify)

Average number of days you actively walk for at least 30 min per week |__|

Average number of days of physical exercise per week: |__|

Overall level of activity (including work, sports etc)	☐ 1- Sedentary ☐ 2. Mild activity	☐ 3- Moderate Activity ☐ 4. Strenuous activity
Tobacco use	☐ 1- Ever	☐ 2- Never ☐ 3. Current (specify chewing or smoking)
Alcohol use	☐ 1- Ever	☐ 2- Never ☐ 3. Current (Specify volumes)

PHYSICAL EXAMINATION / VITAL SIGNS

Weight kg	Heart Rate bpm	Blood Pressure Systolic/ Diastolic mmHg

|__|__|__| , |__|	|__|__|__|	|__|__|__| / |__|__|__|

- **Should be measured on the non-dominant arm after 5 minutes of supine rest**

LABORATORY EVALUATIONS				
FBG	**HbA1c**	**Total Cholesterol**	**HDL**	**LDL**
|__|__|__|	|__|__|__|	|__|__|__|	|__|__|__|	|__|__|__|
Triglycerides	**Creatinine**	**Serum Urea**	**MicroAlbumin**	
|__|__|__|	|__|__|__|	|__|__|__|	|__|__|__|	

CONCOMITANT MEDICATION
Please specify on the Concomitant Medication form if the subject takes any new medication

ADVERSE EVENTS
Please specify on the Adverse Events form if the subject is experiencing any adverse events.

DIETERY / LIFESTYLE HABITS

Average number of meals per day |__|__|

Source of meals (please ☑ one):
☐ 1. Bought in market

☐ 2. Own ground/field

☐ 3. Both market &own ground

☐ 4. Other (Specify)

Who prepares the food at home?

☐ Self (lui-meme)
☐ Spouse
☐ House maid
☐ Other (Specify)

How many times do you eat green fruits/vegetables per week: |__|__|

How often do you eat in a restaurant per week: |__|__|

How often do you add salt in your meal at the table: |__|__|

What kind of physical exercise do you do (Please ☑ all that apply):
☐ Walking
☐ Farming/digging
☐ Fitness (gym-tonic)
☐ Swimming
☐ Sport (foot, volley…)
☐ Other (specify)

Average number of days you actively walk for at least 30 min per week |__|

Average number of days of physical exercise per week: |__|

Overall level of activity (including work, sports etc)	☐ 1- Sedentary ☐ 2. Mild activity	☐ 3- Moderate Activity ☐ 4. Strenuous activity	
Tobacco use	☐ 1- Ever	☐ 2- Never	☐ 3. Current (specify chewing or smoking)
Alcohol use	☐ 1- Ever	☐ 2- Never	☐ 3. Current (Specify volumes)

PHYSICAL EXAMINATION / VITAL SIGNS

Weight kg	Heart Rate bpm	Blood Pressure Systolic/ Diastolic mmHg

|__|__|__| , |__|	|__|__|__|	|__|__|__| / |__|__|__|

- **Should be measured on the non-dominant arm after 5 minutes of supine rest**

LABORATORY EVALUATIONS				
FBG	**HbA1c**	**Total Cholesterol**	**HDL**	**LDL**
|__|__|__|	|__|__|__|	|__|__|__|	|__|__|__|	|__|__|__|
Triglycerides	**Creatinine**	**Serum Urea**	**MicroAlbumin**	
|__|__|__|	|__|__|__|	|__|__|__|	|__|__|__|	

CONCOMITANT MEDICATION
Please specify on the Concomitant Medication form if the subject takes any new medication

ADVERSE EVENTS
Please specify on the Adverse Events form if the subject is experiencing any adverse events.

DIETERY / LIFESTYLE HABITS

Average number of meals per day |__|__|

Source of meals (please ☑ one):
☐ 1. Bought in market

☐ 2. Own ground/field

☐ 3. Both market &own ground

☐ 4. Other (Specify)

Who prepares the food at home?

☐ Self (lui-meme)
☐ Spouse
☐ House maid
☐ Other (Specify)

How many times do you eat green fruits/vegetables per week: |__|__|

How often do you eat in a restaurant per week: |__|__|

How often do you add salt in your meal at the table: |__|__|

What kind of physical exercise do you do (Please ☑ all that apply):
☐ Walking
☐ Farming/digging
☐ Fitness (gym-tonic)
☐ Swimming
☐ Sport (foot, volley…)
☐ Other (specify)

Average number of days you actively walk for at least 30 min per week |__|

Average number of days of physical exercise per week: |__|

Overall level of activity (including work, sports etc)	☐ 1- Sedentary ☐ 2. Mild activity	☐ 3- Moderate Activity ☐ 4. Strenuous activity	
Tobacco use	☐ 1- Ever	☐ 2- Never	☐ 3. Current (specify chewing or smoking)
Alcohol use	☐ 1- Ever	☐ 2- Never	☐ 3. Current (Specify volumes)

PHYSICAL EXAMINATION / VITAL SIGNS

Weight kg	Heart Rate bpm	Blood Pressure Systolic/ Diastolic mmHg

|__|__|__| , |__|	|__|__|__|	|__|__|__| / |__|__|__|

- **Should be measured on the non-dominant arm after 5 minutes of supine rest**

LABORATORY EVALUATIONS				
FBG	**HbA1c**	**Total Cholesterol**	**HDL**	**LDL**
|__|__|__|	|__|__|__|	|__|__|__|	|__|__|__|	|__|__|__|
Triglycerides	**Creatinine**	**Serum Urea**	**MicroAlbumin**	
|__|__|__|	|__|__|__|	|__|__|__|	|__|__|__|	

CONCOMITANT MEDICATION
Please specify on the Concomitant Medication form if the subject takes any new medication

ADVERSE EVENTS
Please specify on the Adverse Events form if the subject is experiencing any adverse events.

Protocol No.: LIFESTYLE	CONCOMITANT MEDICATION	Center Nbr: |__|__|__|	Site number: |__|__|	Subject Num |__|__

Were there any Concomitant Medications? ☐ 1-Yes

All ongoing Medication taken by the patient at study entry and throughout the study is to be recorded on the Concomitant Medication log

Medication Trade/Generic Name	**Route**	**Start and stop date** (DD/MON/YYYY)	**Ongoing**	**Dose**
		Start: |__|__|/|__|__|__|/|__|__|__|__| **Stop:** |__|__|/|__|__|__|/|__|__|__|__|	☐ 1	
		Start: |__|__|/|__|__|__|/|__|__|__|__| **Stop:** |__|__|/|__|__|__|/|__|__|__|__|	☐ 1	
		Start: |__|__|/|__|__|__|/|__|__|__|__| **Stop:** |__|__|/|__|__|__|/|__|__|__|__|	☐ 1	
		Start: |__|__|/|__|__|__|/|__|__|__|__| **Stop:** |__|__|/|__|__|__|/|__|__|__|__|	☐ 1	
		Start: |__|__|/|__|__|__|/|__|__|__|__| **Stop:** |__|__|/|__|__|__|/|__|__|__|__|	☐ 1	
		Start: |__|__|/|__|__|__|/|__|__|__|__| **Stop:** |__|__|/|__|__|__|/|__|__|__|__|	☐ 1	
		Start: |__|__|/|__|__|__|/|__|__|__|__| **Stop:** |__|__|/|__|__|__|/|__|__|__|__|	☐ 1	

Route: For example: Oral, Subcutaneous, Intramuscular, Intravenous, Rectal, Topical, Nasal, Inhaled, Transdermal, Ocular, Other, etc.

Dose Unit: For example: mg, ml, gr, other, etc. **Frequency:** For example: Daily, BID,

Appendix 2. Consent form (English version)

CONSENT FORM

Date: Valid for Use Through:

Study Title: EFFECTS OF LIFESTYLE EDUCATION PROGRAMS ON DIABETES CONTROL AMONG DIABETIC PATIENTS IN RWANDA

You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

This study plans to learn more about the effects of lifestyle education program on diabetes control among people with diabetes.

You are being asked to be in this research study because you are one of people living with diabetes serviced by/at CHUK Diabetes clinic.

Other people in this study

Other people living with diabetes aged 18 and above who are or have possibility to be followed up at CHUK.

What happens if I join this study?

If you join the study, you will be asked to complete a survey about some demographic information, lifestyle habits including what you eat, whether you smoke, whether you drink alcohol, and how much physical activity you get. A member of the research team will also measure your blood pressure, weight, height, wrist circumference and check your blood sugar, glycated hemoglobin, urinalysis, Renal function tests and lipid levels. These biological parameters however, together with a clinical examination, will be collected every three months for a year.

After baseline data collection, you will be randomly assigned to an interventional group (a group that will, besides the standard care delivered at CHUK, meet lifestyle educators every month for a 30 min group counselling for a year), or to a control group that will continue receiving the standard care of diabetes delivered at CHUK Diabetes clinic. The comparison of clinical and biological parameters will help researchers to estimate the impact of using lifestyle education programs in the management of diabetes in our settings, and hence to improve the quality of care of all diabetic patients.

What are the possible discomforts or risks?

Discomforts you may experience while in this study include the time it will require to complete the survey and screening and discomfort from drawing a small amount of blood from your arm with a small needle. Nevertheless, the research team will organize meeting with research subjects on their usual scheduled appointments at CHUK.

What are the possible benefits of the study?

This study is designed for the researchers to learn more about the effects of lifestyle education programs using group counselling in diabetes care. Globally, the results will be applied on diabetic people followed up in Rwanda and elsewhere in order to better control diabetes.

As a participant in this study you will be regularly and strictly followed up for a year. It is expected that your glycemic profile will be stabilized with this kind of strict control and follow up. The results of the study will be used to make recommendations about what medical information and resources should be developed and made available for health personnel working on diabetes control in Africa and worldwide.

Who is paying for this study?

This research is being supported by SANOFI Aventis and Kigali University Teaching Hospital.

Will I be paid for being in the study?

You will not be paid to be in the present study.

Will I have to pay for anything?

It will not cost you anything to be in the study, other than what you normally pay for your usual diabetes care. However, glycated hemoglobin measurements will be paid for you by the study.

Is my participation at my own will?

Taking part in this study is entirely voluntary and at your own will. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

Who do I call if I have questions?

The principal researchers carrying out this study are Dr. Etienne Amendezo and Dr Charlotte Bavuma. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Dr. Etienne Amendezo at 250-788-858-756 or Dr Charlotte Bavuma at 250-788-767-352. You will be given a copy of this form to keep.

You can also call the CHUK research commission chair and/or v/chair persons Dr Stephen Rulisa at +250-788-571-436 and Dr Olivier Manzi at 250-788-734-849 if you have any question concerning ethics or your rights.

How will be used information obtained from you?

The research team will try the best to keep all information about you confidential. Only the research team will be allowed to use the information obtained from you. Your names will not be presented in any of the reports that will be produced from the compilation of all information obtained from study subjects.

Agreement to be in this study

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I know that being in this study is at my own will. Signing below is a confirmatory sign that I choose to be in this study. I will get a copy of this consent form.

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name: _____

Appendix 3. Consent form (Kinyarwanda version)

INYANDIKO ISOBANURA UBUSHAKASHATSI ISHYIRWAHO UMUKONO N'UWEMERA KUGIRA URUHARE MU BUSHAKASHATSI

Itariki:

Inyito y'ubushakashatsi:

« URUHARE RWO KWIGISHA BYIMBITSE IMIBEREHO, IMIRIRE N'IMYITOZO NGORORANGINGO MU KUNOZA IBIPIMO BYA DIYABETE »

Uhamagariwe kugira uruhare muri ubu bushakashatsi. Iyi nyandiko irasobanura ibyerekeye ubu bushakashatsi. Umwe mu itsinda ry'abakora ubu bushakashatsi aragusobanurira uko ubu bushakashatsi bukorwa kandi asubize ibibazo byose waba ufite, byerekeranye n'ubu bushakashatsi. Urasabwa gusoma ibisobanuro bikubiye muri iyi nyandiko, hanyuma ukabaza ibyo wumva udasobanukiwe, mbere yo gufata icyemezo cyo kugira uruhare muri ubu bushakashatsi.

Impamvu y'ubu bushakashatsi

Ubu bushakashatsi bugamije gushyira ahagaragara uruhare rwo kwigisha imibereho (lifestyle) y'umurwayi wa diyabete mu gukurikirana neza indwara ya diyabete.

Uhamagariwe kugira uruhare muri ubu bushakashatsi kuko uri umwe mu barwayi ba diyabete bakurikiranirwa mu bitaro bikuru bya Kigali CHUK.

Abandi bantu bazagira uruhare muri ubu bushakashatsi

Abandi bantu bazitabira ubu bushakashatsi ni abarwayi ba diyabete bafite nibura imyaka 18 kujyana hejuru kandi bashobora gukurikiranirwa mu bitaro bikuru bya Kigali CHUK.

Bizagenda bite ninemera kugira uruhare muri ubu bushakashatsi?

Niwinjira muri ubu bushakashatsi, uzabazwa amakuru ajyane n'imibereho yawe, imirire, niba unywa itabi cyangwa inzoga, ndetse n'ibyerekeye gukora imyitozo ngororamubiri (siporo).

Umwe mu bagize itsinda ry'abashakashatsi kandi azapima umuvuduko w'amaraso, ibiro, uburebure, umuzenguruko w'inda ndetse afate n'ibizamini by'amaraso n'inkari. Icyakora ibizamini by'amaraso n'inkari bizagenda bifatwa buri mezi atatu kugeza umwaka ushize.

Nyuma yo gufata ibipimo by'ibanze, abitabira ubushakashatsi bazashyirwa mu matsinda abiri hakoreshejwe uburyo bwa tombola.

Itsinda rimwe rizabamo abantu bazakomeza gukurikiranwa n'abaganga ku byerekeye diyabete uko bisanzwe, ariko bakazanajya bahura n'abigisha ibyerekeye imibereho n'imyifatire y'abarwayi ba

diyabete buri kwezi mu gihe cy'umwaka. Ibi bikazajya bikorwa mu biganiro mu matsinda bizajya bimara iminota mirongo itatu kandi bikabera ku munsi n'ubundi wo kubonaniraho na muganga.

Itsinda rindi rizabamo abantu bazakomeza gukurikiranwa n'abaganga ku byerekeye diyabete nk'uko bisanzwe.

Nyuma y'ubushakashatsi, kugereranya ibipimo by'amatsinda yombi bizafasha abashakashatsi kugereranya uruhare rw'inyigisho mu matsinda mu gukurikirana neza indwara ya diyabete, bityo bizanafashe mu gushyiraho gahunda zihamye zo gufasha abarwayi ba diyabete mu Rwanda no mu mahanga.

Ni izihe mbogamizi zishoboka?

Imbogamizi uwitabira ubushakashatsi ashobora guhura nazo mu gihe ari muri ubu bushakashatsi ni izijyanye n'ububababre buto bw'urushinge mu gihe atanga amaraso y'ibipimo bizakorwa.

Abagize itsinda ry'abashakashatsi bazakora ibishoboka byose kugira ngo abitabira ubushakashatsi bazaze ku minsi basanzwe babonaniraho n'abaganga babakurikirana mu bitaro bikuru bya Kigali CHUK.

Ni izihe nyungu zo kwitabira ubu bushakashatsi?

Ubu bushakashatsi bugamije gufasha abaganga kumenya uruhare rwo kwigisha imibereho y'abarwayi ba diyabete hakoreshejwe inyigisho mu matsinda. Muri rusange, ibizava muri ubu bushakashatsi bizafasha mu kurushaho gukurikirana abarwayi ba diyabete mu Rwanda ndetse no mu mahanga.

Uwitabira ubu bushakashatsi azakurikiranwa buri kwezi mu gihe cy'umwaka. Hateganijwe ko igipimo cy'isukari cye kizajya mu buryo bukwiye. Ibizava muri ubu bushakashatsi bizakoreshwa kandi mu gutanga amakuru ku buryo abakozi bo mu rwego rw'ubuzima bajya bavura indwara ya diayabete muri Afurika no ku isi hose.

Ni nde utera inkunga ubu bushakashatsi?

Ubu bushakashatsi buraterwa inkunga iturutse mu kigo cya SANOFI Aventis ndetse no mu bitaro bikuru hya Kigali CHUK.

Haba hari igihembo ku muntu uzemera kugira uruhare muri ubu bushakashatsi?

Oya, nta gihembo giteganyijwe.

Ese hari icyo ngomba kwishyura ngo nemererwe kwitabira ubu bushakashatsi?

Nta kintu na kimwe uzishyura kugira ngo ugire uruhare muri ubu bushakashatsi, uretse ibyo usanzwe wishyura mu gukurikiranwa ku ndwara ya diyabete. Icyakora ibipimo uzakorerwa birebana n'uko isukari yari imeze mu mezi atatu ashize (hemoglobine glyqué) bizishyurwa n'ubushakashatsi.

Ese kugira uruhare muri ubu bushakashatsi ni ubushake bwawe?

Kugira uruhare muri ubu bushakashatsi ni ubushake bwawe busesuye. Ufite uburenganzira bwo guhitamo kutitabira ubu bushakashatsi. Uhisemo kwitabira, ufite n'uburenganzira bwo guhagarika

igihe cyose ushakiye. Uramutse uhisemo kutitabira cyangwa guhagarika, ntabwo uzatakaza uburenganzira bwawe ku buryo wari usanzwe ukurikiranwamo.

Ni bande nahamagara ndamutse ngize ikibazo?

Abashakashatsi bakuru b'ubu bushakashatsi ni Dr Etienne Amendezo na Dr Charlotte Bavuma.

Ushobora kubaza ibibazo ufite none aha; ariko uramutse ugize ikibazo nyuma, ushobora guhamagara Dr Etienne Amendezo kuri 250-788-858-756 cyangwa Dr Charlotte Bavuma kuri 250-788-767-352. Urahabwa kopi y'iyi nyandiko.

Ushobora kandi guhamagara abakuriye komisiyo y'ubushakashatsi muri CHUK aribo Dr Stephen Rulisa 250-788-571-436 cyangwa Dr Olivier Manzi 250-788-734-849, uramutse ugize ikibazo ku byerekeranye n'uburenganzira bwawe nk'uwitabira ubushakashatsi.

Ni gute amakuru aturutse ku bizamini ukorerwa azakoreshwa?

Abashakashatsi bazakora ibishoboka ngo amakuru akwerekeyeho agume ari ibanga. Uretse itsinda ry'abashakashatsi, nta wundi muntu uzemererwa gukoresha amakuru akwerekeyeho. Amazina yawe nta na hamwe azagaragara mu ma roporo azakorwa nyuma yo gushyira hamwe amakuru azaturuka ku bitabiririye ubu bushakashatsi bose.

Kwemera kugira uruhare mu bushakashatsi

Nasomye cyangwa nasomewe ibikubiye muri iyi nyandiko.

Ndumva neza inyungu n'imbogamizi ziri muri ubu bushakashatsi.

Numvise neza ko kwitabira ubu bushakashatsi ari ubushake bwanjye busesuye.

Gushyira umukono kuri iyi nyandiko ni ikimenyetso cyerekana ko nemeye kugira uruhare muri ubu bushakashatsi.

Ndahabwa kopi y'iyi nyandiko

Umukono:_____ Itariki:_____

Amazina :_____

Iyi nyandiko yasobanuwe na:_____ Itariki:_____

Amazina: _____

Appendix 4. List of education topics

Topics for education sessions

1. Natural history of diabetes
    a. What is diabetes?
    b. What causes diabetes?
    c. Is diabetes curable?
    d. What type of diabetes do I have?
    e. How can I help myself?
        i. Diet
        ii. Physical exercise
        iii. Behavior change
    f. What resources are available at KUTH to help me and my family deal with my disease and how can I access them?
    g. Discussion Groups: Topic: Meet your group and exchange information if you want. Tell about each other and maybe discuss the history of your disease and what you think are the biggest barriers to improvement or biggest concerns about your disease.
2. Complications
    a. Reinforce day 1
    b. Diabetes complications
        i. Hypoglycemia and it's treatment
            1. Educating the patient and family about sudden low blood sugars.
        ii. Eye disease
            1. When to get a fundoscopy exam
        iii. Heart Disease
            1. Aspirin therapy
            2. Cholesterol evaluation
        iv. Kidney disease
        v. Feet care
            1. Teach home foot care techniques
            2. Warning signs of ulcer or damage
        vi. What can the patient do to prevent disease?
        vii. What is the doctor's job in your care? What to expect from your doctor.
    c. Group discussions: Don't take no for an answer: What you expect from your doctor. Spend some time discussing any fears you have about your disease with your group.
3. Diabetes medications
    a. Reinforce diet and exercise
    b. Importance of taking medications as directed
    c. Importance of being responsible for your own medications.
        i. Ask questions about your medications
    d. Types of diabetes medications
    e. Proper use of insulin
    f. Group discussions: Talk about how your last glyco hemoglobin and what that means to you. Help each other by offering encouragement and share an idea of how others can learn from what you do.
4. Importance of getting regular check ups
    a. Reinforce diet and exercise
    b. Why should I come to the doctor so often?
    c. When will my doctor let me come less often?
    d. What can I do to help myself between visits?
    e. What happens at each visit?

f. Group discussion: spend some time talking about problems at home that keep you from taking your meds or keep you from coming to your visits. How can the group encourage those who are struggling?

5. CV risk factors
   a. Revisit diet and exercise and this time discuss how these can reduce risk for heart disease?
   b. How can lowering my HbA1c improve my heart health?
   c. Aspirin
   d. Checking cholesterol and taking cholesterol medications.
   e. Group discussions
6. Sick day plan: What happens to a diabetic when they get sick?
7. Diet and diabetes:
   - What to eat and what to not eat.
   - What resources are available to help me and my family deal with my disease and how can I access them?
   - Sharing experiences
8. Physical exercise and diabetes:
   - What are the benefits? What are the risks
   - How do I prepare for a physical exercise session/what are the precautions?
   - Sharing experiences
9. Behavior change
   - How to "better" live with diabetes?
   - How to cope with stress?
   - Sick day plan
   - How a diabetic can cope with stressful live events, e.g. in periods of loss of a relative, travelling, pregnancy, etc…
   - Sharing experiences
10. Questions/discussion session (particularly on medications in diabetes).
    - The role of lifestyle change, Insulins, oral hypoglycemiants, other approaches?
    - The importance of regular medical follow up
    - How to know and how to manage hypoglycemia
    - Discuss any more personal fears about the disease
    - Re-emphasize education on diet and physical exercise.
    - Sharing experiences
11. Group self-assessment.
    - How participants benefited from education sessions.
    - What are the key messages taken from the education sessions
    - What are the points that were not discussed and that participants would like to add in the package
12. All the members of the group (participants, educators) write a summary of all the sessions
    - Conclusions, recommendations and future plans.

Appendix 5. Education brochure

Kumenya gutandukanya igihe isukari yabaye nyinshi cyangwa nkeya mu maraso.

-Gukora imyitozo ngorora mubiri.

-Gukurikiza no kubahiriza inama z'abaganga n'abashinzwe imirire iboneye.
-Gufata imiti uko iteganyijwe.

6. Ni ryari diyabete itera ibibazo?

Umurwayi wa diyabete ahura n'indwara z'ibyuririzi bitandukanye iyo isukari mu maraso ihindagurika, yabaye nyinshi cyangwa nkeya cyane.

Diyabete yanjye

Kuki mbana n'uburwayi bwa diyabete?

Abantu benshi babana na diyabete bagira inkomoko yayo mu miryango yabo.

1. Diyabete ni iki?

Ni indwara iterwa ni uko urwagashya rw'umuntu ruba rutakivubura umusemburo wa "insuline" cyangwa se ruvubura udahagije, bityo umubiri ntubashe gukoresha neza isukari ikomoka mu mafunguro ya buri munsi.

2. Diyabete iterwa ni iki?

Diyabete iterwa ni ibi bikurikira:
- Umurage cyangwa uruherere kane mu muryango
- Umubyibuho ukabije
- Gusaza

- Gukora akazi gatuma uhora ahantu hamwe(Kutanyeganyega)
- Imibereho imwe n'imwe (Inzoga cyangwa itabi bikabije, imihangayiko…)
- Ibinure byinshi mu maraso
- Indwara zimwe na zimwe(umuvuduko w'amaraso ukabije…)

3. Wabana ute na diyabete?

Umurwayi wa Diyabete agomba kwita kuri ibi bikurikira :
- Kumenya ubwuzuzanye bw'imiti n'imirire iboneye igihe cyose, akirinda guhindura cyangwa guhagarika imiti atabibwiwe na Muganga, cyangwa ngo arye ibyo yishakiye atagishije inama abashinzwe imirire iboneye.

4. Ni ayahe moko ya diyabete akunze kubaho?

Diyabete yo mu bwoko bwa mbere

Iboneka igihe isukari yiyongera cyane mu maraso kuko urwagashya rutakibasha gukora umusemburo wa insuline. Akenshi ikunda kugaragara ku bantu bakiri bato bafite imyaka mike.

Diyabete yo mu bwoko bwa kabiri

Muri ubu bwoko, umubiri uba ufite umusemburo wa insuline; icyo gihe urwagashya rushobora gukora umusemburo uhagije cyangwa se udahagije ariko umubiri ntubashe kuwukoresha neza uko bikwiye.
Iyi diyabete ikunda gufata akenshi abantu bakuze cyangwa bafite umubyibuho ukabije.

5. Wakwifasha ute urwaye diyabete?

Umurwayi wa diyabete agomba :
- Kumenya ko ibiro bye bijyanye n'uburebure kandi akirinda umubyibuho ukabije.

-Gufata indyo yuzuye: igaburo ririmo ibitera imbaraga, ibyubaka umubiri, ibirinda indwara ariko bikaba byingajemwo imboga rwatsi, n'amazi.
-Abafite umubyibuho ukabije birinda ibinyamavuta.

Gufata indyo yuzuye ukayihuza n'imiti, n'ibyo umubiri ukeneye nibyo binoza ibipimo by'isukari mu maraso.