EFFECT OF A NUTRITION EDUCATION PROGRAMME ON THE MANAGEMENT OF METABOLIC SYNDROME BY PATIENTS WITH TYPE 2 DIABETES MELLITUS ATTENDING CARE AT THIKA LEVEL 5 HOSPITAL, KENYA

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Effect of a Nutrition Education Programme on the Management of Metabolic Syndrome by Patients with Type 2 Diabetes Mellitus Attending Care at Thika Level 5 Hospital, Kenya

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DECLARATION

This thesis is my original work and has not been presented for a degree in any other university.

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DEDICATION

To, my husband Samuel Wambugu Ndiritu, My children Simon Mark Ndiritu, Joseph Thuita, Veronica Wanjiku, my parents Joseph Thuita Kibacio and Jacinta Gathoni Thuita and all Type 2 Diabetes Mellitus patients.

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LIST OF ABBREVIATIONS AND ACRONYMS

AACE	American Association of Clinical Endocrinologists
ACE	American College of Endocrinology
ADA	American Diabetes Association
ADDRF	Africa Doctoral Dissertation Research Fellowship
AGE	Advanced Glycation End products
AIDS	Acquired Immune Deficiency Syndrome
ANCOVA	Analysis of co-variance
APHRC	Africa Population and Health Research Center
BMI	Body Mass Index
BP	Blood pressure
CCF	Congestive Cardiac Failure
CDC	Centre for Disease Control
CHOD/POD	Cholesterol Oxidase Peroxidase
CI	Confidence Interval
CVD	Cardiovascular Disease
DALYS	Disability Adjusted Life Years
DCC	Diabetes Comprehensive Care Centre
DM	Diabetes Mellitus
DMI	Diabetes Mellitus Information
EQA	External Quality Assurance
FBG	Fasting Blood Glucose
FFA	Free Fatty Acids
FFSM	Face to Face Self-Management
FHD	Family History of Diabetes
GI	Glycemic Index
GOK	Government of Kenya
GPO/POD	Glycerol Phosphate Oxidase Peroxidase
Hb1Ac	Glycated Hemoglobin
HDL-c	High Density Lipoprotein cholesterol
HH	House Hold
HIV	Human Immun0-deficiency Virus

HPLC	High Performance Liquid Chromatography
HQAS	Human Quality Assessment Services
IDF	International Diabetes Federation
IDRC	International Development Research Centre
IFG	Impaired Fasting Glucose
IQA	Internal Quality Assurance
IPT	Integral Proficiency Test
KNH-UoN ERC	Kenyatta National Hospital –University of Nairobi Ethical Research Committee
LDL-C	Low Density Lipoprotein
MDG	Millennium Development Goal
MET	Metabolic Equivalent
MoPHS	Ministry of Public Health and Sanitation
MNT	Medical Nutrition Therapy
MUFAs	Monounsaturated Fatty Acids
NACOSTI	National Commission for Science Technology and Innovation
NCEP-ATP	National Cholesterol Education Programme Adult Treatment Panel
NE	Nutrition education group
NEP	Nutrition education peer to peer support group
NT	Nutrition Therapy
OR	Odds ratio
PA	Physical activity levels
PAL	Peer Assisted Learning
PC	Peer Coach
SD	Standard Deviation
SPSS	Statistical Package for Social Sciences
TC	Total Cholesterol
TG	Triglyceride
TL5H	Thika Level 5 Hospital
WC	Waist circumference
WDF	World Diabetes Federation

WHO	World Health Organization
WHR	Waist Hip Ratio
YLWD	Years lived with Type 2 Diabetes Mellitus

DEFINITION OF TERMS

Diabetes Mellitus A group of metabolic diseases characterized by high levels of blood glucose (hyperglycemia) resulting from defects in insulin production, insulin action, or both. The management practices by diabetes patient are to keep blood glucose near normal through inclusion of hypoglycemic drugs, appropriate dietary patterns and physical activity (ADA, 2016).

Blood Glucose The main sugar found in the blood and the body's main source of energy. It is influenced by socio demographic factors and lipid profile. Other contributing variables are nutrition status (BMI), waist hip ratio, waist circumference and duration of Type 2 Diabetes Mellitus.

Glycated Hemoglobin (Hb1Ac) This is the measure of glycated hemoglobin in the blood over the previous two to three months. Normal level is less than 7%. A treatment goal for diabetics is less than 7%. (ADA, 2016)

Lipid Profile The levels of various types of lipids in a person's blood. The profile includes concentrations of low-density lipoprotein (LDL or LDL-C also known as "bad" cholesterol), high-density lipoprotein (HDL or HDL-C also known as "good" cholesterol), triglycerides and total cholesterol (the sum of LDL and HDL in the blood). In the current study cut of levels recommended by American Diabetes Association; ADA (ADA, 2018, 2019) and American Association of Clinical Endocrinologists and American College Of Endocrinology (AACE-ACE) (AACE & ACE, 2017) were used.

Physical activity This is defined as any form of exercise an individual may be involved in formally or informally (WHO, 2010b)

Social demographic factors This refers to individuals' education level, occupation levels, age, and gender. These factors have been shown to be related

to diabetes (Borah & Goswami, 2017; Gohel et al., 2012; Pedra et al., 2014).

Type 1 Diabetes Mellitus

This is a form of diabetes that usually strikes children and young adults, although the disease onset can occur at any age. It develops when the body's immune system destroys pancreatic beta cells that produce the hormone insulin that regulates the level of blood glucose. Type 1 Diabetes Mellitus accounts for approximately 5-10% of all diagnosed diabetics. This type of diabetes requires insulin therapy (ADA; American Diabetes Association, 2016; IDF; International Diabetes Federation, 2015).

Type 2 Diabetes Mellitus

This is a form of diabetes that is characterized by variable beta cell (insulin deficiency) and peripheral resistance. Type 2 Diabetes Mellitus accounts for about 90% to 95% of all diagnosed cases of diabetes (ADA, 2016; IDF, 2015).

Metabolic syndrome

Metabolic syndrome in the study was defined according to the definition of "Harmonizing the Metabolic Syndrome" (Alberti et al., 2009) and WHO (1998). The earlier requires i.e., the presence of at least two of the following four components: central obesity for Africans (waist circumference ≥90 cm in males and ≥80 cm in females), elevated triglycerides (≥1.7 mmol/l and/or the use of triglyceride-lowering drugs), reduced HDL cholesterol (<1.03 mmo/l in males and <1.3 mmol/l in females) and elevated blood pressure (systolic blood pressure ≥130 mmHg and/or diastolic blood pressure ≥85 mmHg and/or the use of antihypertensive drugs). This criteria requires the presence of Diabetes Mellitus, impaired glucose tolerance or insulin resistance, and any two of the following: (1) body mass index (BMI) ≥ 30 kg/m2 and/or waist-to-hip ratio >0.90 (male), >0.85 (female); (2) blood pressure ≥140/ ≥90 mmHg

	or on hypertension medication; and (3) triglyceride ≥ 1.7 mmol/L and/or HDL-C < 0.91 mmol/L (male), <1.01 mmol/L (female).
Adherence	Adherence has been defined as the "active, voluntary, and collaborative involvement of the patient in a mutually acceptable course of behavior to produce a therapeutic result (WHO , 2003). In this study adherence refers to compliance to lifestyle modification in Type 2 Diabetes mellitus patient.

ABSTRACT

Type 2 Diabetes Mellitus (T2DM) is a chronic disorder of global public health concern. Presence of the metabolic syndrome (MetS), a complex clinical disorder characterized by known risk factors, including insulin resistance, obesity, atherogenic dyslipidemia and hypertension, worsens T2DM further. The prevalence of T2DM in Kenya is estimated at 2.2%. Non-adherence to lifestyle modification as well as low knowledge levels of management of T2DM may further worsen the situation. This study aims to test the effectiveness of a nutrition education programme on MetS, knowledge level of management of T2DM, adherence to lifestyle modification (diet and physical activity) and health care cost incurred by T2DM patients. The study was a randomized control clinical trial with one control group (C; n=51) and two intervention groups (i) nutrition education with peer to peer support (NEP; n=51) and (ii) Nutrition education alone (NE; n=51. Analysis of Co-variance and regression were used in the analysis six months' post intervention. At baseline, the overall mean age of participants was 56 years. The prevalence of MetS at baseline was 86.3% as per WHO criteria and 88.2 as per Harmonized criteria. The prevalence of poor glycemic control, as indicated by glycated hemoglobin (HbA1c > 7%) was 77.8%. The MetS prevalence significantly reduced among the NEP (90% to 52%) and NE groups (86% to 69%), while it worsened in C (88% to 91%) post intervention. Changes in the anthropometric and metabolic indicators mirrored the changes in food intake patterns and physical activity, where the greatest improvements occurred in the NEP group, followed by the NE, with the control group having the least improvements. An adherence rate of below 15% in diet adherence and below 50 % in physical activity level was reported at baseline. Changes in mean dietary adherence score were significant post intervention with NEP registering highest improvement (+32.37%) followed by NE (+19.92%) while the least improvement was observed in the C group (+9.99%). Knowledge score improved significantly ($p<0.01$) post intervention in the NEP; +42.45% at the end of the intervention, +40.00% at 1month post intervention, +34.53% at 3 months post intervention and +36.68% at 6 months post intervention. The corresponding improvement in the NE was +38.34% at the end of the intervention, +35.37% 1-month post intervention; +31.12% 3 months' post intervention and +33.10% 6 months' post intervention. The current study showed that participants spent an average of Kenya Shillings 4821 per month on care for the management of T2DM. Changes in health care cost incurred by the participants six months' post intervention was not significant. In conclusion, nutrition education in T2DM patients significantly reduced the prevalence of MetS and MetS risk factors, and improved adherence to lifestyle intervention and knowledge level. Peer to peer support in the intervention had a significantly better impact on the outcomes (knowledge score MetS, MetS indicator, adherence to diet and physical activity). There was no significant change in health care cost incurred by the participants due to the intervention in all the groups. Since nutrition education with and without peer to peer support showed positive outcomes, there is need for its adoption by policy makers in management of T2DM.

CHAPTER ONE

INTRODUCTION

1.1 Background information

The burden of diabetes mellitus and other non-communicable diseases is overwhelming globally (WHO; World Health Organization, 2014b, 2016). In fact, diabetes, in particular, has attained a pandemic status because according to estimates, in every 5 seconds someone is diagnosed with diabetes and in every 10 seconds someone dies of it (Coliaguri, 2010).

Diabetes mellitus is a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, action or both causing disturbances in carbohydrates, protein and fat metabolism (ADA; American Diabetes Association, 2014). Diabetes mellitus is classified on the basis of etiology and clinical presentation into; Type 1 Diabetes mellitus (T1DM), Type 2 Diabetes mellitus (T2DM) and Gestational Diabetes (ADA, 2014). Type 1 diabetes mellitus (T1DM) is a result of autoimmune destruction of pancreatic β- cells; leading to insulin deficiency (ADA, 2014). Type 2 diabetes mellitus (T2DM) is the most common affecting over 90% of diabetics (ADA, 2014; IDF, 2015; WHO, 2016). It is caused by the inability of the pancreatic β- cells to produce sufficient amounts of insulin to overcome insulin resistance in peripheral tissues like the adipose tissue, skeletal muscle and the liver established by genetic and environmental factors (ADA, 2014).

Insulin resistance is as a result of a combination of impaired uptake of glucose by the muscle and adipose tissue and reduced suppression of hepatic glucose output in response to insulin (Abel et al., 2013; Samuel & Shulman, 2016). Insulin resistance is the hallmark of T2DM. During the early stages, increased blood glucose (hyperglycemia) characterizes T2DM despite the presence of normal to high insulin concentrations in the blood. During the later stages, T2DM is characterized by low insulin concentrations and this necessitates the use of exogenous insulin due to exhaustion of insulin secretion capacity of pancreatic β- cells (ADA, 2014). Persisting hyperglycemia causes clinical complications such as neuropathy, retinopathy,

nephropathy and cardiovascular disease, increasing morbidity and mortality (Papatheodorou et al., 2016; Tripathi & Srivastava, 2006; Yadav et al., 2008).

Type 2 Diabetes mellitus (T2DM) is a major global public health concern (IDF, 2015; WHO, 2016). Studies indicate that diabetes prevalence is increasing and will continue to do so. It was estimated that 415 million people in the year 2015 had diabetes and this was 8.8% of the world population (IDF, 2015). It is now projected that by 2045 this figure will rise to 642 million people which will be 10.4 % of the world population (IDF, 2017). Most of this increase is speculated to be in developing countries. In fact, Shaw et al., (2010a) reported that between 2010 and 2030, there will be a 69% increase in numbers of adults with diabetes mellitus in the developing world compared with a 20% increase in the developed world. Type 2 diabetes mellitus (T2DM) is diagnosed in people aged 20 years or older (IDF, 2015). Increasingly, however, it is being diagnosed in younger patients as well, as a consequence of the growing incidence of childhood obesity (IDF, 2017).

In Africa in 2010 for instance, the prevalence was 3.8% and projections were made at 4.7% by 2030. And in Sub-Saharan Africa alone, the current prevalence ranges from 1% in rural areas to 6% in urban areas (Assah & Mbanya, 2009; Azevedo & Alla, 2008). But, this prevalence is also varied from country to country with prevalence ranging from 1% in rural Uganda to 12 % in Kenya (Assah & Mbanya, 2009; Azevedo & Alla, 2008). In Kenya, the prevalence was estimated at 3.5% in 2010 and was projected to rise to 3.7% by 2030 (Shaw et al., 2010a) . According to a recent report by the WHO that was published in the Daily Nation of 19th May 2012, Kenya, however, is clearly facing a dramatic increase of lifestyle diseases including obesity and T2DM.

Type 2 diabetes mellitus (T2DM) remains a threat to national development due to its association with longstanding complications like blindness, renal failure and lower limb amputation that are usually very costly to treat (IDF, 2017; WHO, 2016). In addition, a high percentage of undiagnosed diabetes ends up in irreversible medical conditions thus posing a bigger challenge to this burden (IDF, 2015). Type 2 Diabetes mellitus (T2DM) is often associated with obesity, which itself causes insulin resistance

and lead to elevated blood glucose levels. Other risk factors to diabetes include psycho-social stress, unhealthy dietary habits, physical inactivity, increasing age, insulin resistance, family history of diabetes, less than optimum intrauterine environment and ethnicity (Bi et al., 2012; WHO, 2016; Wu et al., 2014). Some of these risk factors like obesity/overweight, consumption of refined carbohydrates, consumption of high fat diets and lack of physical activity due to sedentary lifestyle are modifiable and, if addressed, can reduce the incidence as well as related complications (Bhattacharya & Roy, 2016; Khavandi et al., 2013; Shi, 2016; WHO, 2016). These risk factors for T2DM are also risks to MetS (Alberti et al., 2009).

Metabolic syndrome (MetS) is associated with a 5-fold increase in T2DM and a 3 fold increase in cardiovascular diseases (Alberti et al., 2009; Kaur, 2014a). Studies have reported a prevalence of between 30-70% of metabolic syndrome in T2DM (Hajian-Tilaki et al., 2014; Pokharel et al., 2014; Tamang et al., 2013). Some of the risk factors to MetS includes elevated waist circumference (WC),high triglycerides (TG) decreased high density lipoprotein- cholesterol (HDL-c) and elevated blood pressure (BP) (Alberti et al., 2009; Kaur, 2014a). These are also risk factor associated with T2DM thus escalating the problem further. Poor diet and sedentary lifestyle lead to development of MetS and progression of complication in T2DM patient (Matsuda et al., 2013; Shu-Hung et al., 2016; Ulrichsen et al., 2014). In addition, lack of adherence by patients to diet, physical activity and other lifestyle conditions aggravate the conditions further (T2DM and MetS). Thus, addressing both poor dietary intake and sedentary lifestyle through lifestyle modification is crucial to the management and improvement of quality of life of T2DM patients (Anderson et al., 2015; Bayat et al., 2013; Melchart et al., 2015).

Health care expenditure on Type 2 diabetes mellitus accounts for about USD 727 billion of total health care expenditure in the world and about 80% of countries are predicted to spend between 5% and 13%, of their total healthcare finance on T2DM management (IDF , 2017). The MetS aggravates the large economic burden on individuals, the national healthcare system and economy, which is associated with T2DM. Non- adherence to lifestyle modification also contributes to the burden. Beside increased burden associated with excess health expenditure, T2DM and MetS also

imposes large economic burdens in the form of loss of productivity and foregone economic growth, as a result of reduced earnings due to lost work days, restricted activity days, low productivity at work, increased morbidity and mortality due to complications and permanent disability (Mcbrien et al., 2013; Seuring et al., 2015; Zhuo et al., 2014). Such losses are perhaps relatively larger in low and middle income countries like Kenya due lack of quality health care. These implications due to T2DM as well as metabolic syndrome on individuals and society at large calls for further research in form of preventive and management programs.

Non-adherence to prescribed regimen schedule is a major problem globally, especially in low and middle income countries in particular (Ganiyu et al., 2013; Matsuda et al., 2016; Riaz et al., 2014). Poor adherence to treatment regimens results in major and minor complications and ultimately poor quality of life (Kanauchi & Kanauchi, 2015; Musee et al., 2016; Sharma et al., 2014). Recent epidemiological data from various regions of the world show most patients with diabetes do not achieve the recommended glycemic control at HbA1C < 7% (IDF, 2015; WHO, 2016). Non-adherence could have a major effect on treatment outcomes and direct clinical consequences (Alharbi & Alsubhi, 2016; Ganiyu et al., 2013; Kanauchi & Kanauchi, 2015; Sharma et al., 2014). Besides undesirable impact on clinical outcomes, non-adherence might also cause an increased financial burden for society including excess urgent care visits, hospitalizations and higher treatment costs (Alharbi & Alsubhi, 2016; Saleh et al., 2014; Sharma et al., 2014). Furthermore, there is also a high rate of undetected or unreported therapeutic non-adherence and this increases the cost or complexity of the treatment, thus further increasing the burden on the healthcare system. This underscores the need to intervene in order to improve on adherence to lifestyle modification in T2DM overall treatment regimen.

1.2 Statement of the Problem

Metabolic syndrome (MetS); a cluster of interrelated clinical factors that include insulin resistance, dyslipidemia, excess weight and elevated blood pressure is on the increase with a prevalence of between 50-80% being reported in T2DM patients as well as in the general population (Kengne et al., 2012; Ogbera, 2010; Tamang et al.,

2013; Yadav et al., 2013). These clinical factors to MetS, are also on the increase in T2DM patient. In fact, the presence of MetS in T2DM patients increases the metabolic risks associated with T2DM condition further by 5 folds and 3 folds in cardiovascular diseases (Alberti et al., 2009; Kaur, 2014a; Neill & Driscoll, 2015). Studies indicate that modifiable risk factors such as unhealthy diet and physical inactivity, just to name a few, are similar in T2DM and MetS (Chaudhuri et al., 2016; Shaw et al., 2010b; WHO, 2016). Therefore, reducing these risk factors will have a positive impact on health cost, morbidity, and mortality (Bhattacharya & Roy, 2016; Khavandi et al., 2013; Shi, 2016).

Lifestyle intervention applied using different models has been shown to improve metabolic out come in T2DM as well as MetS in T2DM patients (Mohamed, 2014; Muchiri et al., 2015; Yamaoka & Tango, 2012). However, achieving this has been a key challenge as it has been associated high level of non-adherence as well as lack of inform management on management strategy of T2DM and MetS (Maisharah et al., 2011). Additionally, non-adherence to lifestyle modification in T2DM, as well in MetS is high with a prevalence of between 50-80% (Alharbi & Alsubhi, 2016; Ganiyu et al., 2013; Musee et al., 2016; Saleh et al., 2014). Some of the contributing factors include poor self-management, lack of information, and support among other. Indeed, studies have reported that lack of knowledge is one of the key barriers to diabetes self-care (Odenigbo & Inya-osuu, 2012; Tsou, 2017). Poor knowledge levels on importance of diet and physical activity have been shown as a key factor contributing to low adherence level (Breen, Ryan, Gibney, & Shea, 2017)

Additionally, studies have reported that continued support to diabetes management using different models like peer to peer support, psychological support just to mention a few, is also poor despite its importance in management of T2DM as well as MetS in T2DM. The increased level of non-adherence to lifestyle modification (diet and physical activity) as well as poor knowledge on management of T2DM and MetS has aggregated the condition further due to associated complication leading to increased economic burden.

Therefore, this study aims to test the effectiveness of a nutrition education intervention with inclusion of peer to peer support on knowledge levels of T2DM patients, metabolic syndrome in T2DM patients, adherence to lifestyle modification and health cost incurred by T2DM patients.

1.3 Justification

Type 2 diabetes mellitus (T2DM) is no longer an epidemic that can be ignored. Each new edition of the Diabetes Atlas**,** confirms the fact that diabetes prevalence is increasing and increasing rapidly in every part of the world (IDF, 2009, 2011, 2013, 2015). Type 2 diabetes mellitus (T2DM) imposes a heavy health and economic burden due to its chronic nature, costly complications, and predisposition to premature mortality with presence of MetS, poor knowledge level as well as high prevalence to non-adherence to lifestyle modification increasing the burden further (Saleh et al., 2014; Shankar & Ramya, 2012). At the same time, there is good evidence showing that T2DM can be prevented in many cases, and that there are cost-effective measures for preventing T2DM complications. Therefore, addressing T2DM through lifestyle modification (diet and physical activity) might lead to reduction in disease burden and the overall reduction of morbidity and mortality as well as reduced cost of care (Abdi et al., 2015; Askari et al., Rabiei, & Rastmanesh, 2013; Muchiri et al., 2015; Sayka et al.,2015). Moreover, increasing the effectiveness of adherence to lifestyle interventions might have a far greater impact on the health of the T2DM patients than any improvement in specific medical treatments (Alharbi & Alsubhi, 2016; Sayka et al., 2015) .Thus, introduction of a program on peer to peer support and lifestyle modification with emphasis on adherence may increase its cost-effectiveness significantly and subsequently, improve glycemic control hence reducing diabetes complication (Mohamed, 2014; Muchiri et al., 2015; Orchard et al., 2017).

This study is therefore timely because there is lack of studies done on implementation of available policies in Kenya as well as role of nutrition intervention in management of T2DM (WHO, 2014). The results of the study add to the body of knowledge on the role of nutrition peer to peer support education on T2DM patients. The results of the study may be used by policy makers to formulate preventive measure aimed at

reducing morbidity and mortality due to diabetes. The finding of the study might facilitate informed decision making in management and care of T2DM patients by Thika Level 5 Hospital (TL5H) management as well as Kiambu County Health Committee (KCHC). The study finding might also contribute to the ongoing research efforts on management of T2DM.

1.4 Main objective

The main objective of this study was to determine the effect of nutrition education on management of metabolic syndrome in T2DM patients at Thika Level 5 Hospital.

1.5 Specific objectives

The specific objectives of the study were:

i. Determine the association between T2DM patient characteristics with MetS indicators and glycemic control (HbA1c).
ii. To determine the effect of a nutrition education on knowledge levels (general diabetes management and importance of diet, physical activity and glycemic index on T2DM management) of patient with Type 2 diabetes mellitus.
iii. Evaluate the effect of nutrition education on prevalence of MetS indicators in T2DM patients.
iv. Assess the effect of a nutrition education on adherence to lifestyle modification (diet and physical activity) of patients with T2DM.
v. Assess the effect of nutrition education on health care cost incurred by T2DM patients.

1.6 Research hypothesis

Ho_1 There is no significant association between T2DM patients' characteristics and MetS indicators or Glycemic control (HbA1c).

Ho_2 Nutrition education has no significant effect on knowledge levels (general diabetes management and importance of diet, physical activity and glycemic index on T2DM management) of patients with T2DM.

Ho_3 Nutrition education has no significant effect on the prevalence of MetS indicators among T2DM patients.

Ho_4 Nutrition education has no significant effect on adherence to lifestyle modification (diet and physical activity) among patients with T2DM.

Ho_5 Nutrition education has no significant effect on health care cost incurred by patients with T2DM

1.7 Limitation of the study

The study was conducted among patients aged 20-70 years with T2DM attending care at Diabetes Comprehensive Care Centre (DCC) at Thika Level 5 Hospital (TL5H). The patients attending this clinic are from low- and middle-income brackets hence the study findings can only be generalized to T2DM patients with similar characteristics with study participants.

1.8 Conceptual framework

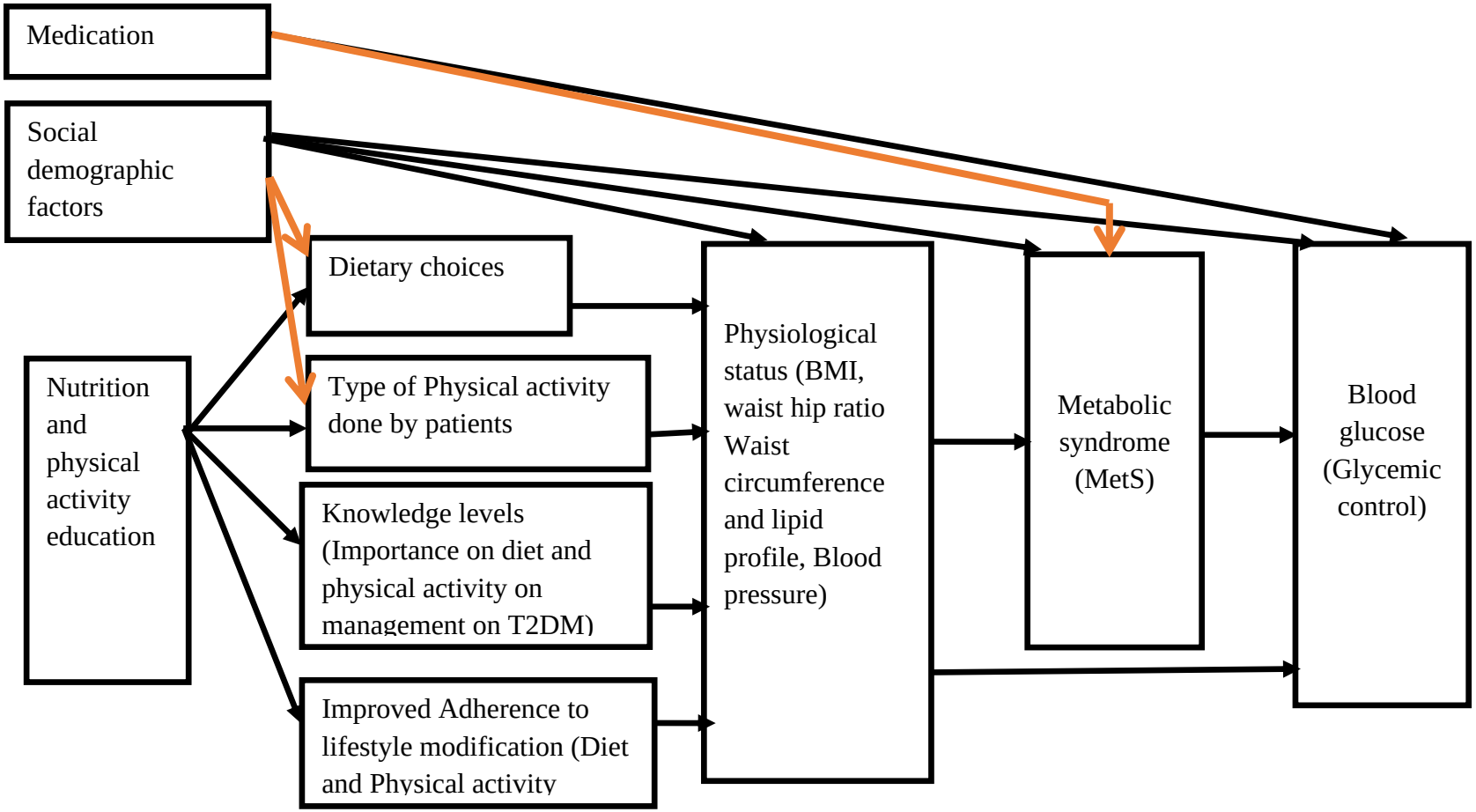

Figure 1. 1: Conceptual Frame work; Modified from Oso & Onen (2009)

The conceptual framework of the study is presented in Figure 1.1. Blood glucose is influenced by physiological status of the body which includes nutrition status, and lipid profile (IDF, 2015). Additionally physical activity and dietary choices influences one's physiological status which overall influences blood glucose level as well as metabolic syndrome status (Polikandrioti & Dokoutsidou, 2009).

Moreover adherence to lifestyle modification influences physical activity levels and dietary choices and, in the long run, physiological status and blood glucose level (Lv et al., 2017). However, poor adherence level to lifestyle (diet and physical activity) have been reported to be a major challenge in T2DM management due to low knowledge levels hence the need for lifestyle education programmes (Ebrahim et al., 2014; Sharma & Agrawal, 2017; Sharma et al., 2014). Such a lifestyle intervention can apply nutrition education with peer to peer support as one of the strategy to address existing gap of poor knowledge levels on importance of diet and physical activity in management of T2DM Other contributing variables that are related to blood glucose levels includes, social demographic indicators (Veghari et al., 2010).

Demographic variables such as age, gender, marital status, educational status and occupation of the head of the family have been reported to influence health-seeking behavior in T2DM patients, which in the long run impact on blood glucose level (Abubakari et al., 2016; Ondicho et al., 2016; Pedra et al., 2014). In addition demographic factors such as ethnic minority, low socioeconomic status, and low levels of education as well as low knowledge level on of T2DM self-care management have been associated with lower regimen adherence to treatment recommendation given to diabetes patients and greater diabetes-related morbidity (Veghari et al., 2010). Finally, social demographic characteristic and adherence to lifestyle modification have also been shown to influence physiological level of the body key components of metabolic syndrome and metabolic syndrome indicators in T2DM patient (Nazaimoon et al., 2011).

CHAPTER TWO

LITERATURE REVIEW

2.1 General introduction

Type 2 Diabetes mellitus (T2DM) is a chronic disorder of public health concern with increasing prevalence each year (IDF, 2015, 2013; WHO, 2016). It is the fourth leading causes of death in most developed countries and studies, also indicates that it is an epidemic in many developing countries including Kenya (IDF, 2015, 2017; WHO, 2016). Worldwide, in 2017, T2DM accounted for 4 million deaths a number higher than mortality caused by HIV/AIDS, tuberculosis and malaria (IDF, 2017). It is a debilitating and costly disease which represents challenges to agreed development goals including the millennium development goals (MDG), yet it is given little attention globally, as well as in individual nation like Kenya (IDF, 2015, 2017; WHO, 2016).

Compared to diseases like HIV and TB, T2DM receives little funding and concern (IDF 2015, 2017). Diabetes costs everyone, not just those with diabetes. However, the largest costs are not on expenditure for diabetes care, they are on mortality, disability, and economic stagnation (IDF, 2015, 2017). Hence wise spending on diabetes will actually reduce medical expenditures. Additionally, in terms of disability –adjusted years of life lost (DALYS) T2DM patient are at 55.6 million globally.

The debilitating effects of diabetes can be attenuated, especially in economically viable individuals between age 20-79 years who are mostly affected by T2DM (IDF, 2015, 2017; MoH, 2015; WHO, 2016). Additionally, poor glycemic control in T2DM is on the increase and has been associated with an increased prevalence of long term complications thus aggravating the condition further (Ceriello, 2009; Van-Dijk et al., 2011). Furthermore, T2DM has worsened further due to the presence of metabolic risk that includes, insulin resistance abdominal obesity and dyslipidemia among others (Catoi, Parvu, Muresan, & Busetto, 2015; Eckel et al., 2011; Vinodmahato et al., 2011). Presence of MetS and MetS risk factors in T2DM is on the increase, and has been associated with increased risk to microvascular and macrovascular

complications, and this even aggravate the condition further. Higher prevalence of >60 % of MetS as well as MetS risk factor have been reported in T2DM patients, with a strong relationship between MetS risk factor being associated with T2DM progression (Pokharel et al., 2014; Tamang et al., 2013;Chung, et al., 2013). This escalating problem due to T2DM as well as associated risks presents a great challenge globally (IDF, 2015, 2017; WHO, 2016).

Type 2 diabetes Mellitus (T2DM), MetS as well as metabolic risk are exacerbated by modifiable factors such as unhealthy diet and physical inactivity. Sedentary lifestyle, urbanization just to mention a few have been associated with an increase in the numbers of people suffering from T2DM and MetS as well as progression to complications during the last decade (Ayah et al., 2013; IDF, 2017; Karekezi et al., 2011; Shaw, Sicree, & Zimmet, 2010). Furthermore, failure by patients to adhere to the total diabetes self-care management, especially therapeutic lifestyle changes like physical activity and health diets among others have been shown as major causes of poor glycemic control as well as increased risk to MetS (IDF, 2015, 2013; WHO; WHO, 2016). Moreover, prolonged years with MetS, MetS risk factor as well as T2DM lead to increased morbidity and mortality. This rise lead to an increase in overall cost of care (IDF, 2015). Studies have shown that T2DM, MetS in T2DM as well as associated risk and complication can be prevented and mortality levels reduced (Adachi et al., 2010; Nilsen et al., 2011; Yamaoka & Tango, 2012). One of the strategy that can be used is use of lifestyle programmes aimed at reducing the risks as well as maintaining good glycemic controls (Azizi et al., 2013; IDF, 2015; Mohamed, 2014). Application of primary prevention aimed at preventing risk factors have shown positive result hence reducing the economic burden associated with T2DM (Askari et al., 2013; Azizi et al., 2013; Mohamed, 2014). It has also been found that strengthening adherence to these preventive measures leads to improved metabolic outcomes as well as quality of life (Islam et al., 2014; Mardani, Shahraki, & Piri, 2010).

2.2 Type 2 Diabetes Mellitus

2.2.1 Overview of T2DM

Type 2 Diabetes Mellitus (T2DM), is on the increase with high prevalence's being reported. Globally it estimated that about 425 million adults (8.8%) aged between 20-79 years had T2DM in 2017, 415 million in 2015 , 387 million in 2014 and 285 million in 2010 (IDF, 2009, 2011, 2013, 2015, 2017). Type 2 Diabetes mellitus (T2DM) is also projected to increase to 642 million by the year 2040, if no interventions are put in place (IDF, 2017). The problem is especially serious in West Pacific that have recorded 159 million cases, followed by South East Asia with 82 million and Africa having registered a prevalence of 15.5 million with a projected increase by 162.5% or 40.7 million cases of T2DM by 2045 (IDF, 2017). This varies from 6.3% in rural areas, to 5.3% in urban areas (IDF, 2017). International Diabetes Federation (IDF) also estimates that the largest proportion and absolute increase in T2DM will occur in developing countries and Kenya is not an exception (IDF, 2017).

In Sub-Saharan Africa, T2DM is becoming a public health concern epidemiologically and economically (IDF, 2015, 2017; WHO, 2016). At the beginning of the 20thcentury, T2DM was rare in Africa, but with the rapid urbanization and change in social life style in the 21stcentury there has been a rise in the disease and its complications (IDF, 2013, 2015, 2017). In Africa 16 million adults had been diagnosed with T2DM by 2017 and the number is expected to rise to 41 million by 2045 (IDF, 2017). This prevalence is apparently low due to the fact that a proper diagnosis is often not made and also many die at home or in an emergency department without a diagnosis (IDF, 2013, 2015, 2017). There is therefore the need to intensify blood glucose test at outpatient clinics and community level to diagnose T2DM early and lay out intervention to reduce morbidity and mortality due to T2DM in Africa and the world at large (IDF, 2017; WHO, 2016). Also to reduce this burden, obstacles to care such as unsettled political situations, inadequate infrastructure, and inadequate health personnel especially in the developing world need to be tackled (IDF, 2015, 2017) Other strategies that include stepwise approach for people living with T2DM, increasing funding to chronic disease docket, if applied can also lead to reduced burden (IDF, 2015, 2017).

In Kenya, the prevalence of T2DM has been reported over the years. According to IDF, in 2011 a prevalence of 3.96% was reported , in 2013 a prevalence of 3.6% and a prevalence of 2.2% in 2015 (IDF, 2011, 2013b, 2015). However, several studies carried either in the rural areas or urban areas have reported varying prevalence. A study by Oti et al (2013) carried in in a slum population Nairobi, Kenya reported a prevalence of 4.8% in women and a prevalence of 4.0% in men. Additionally, another study by Ayah et al (2013) also reported similar prevalence (5.3%) in Nairobi with prevalence increasing as age advances. A study by El-busaidy et al (2014) reported a prevalence of 16% in a rural area in Isiolo, Kenya while another study by Maina et al (2010) reported a prevalence of 8.6% in the rural areas and 13.2% in the urban areas. Diabetes in Kenya has been listed as a major cause of mortality. According to WHO (2014b) 1% of the total death in the country were attributed to Diabetes

2.2.2 Pathophysiology of T2DM and associated risk factors

Type 2 Diabetes Mellitus (T2DM) is a chronic disorder, characterized by hyperglycemia due to insulin insufficiency and insulin resistance (ADA, 2014). It is usually diagnosed with fasting blood glucose of 6.1 mmol/l. Type 2 Diabetes Mellitus (T2DM) mostly afflict adult aged 20-79 years, but, recently it has been diagnosed in young children due to the increase rise of obesity in this cohort (IDF, 2015, 2017; WHO, 2016). It usually leads to dryness of the mouth and increased thirst, excessive and frequent urination, excessive hunger, weakness, body ache and fatigue, unexplained weight loss as well as poor concentration (IDF, 2015, 2017). Type 2 Diabetes Mellitus (T2DM) occurs as a results interaction of genetic, lifestyle and environmental factors.

Modifiable behavioral risk factors including among others unhealthy diet, lack of physical activity, and the harmful use of alcohol, which in turn lead to overweight and obesity, raised blood pressure, and raised cholesterol, have been shown to be major contributor of T2DM (WHO, 2014a). These factors continue to be a public health challenge in all countries including low- and middle-income countries, Kenya included. Increased prevalence’s in these factors have been linked to an increase in T2DM as well as related complications (WHO, 2014a).

Type 2 Diabetes Mellitus (T2DM) development and progression have been aggravated by obesity and dyslipidemia, which are key metabolic risk factor (Elfaki, 2016; Kaithala et al., 2016; Zhou et al., 2016). Obesity is on the increase with an estimation of 600 million peoples being obese worldwide with Kenya recording a prevalence of 5.9% (ADA, 2014). Obesity has been associated with insulin resistance, a key player in the pathogenesis and progression of T2DM. Additionally dyslipidemia; characterized by increased low density lipoprotein (LDL) and increased (TG) as well as reduced HDL often due to accumulation of fat around the abdominal muscles, has also been shown to be a key risk to T2DM. Excessive abdominal fat mass leads to release of free fatty acid in the liver and circulatory system leading to insulin resistance in the liver and muscles, thus aggravating the problem further (Olokoba et al., 2012). Other factors that have been shown to be associated with development of T2DM include family history of diabetes.

2.2.3 Co morbidities due to T2DM

Type 2 Diabetes Mellitus (T2DM) progression leads to micro and macrovascular complications. Complications due to T2DM leads to increased morbidity and mortality, thereby placing a large financial burden on individuals and families due to the cost of essential medicines for care as well as loss of productivity and the long-term support needed to overcome these complications (IDF, 2015; IDF, 2013). The complications may be acute or chronic. The major acute complication of T2DM is non-ketosis hyperosmolar state that is most commonly seen in elderly individuals caused by Insulin deficiency and inadequate fluid intake (Tripathi & Srivastava, 2006). Other acute complication includes hypoglycemia and lactic acidosis that may occur with a coma or altered consciousness. According to IDF, (2015) hyperglycemic comas in T2DM accounted for 10% of all hyperglycemia emergencies, giving rise to up to 45% mortality (IDF, 2015).

Chronic complications due to T2DM includes micro vascular; retinopathy, neuropathy, and nephropathy, and macro vascular complications; coronary artery disease, peripheral vascular disease, and cerebrovascular disease(IDF; 2015, 2017; Papatheodorou et al, 2016). These complications in T2DM are prone to worsen in the

presence of Mets, MetS risk as well as unhealthy lifestyle factors. A study by Litwak et al (2013), in Asia, Africa, Europe and South America reported a prevalence of 27.2% and 53.5% for macro vascular and micro vascular complications in T2DM patients. Other studies have reported rates ranging from 10-90% of micro vascular and macro vascular complications (Heydari. et al, 2010; Kengne et al., 2005; Litwak et al., 2013; Worku et al., 2010 Hamza, & Woldemichael, 2010). A study by Worku et al(2010).reported a high prevalence of 90.1% of hypertension and an acute complication of 30.5% in patient withT2DM from South West Ethiopia.

Cardiovascular disease (CVD) is also on the increase in T2DM patients and has been shown as most significant cause of death in the T2DM population (IDF, 2015, 2017). According to Kengne et al (2005), increased likelihood of cardiovascular disease seems to be the consequence of increased frequency of such risk factor as; hypertension, high lipids in blood and physical inactivity. Diabetes retinopathy is a leading cause of adult blindness (Kengne et al., 2005). Diabetics are six more times prone to cataracts and 1.4 times more susceptible to open-angle glycoma when compared to the general population (Kengne et al., 2005). Diabetic neuropathy may result in significant morbidity and may contribute to other major complications, such as lower extremity amputation a major debilitating complication (Fenwick, et al., 2012a; 2012b). A study by Awori & Atinga (2007) in Kenya suggested that the prevalence of foot ulcers was found to be significant at tertiary clinics like Kenyatta National Hospital (KNH). The risk factors attributed to foot ulcers were poor glycemic control, diastolic hypertension, infection, dyslipidemia and poor self-care. These risk factor are modifiable and manageable according to Muthuuri (2007). Poor glycemic control is related to increased complications such as hyperglycemia that has been shown to be an important modifiable risk factor in their development (Chawla et al., 2016; Litwak et al., 2013). Thus, there is a need to explore preventive measures aimed at achieving good glycemic control. Such preventive programmes may include lifestyle modification programmes aimed at promoting healthy food choices, physical activity as well as improving adherence to drug and lifestyle intervention. Such programmes have shown promising results (Abdi et al., 2015; Henry et al., 2013; Makrilakis et al., 2012; Mohamed, 2014; Muchiri et al., 2015; Sayka & Khan, 2015).

2.2.4 Management of T2DM

Overall management of T2DM encompasses medication therapy, lifestyle modification as well as enhanced support. Primary prevention which is key in T2DM management is defined as prevention of a disease before it starts Studies indicate that 80% of diabetes cases can be prevented using primary prevention such as lifestyle changes, healthy diets, and physical activity among others. This can be done by addressing common behaviors and risk factors responsible for diabetes. Some risk factors to diabetes are overweight, obesity, unhealthy diets, physical inactivity, sedentary lifestyle, high alcohol and tobacco use (IDF, 2015; WHO, 2014b, 2016). These risk factors if prevented can lead to reduced prevalence of T2DM as well as delayed progression to complications like kidney failure, heart problem, neuropathy, and eye problems that are difficult and costly to treat. Risk for T2DM complications is increased in patients who are overweight or obese, and in those with elevated cholesterol and/or elevated blood pressure. Thus, weight management is an important goal for the long-term health outcomes of many patients. Clinical research has shown that a modest weight loss of 5% to 10% of body weight can improve glycemic control, as well as reduce blood pressure and improve lipid profile (Cherrington et al., 2015; Melchart et al., 2017; Mohamed, 2014).

2.3 Metabolic syndrome (MetS) and its relation to T2DM

2.3.1 Definition of metabolic syndrome (MetS)

Metabolic syndrome (MetS) is a chronic disorder of global health characterized by occurrence of a number of clinical disorders that include abdominal obesity, elevated blood pressure, dyslipidemia and insulin resistance (Alberti et al., 2009). It leads to increased inflammatory cytokine activity due to its pro-thrombotic and pro-inflammatory state (Eckel, Grundy, & Zimmet, 2005). Presence of MetS in T2DM patients has been associated with increased risk to microvascular and macrovascular complications as well as increased mortality.

Different criteria have been used in the definition of MetS. According to National Institute of Health; NIH (MetS) is diagnosed if a patient has any of the three clinical indicators; abdominal obesity with waist circumference for men >102cm and women

>88cm, serum; triglyceride >1.7mmol/l, high density, lipoprotein (HDL) cholesterol for men <0.9mmol/l and for women <1.0mmol/l, blood pressure >130/85mmHg and fasting plasma glucose > 110mg/dl. Additionally according WHO (1998). Mets is diagnosed if one has T2DM or impaired glucose tolerance or insulin sensitivity plus other risk factors that includes central obesity characterized by WHR of >90 for men or >85 for women and /or BMI of >30kg/m2, dyslipidemia characterized by TG levels of >150mg/dl or >1.7mmol/l and/ HDL levels of <35mg/dl in men or <39mg/dl in women; elevated arterial blood pressure (>140/90mmhg) and micro-albuminuria characterized by urinary excretion of albumin >20µg/min or albumin creatinine ratio of 30mg/g.

Moreover, according to IDF (Grundy, 2006) MetS is present if there is presence of central obesity indicated by a BMI is ≥30Kg/m2 or a waist circumference of ≥35 inches and other two of these factors; raised triglycerides of ≥1.7 mmol/L or reduced HDL cholesterol of < 1.3 mmol/L in men and 1.0mmol/l in women or raised blood pressure of systolic BP ≥ 130 or diastolic BP ≥ 85 mm Hg or previous diagnosis of hypertension and raised fasting plasma glucose of ≥5.6 mmol/L or previous diagnosis of diabetes mellitus. Furthermore, according to NCEP-ATP III criteria (Grundy, 2004b). MetS is diagnosed if one has any three of the following metabolic disorders; abdominal obesity given by WC of 120cm in men and 88 cm in women, elevated triglycerides ≥1.7 mmol/L, reduced HDL cholesterol <1.03 mmol/L in men and <1.29 mmol/L in women, systolic BP ≥130 mmHg and/or diastolic BP ≥85 mmHg and a fasting Plasma Glucose ≥6.1 mmol/L. Albert et al (2009).in the consensus statement revised the definition to include any three of the following criteria; elevated waist circumference with population- and country-specific cut-off, elevated triglycerides >150 mg/dL or 1.7 mmol/L) or drug treatment for elevated triglycerides is an alternate indicator , reduced HDL-C < 40 mg/dL / 1.0 mmol/L in men or 50 mg/dL (1.3 mmol/L) in women or drug treatment for educed HDL-C , elevated blood pressure i.e. Systolic blood pressure of ≥130 and/or diastolic pressure of ≥85 mm Hg or antihypertensive drug treatment in a patient with a history of hypertension and elevated fasting glucose >100 mg/dL or drug treatment of elevated blood glucose. In the current study harmonized and WHO criteria were used in the definition of MetS (Alberti et al., 2009; WHO, 1998).

2.3.2 Pathophysiology of metabolic syndrome

Regardless of the criteria used in the definition of MetS, insulin resistance and central obesity have been shown to be key to its pathogenesis (Eckel et al., 2005). Insulin resistance in the adipose tissue impairs inhibition of lipolysis mediated by insulin, leading to an increase in circulating free fatty acids. The increased free fatty acids (FFA) leads to inhibition of anti-lipolytic effect of insulin (Boden & Shulman, 2002; Karpe et al., 2011). Additionally, the increased FFA leads to a reduction in glucose uptake by muscles as a result of inhibition of protein kinase in the; as well as increased gluconeogenesis and lipogenesis linked to increased protein kinase activation in the liver. Moreover increased FFA also leads to reduced insulin production by beta cell of the pancreas due to their lipotoxic effect giving rise to T2DM as well as MetS (Boden & Shulman, 2002).

Additionally, insulin resistance has been linked to elevated blood pressure, a key risk to MetS, that occurs due to loss of the vasodilator effect of insulin and vasoconstriction caused by FFA (Sheng et al., 2012; Zhou et al., 2014). Insulin also, leads to increased risk of cardiovascular disorder as a result of increase in serum viscosity, induction of a pro-thrombotic state and release of pro-inflammatory cytokines from the adipose tissue (Abel, O'Shea, & Ramasamy, 2013; Matsuzawa et al., 2011). Hence insulin resistance has been shown to be important in the development of MetS as well as associated risk. Moreover, increased level of FFA have also been associated with rise in triglycerides a key indicator of MetS. Likewise, increased levels of low density lipoprotein (LDL-c) as well as reduced level of high density lipoprotein cholesterol (HDL-c) have also been indirectly associated with insulin resistance.

2.3.3 Prevalence of MetS and MetS indicators in T2DM patients

The prevalence of MetS as well as associated risk is on the increase in T2DM patients as well as in the general population. A study by Tamang et al (2013), reported that 69% of T2DM patient had MetS, 52.35% had hypertension, 84.70% had reduced HDL-c and 63.35% had increased WC as per NCEP ATPIII definition. Additionally, in their study a high frequency of MetS was seen in patients who were obese (81.58%) and overweight (79.49%) supporting the evidence that central obesity is key to

development of MetS (Tamang et al., 2013). Another study by Raman et al (2010) reported a prevalence of 73.3% of MetS in T2DM patients as defined by IDF criteria while a study by Kengen et al (2012) on T2DM patient reported a prevalence of 71.7% according to the IDF criteria and 60.4% according to NCEP-ATP III criteria.

Additionally, a study Osei-Yeboah et al (2017) on T2DM reported a prevalence of MetS, of 43.83%, 63.58%, and 69.14% as per the NCEP-ATP III, WHO, and IDF definition criteria respectively. The study also reported a prevalence of 66.7% and 62.96% of high blood pressure and abdominal defined as per the NCEP-ATP III and WHO criteria respectively and abdominal obesity of 69.14% as per IDF criteria (Osei-yeboah et al., 2017). Furthermore, a study by Oberga (2010) in T2DM patient reported a prevalence of MetS, of 86% as per harmonized criteria with reduced HDL-c being the most significant metabolic disorder. A study by Kaduka et al (2012) in a Kenyan population reported a prevalence of MetS of 34.6% as defined by harmonized criteria, with elevated blood pressure; (men: 38.6%; women: 63%), higher waist circumference (men: 76.8%; women: 56.1%), and low HDL cholesterol (men: 52%; women: 53.9%). Moreover, a study by Hajian-Tilaki et al (2014) on a general population reported a prevalence of MetS of 42.3% as defined by ATP III criteria. Additionally, a study by Soares et al (2015) reported a prevalence of MetS of 66.1 % as per IDF and AHA/NHLBI definition criteria increased WC, and reduced HDL-c being the most more commonest components of MetS.

2.3.4 Relationship between demographic factors with MetS and T2DM

Studies have shown a strong relation between MetS and T2DM as well as patients characteristic with MetS and T2DM. Some of these patients' characteristics include social demographic and social economic, medical as well as metabolic parameters. For example advanced age has been associated with increased prevalence of MetS. This has been supported by a study by Ogbera (2010) which indicated an increased prevalence (89%) in patients aged 70-79 years compared to 11% in patients aged 20-29 years and Unadike et al (2009) who also showed an increased prevalence of MetS with increasing age (41-70 years). Additionally, a study by Kaimuri et al (2016) carried

out on women of reproductive age also showed significant determinant of MetS with increased age.

Moreover, gender has also been seen to be related to MetS, with increased prevalence being reported in women compared to male despite the criteria used. Kengne et al (2012), Hajian-Tilakiet al (2014) and Soares et al (2015) in their study reported a higher prevalence of MetS in women compared to men while Ogebra (2010) showed similar prevalence in both men and women which increased with age in both gender. Additionally, Hajian-Tilaki et al (2014), also showed an inverse relationship of MetS with advanced education.

2.3.5 Relationship between lifestyle factors (Diet and Physical activity) and MetS indicators in T2DM patients

Studies have shown also a strong relationship between MetS and T2DM. Metabolic syndrome (MetS), have been shown to increase the risk of T2DM by 5 folds (Alberti et al., 2009). Additionally, the risk factors to MetS have also been associated with development and progression of T2DM. Obesity has been linked to insulin resistance, an important factor to development of MetS as well as T2DM (Eckel et al., 2011a; Nyamdorj, 2012; Sharma & Lau, 2013). Poor dietary habits as well as physical inactivity are associated obesity and poor glycemic control in T2DM as well as increased prevalence of MetS. Additionally, Hajian-Tilaki et al (2014) reported increased physical activity being associated with reduced MetS incidence, an indication that diet and physical activity have a role to play in development and progression of MetS. Increased consumption of energy dense food worsens the conditions due to increased fat deposition in the body leading to insulin resistance. Furthermore, Kaimuri et al (2016) in their study reported increased consumption of red meat as a significant determinant of MetS.

Waist circumference is a useful clinical measure for determining visceral fat which is an important cause of insulin resistance, T2DM and MetS. Other factors used in the diagnosis of MetS that include elevated blood pressure as well as elevated TG and reduced HDL have also been shown to be risk factors to T2DM that are aggravated by increased physical inactivity as well as unhealthy diets (Alberti et al., 2009; Alberti et

al., 2006; Grundy et al., 2004a). Elevated blood pressure is one of the major complications to T2DM and studies have also recorded high prevalence in T2DM with MetS. Dyslipidemia characterized by elevated TG and reduced HDL-C have often resulted from consumption of energy dense foods high in fat and/or use of saturated fat as well as physical inactivity. It has been linked to development of T2DM as well as MetS in T2DM patients due to increase in insulin resistance. Metabolic syndrome (MetS) is a strong predictor to cardiovascular disorder, and studies have also shown that poor glycemic control in T2DM is associated to development of CVD. Some of the major causes of poor glycemic control in T2DM are also risk factors to MetS, and this support the evidence that Mets has a strong relationship with T2DM.

The presence of MetS in T2DM has been associated with development of microvascular as well as macrovascular complication. Prolonged stay with MetS in T2DM as well as higher the number of MetS risk factors has been associated with progression of macro vascular complication and increased mortality. A study by Tamang et al (2013) support this as it reported an increased prevalence of hypertension, obesity, overweight as well as elevated WC in T2DM with MetS. Another study by Ahmed et al (2012) on T2DM indicated low HDL cholesterol levels and high systolic blood pressure as strong predictor of MetS in T2DM patient. Therefore, management of MetS in T2DM patient will lead to greater impact in improving health outcome of T2DM patients.

2.4 Effect of nutrition education on management of T2DM

2.4.1 Overview of nutrition education in management of T2DM

Primary prevention though implementation of a lifestyle modification programme using either nutrition education or physical activity or both are key to T2DM management. Studies have indicated that 80% of T2DM cases can be prevented using primary prevention (Alouki et al., 2016; Saaristo et al., 2010; Vermunt et al., 2013). These strategies aim at promoting lifestyle changes that includes healthy diets and enhanced physical activity among others. This can be done by having a lifestyle intervention programs that incorporate nutrition education as well as physical activities

lessons. These programmes if implemented well can lead to reduction of risk factors to T2DM as well as MetS, hence delaying progression to associated complications.

Risk for T2DM complications is increased in patients who are overweight or obese. Additionally, it is increased in patients who have elevated cholesterol as well as elevated blood pressure. Thus, weight management that can be achieved through healthy dietary choices is an important goal for the short and long-term health outcomes of T2DM patients (Franz, 2016; Van Gaal & Scheen, 2015; Wilding, 2014). Clinical research has shown that a modest weight loss of 5% to 10% can improve glycemic control, as well as reduce blood pressure and improve lipid profile (Cherrington et al., 2015; Melchart et al., 2017; Mohamed, 2014).

Nutrition education has been found to be effective, and is now considered an integral part of diabetes care management. In Kenya, nutrition education in T2DM management is up-coming and with several guidelines in place , however, their utilization in management of T2DM is poor (MoPHS, 2010; WHO, 2014b). Diabetes self-management education (DSME) has been shown to be effective in improving knowledge, self-care behaviors, glycemic control and other health outcomes (Essien et al., 2017; Yuan et al., 2014). Medical nutrition therapy (MNT) is an integral component of DSME (ADA, 2016; Morris et al., 2010). Medical nutrition therapy (MNT), both as an independent variable and in combination with other components of DSME, has been shown to be effective in improving health outcomes in individuals with Type 2 diabetes mellitus. However, despite the established role of MNT in enhancing diabetes control, its contribution to diabetes management in Africa, including Kenya, is not well established. There is a paucity of data on structured nutrition education (NE) programmes and their effects on dietary and health outcomes in individuals with T2DM. Education that addresses the needs, abilities and interests of participants is considered effective in improving health and related outcomes.

2.4.2 Importance of nutrition education in management of T2DM and MetS

Nutrition education in T2DM and MetS management is one of the components of lifestyle modification. Nutrition education in T2DM patients leads to the provision of knowledge and skills that empower patients to render self-care in the management of

diseases and associated disorders (Mohamed, 2014; MoPHS, 2010; Muchiri et al., 2016). It involves translation of nutrition and health concepts into knowledge and skill to individuals and groups of people in disease management (Contento, 2008; McNulty, 2015). This transition is meant to influence knowledge and health seeking behavior as well as improved health outcomes (Contento, 2008; McNulty, 2015). Nutrition education in T2DM patients with and without MetS provides information on curative and preventive management of the disease, using diet and other lifestyle factor like physical activity (Contento, 2008; Muchiri et al., 2016). This in consequence helps people to control their condition leading to improved quality of life as well as promoting of good services and patient satisfaction (Groene & Mila, 2005). Nutrition education also empowers the patients with T2DM as well as MetS with the knowledge, skills and motivation that are needed to perform appropriate self-care management.

2.4.3 Nutrition education implementation strategies in management of T2DM and MetS

Nutrition education has been found to be effective, and is now considered an integral part of diabetes care management. Different concepts have been used to implement nutrition education in T2DM patients. Among these concept is diabetes self-management education (DSME). Diabetes self-management education (DSME) has been shown to be effective in improving knowledge, self-care behaviors, glycemic control and other health outcomes (Yuan et al., 2014). Medical nutrition therapy (MNT), an integral module of DSME, is an essential component of T2DM management regardless of the client weight, blood glucose level or use of medication and it said to be the cornerstone of diabetes care (Asaad et al., 2016; Askari et al., 2013; Breen et al., 2017; Meti & Saraswathi, 2007; Muchiri et al., 2015). Medical nutrition therapy; MNT as an independent variable and in combination with other components of DSME, has been shown to be effective in improving metabolic outcomes and MetS for T2DM patients (ADA, 2016; Morris et al., 2010). Medical Nutrition therapy (MNT) is important in preventing diabetes, managing existing diabetes, and preventing, or at least slowing, the rate of development of diabetes complications (Goldhaber, 2003). The goal for MNT is metabolic control through a

balance between food intake, physical activity, and if necessary, medication to avoid complications.

Medical nutritional therapy (MNT) in T2DM patients aims at maintaining optimal metabolic outcomes with respect to glucose and lipid levels essential T2DM (Askari et al., 2013; Muchiri et al., 2016). Moderating the postprandial (after-meal) glycemic response in people with diabetes is integral to meeting these objectives as well as achieving and maintaining a healthy weight (ADA, 2016). However, despite the established role of MNT in enhancing diabetes control, its contribution to diabetes management in Africa, including Kenya, is not well established. There is a scarcity of data on structured nutrition education (NE) programmes and their effects on dietary and health outcomes in patient with T2DM. Education programmes that address the needs, abilities and interests of patients are considered effective in improving health and related outcomes. This can be done through nutrition education.

Different methods have been used to implement nutrition education. This can be achieved by use of individual or group approach. The individual approach is a planned learning experience using a combination of methods, such as: teaching, counseling and behavior modification techniques (MoPHS, 2010). It occurs during personal contact between the health worker and his patient and is a person-to-person communication during which the health worker communicates with an individual in order to improve their health status. In addition the group approach consists of interventions for improving the health of the general public (Hoddinott et al., 2010). It is concerned with modifying social communication to bring about middle or long-term changes in the common behavior of the population and has a complementary role reinforcing other activities aimed at changing the behavior of an entire social group (Hoddinott et al., 2010; MoPHS, 2010). For the program to be successful, community beliefs, cultural and social values need to addressed as they affect lifestyle and social behavior that promote diabetes (Duke et al., 2009; MoPHS, 2010). Other approaches that have been used are community health advisor or health workers to provide peer to peer teaching in the community (Brownson et al., 2016; Taheri et al., 2019). In diabetes management ,peer to peer support involving patients educating one another, with supervision by a community health worker or a health worker, has been shown to be effective in

improving metabolic profiles (Liu et al., 2015; Moskowitz et al., 2013; Patil et al., 2016; Yin et al., 2015)

In T2DM, focus on carbohydrate intake is important because it has a greater impact on postprandial glucose levels. The postprandial glycemic response to carbohydrate is affected by both the amount and the type of carbohydrate consumed. Whole-grain carbohydrates, for instance, produce a lower and slower glycemic response than processed carbohydrates (Fu et al., 2018; Lamothe et al., 2019). Postprandial glycemic response to various foods can be compared using the glycemic index (GI). The higher the GI, the faster a food is digested into glucose and absorbed and the greater the postprandial blood glucose response. Even small improvements in glycemic control help reduce risk for diabetes complications. Thus, nutrition therapy of diabetes is most beneficial at initial diagnosis, but is effective at any time during the disease process, and ongoing evaluation and intervention are essential.

In addition to consuming slowly digested carbohydrate, patients with diabetes can help improve glycemic and elevated lipid by replacing some dietary carbohydrate with non-refined carbohydrates and fat sources high in monounsaturated fatty acids (MUFAs) (Hayes & Benson, 2016; Imamura et al., 2016; Qian et al., 2016). High-MUFA diets do not promote weight gain and are more acceptable than low-fat diets for weight loss by obese patients. Consuming appropriate, specialized nutrition can help patients with T2DM control blood glucose levels and lose weight—two measures that help reduce risk for serious and costly complications. Nutrition education aimed at improving patient knowledge of healthy food choices, as well as portion control can improve clinical outcomes while decreasing cost of managing diabetes hence improving the quality of life, (ADA, 2016).

2.4.4 Importance of physical activity in management of T2DM and MetS

Inclusion of physical activity lessons in the nutrition education programme is key. Physical activity improves endothelial function, which enhances vasodilatation and vasomotor function in the blood vessels (Burr et al., 2010; Sigal et al., 2013). In addition, physical activity contributes to weight loss as well as improvements in muscle and liver insulin sensitivity, muscle glucose uptake and improved glycemic

control (Chimen et al., 2012; Colberg et al., 2010). Additionally it leads to reduction of HbA1c, improved lipid profile, reduced body weight, reduced blood pressure, positive effects on the thromboembolic state, reductions in the overall cardiovascular risk as well as reduced prevalence of MetS and risk factors associated to it (Chimen et al., 2012; Colberg et al., 2010). Despite the studied benefits of physical activity in T2DM patients with and without MetS, different level of physical inactivity ranging from 10-50% have been reported (Kessaram et al., 2015; Lucena et al., 2016). Physical inactivity and low physical fitness are independent predictors of mortality in people with T2DM (WHO, 2010). According to Global status report on non-communicable diseases 2010 and 2014, insufficient physical activity contributes to 3.2 million deaths and 69.3 million DALYs each year.(WHO, 2010, 2014a).

A randomized clinical trial by Warden et al (2012), revealed better performance in weight reduction through brisk walking than those in control group. Structured exercise intervention in clinical trials in T2DM patients exhibited a significant decrease in HbA1c, decreased plasma triglycerides, and increased HDL cholesterol, supporting the importance of physical activity in T2DM management (Chimen et al., 2012; Colberg et al., 2010; Lade et al., 2016; Thent, Das, & Henry, 2013)

2.5 Effect of adherence to lifestyle modification on T2DM management

Adherence has been defined as the "active, voluntary, and collaborative involvement of the patient in a mutually acceptable course of behavior to produce a therapeutic result (WHO, 2003). Implicit in the concept of adherence is choice and mutuality in goal setting, treatment planning, and diabetic implementation of the regimen. Patients internalize treatment recommendations and then either adhere to these internal guidelines or do not adhere (Shankar & Ramya, 2012; WHO, 2003). In T2DM management, adherence to lifestyle modification means having a mutual understanding between a patient and a health worker (nutritionist, physician, physiotherapist, counselor) and following agreed goals which may include, adopting lifestyle changes, dietary modification, and increasing physical activity levels, among others, in the aim of achieving good metabolic outcomes. Adherence to therapeutic life style modification leads to reduction of complications associated with T2DM

(Asaad et al., 2016; Mardani et al., 2010; Santo et al., 2018). In any medical intervention, especially those geared toward prevention of diabetes, adherence is a key principal to the success of any set goal.

Non adherence to lifestyle recommendations occurs when a patient deviate from the mutually agreed collaborative approach to behavior/lifestyle modification aimed at improving the health status of the individual. Non-adherence is likely to lead to increased complications of diabetes which may in turn increase the costs of health care because of increased morbidity and may also decrease productivity of the affected persons (Alharbi & Alsubhi, 2016; Gundala et al., 2016; Lv et al., 2017; Sharma et al., 2014).

Non-adherence to the T2DM treatment regimen is possibly the most common reason for poor health outcomes among people with diabetes as well as increased risk to MetS (Alharbi & Alsubhi, 2016). The rates of non-adherence to T2DM regimen tasks are highly variable, but have significant consequences on diabetes outcomes, the effectiveness of treatments, related complications, development of MetS and associated risk. Research indicates that non-adherence ranges from 35–70% for not following the prescribed meal plan, and 70–80% for inadequate amounts of regular exercise (Alharbi & Alsubhi, 2016; Ganiyu et al., 2013; Mardani et al., 2010; Musee et al., 2016). Factors such as uncontrolled diet, sedentary lifestyle, inappropriate therapeutic regimens as well as medication non-adherence have been known to have significant impact on glycemic control, outcome of T2DM treatment and associated risk to MetS (Ebrahim et al., 2014; Mukonka et al., 2016; Riaz et al., 2014; Saleh et al., 2014; B. Sharma & Agrawal, 2017).

The short-term management of T2DM aims at lowering and stabilizing mean blood glucose levels, while long-term aims focus on avoiding hyperglycemia, dyslipidemia, as well as later complications, all of which result from high blood glucose levels and insulin resistance caused by obesity and their related risk (Eckel et al., 2011; Saboor et al., 2014). Therefore, there is need to intensify lifestyle programs and explore factors that would improve adherence behaviour among people with T2DM.

2.6 Effect of T2DM on health cost

The cost of T2DM treatment is a determinant of the health of the individual and a significant contributor to health disparities(IDF, 2017). These costs consist of direct and indirect cost. Direct cost include all cost used in purchase of drugs, consultations, laboratory investigation, treatment of co morbidities as well as inpatient care cost in case of admission. Indirect cost includes productivity loss due to sick days of the patient as well cost for time loss by care takers while taking care of T2DM patient as well a transport cost incurred by patient as they attend care in health facilities. Global health spending to treat diabetes and prevent complications was estimated at USD 727 by 2017 and USD 673 billion in 2015 (IDF, 2015, 2017). By 2045, this number is projected to exceed USD 776 billion (IDF, 2017). These costs arise from increased use of health services, loss of productivity and disability (IDF, 2015; Seuring et al., 2015). The cost is also likely to increase due to productivity loss and disability associated with T2DM. This increased cost pose large economic burdens on patients with T2DM and their families as well as in the national health systems (IDF 2015; Seuring et al., 2015). This leads to a significant obstacle to sustainable economic development goal attainment (IDF, 2015; Seuring et al., 2015).

According to IDF, a person diagnosed with T2DM spends 2 to 3 times more on medical costs than someone without T2DM (IDF, 2015, 2017). In 2015 it was estimated that a person with T2DM spent a direct cost of USD 1,622 to USD 2,886 in treating and managing the disease (IDF, 2015). Additionally indirect costs associated with workforce, lost productivity, absenteeism, and disease-related disability also contributed a significant amount of diabetes expenditure (IDF, 2015, 2017). Type 2 diabetes mellitus (T2DM) costs everyone, not just those with diabetes. However, the largest costs are not on expenditure for diabetes care, they are mortality, disability, and economic stagnation (IDF, 2015, 2017). A systematic review by Seuring et al (2015) showed a considerable impact of diabetes in terms of costs to society, health systems, individuals and employers and in terms of a reduction in the productive workforce and productivity in general. The Review revealed a strong and direct economic impact of T2DM on people's livelihoods in lower income settings in middle and sub-Saharan Africa (Seuring et al., 2015).

While acknowledging the costs of drugs and treatment for T2DM is a major economic problem; there is need for prevention programmes that may aid in care as well as reduction in cost of care. Such programmes may include, among others, lifestyle intervention aimed at promoting healthy diet as well as physical activity as well as psychological support. Lifestyle interventions have shown promising results that may aid in reduction of complications and delayed onset of complications due to T2DM, and this may lead to reduced cost of care leading to reduction in the large economic burden caused by T2DM (Muchiri et al., 2015; Orchard et al., 2017; Seuring et al., 2015; Zhuo et al., 2014).

2.7 Research Gaps

Type 2 Diabetes mellitus (T2DM) is one of the chronic diseases of public health concern being a major cause of morbidity and morbidity in the world (IDF, 2017; WHO, 2016). In Thika Level 5 hospital based in Kiambu County, Kenya, T2DM is the fifth cause of mortality (MoH, 2014). It is associated with complications that include neuropathy, cardiovascular disorders like hypertension, heart failure, blindness, and kidney failure. All these lead to increased cost of care (IDF, 2017). Furthermore, in most individuals, T2DM is usually diagnosed at late stages when complications have already set in (IDF, 2015). Additionally high prevalence of MetS as well as its association with patient demographic characteristic has been reported in T2DM patients (Hajian-Tilaki et al., 2014; Peer et al., 2015; Pokharel et al., 2014; Rhee et al., 2014). However, data on presence of MetS among T2DM patients in Kenya is limited with the prevalence of MetS being reported separately in the general population (Kaduka et al., 2012; Omuse et al., 2017). Additionally, there is also limited information on the effect of various interventions among T2DM patients, particularly those with the MetS (Henry & Paul, 2009; Kazlauskienė, Butnorienė, & Norkus, 2015; Rhee et al., 2014). Further, there is also need to investigate the development of MetS in T2DM patients as well as its association with patient characteristics (demographic and economic).

Non-adherence to lifestyle modification in T2DM has been associated with increased risk to poor glycemic control as well as progression to complication in T2DM patients.

Studies have reported high prevalence above 50% of non-adherence to lifestyle modification (diet and physical activity) in T2DM (Alharbi & Alsubhi, 2016; Saleh et al., 2014; Shankar & Ramya, 2012; Sharma et al., 2014). Major causes of this high rate of non-adherence to lifestyle modification include lack of information, poor self-control as well as poor support networks (Ebrahim et al., 2014; Ganiyu et al., 2013; Muchiri et al., 2016). However, knowledge levels of patients with T2DM and MetS about proper management of these conditions, as well as associated risk factors are not well established in Kenya. Elsewhere, a study by Odenigbo & Inya-osuu (2012) reported poor knowledge in overall diabetes management, while, a study by Breen et al (2017) reported an association of low nutrition knowledge with reduced fruit consumption and increased dietary glycemic index. In addition the study reported deficit in knowledge on effect of consumption of macronutrient on blood glucose control and lipid profile for T2DM(Breen et al., 2017).

Addressing the identified gaps will contribute to improved management, including lifestyle modification that is crucial to prevent advancement of the conditions (Abdi et al., 2015; Makrilakis et al., 2012a; Sayka et al., 2015; Yamaoka & Tango, 2012). Additionally, the impact of disease from patient lifestyle can be very dramatic hence adhering to lifestyle modification recommendation will often require substantial time and effort from the patient in order to achieve set goals, leading to improved metabolic outcomes and overall quality care (Ebrahim et al., 2014; Gelaw et al., 2014; Gundala et al., 2016; Parajuli et al., 2014). An intensive and continuous intervention specific to each lifestyle modification is recommended. Close follow up is also necessary to ensure success of any lifestyle intervention. Such strategies can incorporate education lessons with peer to peer support components. Studies employing either nutrition education alone or in combination with peer to peer component have reported better metabolic outcomes in T2DM patients (Fisher et al., 2014; Pan et al. 2016; Werfalli et al., 2017). However, application of such programme in Kenya is lacking hence the need to adopt it and study its effectiveness to metabolic outcomes, adherence, knowledge and health cost incurred by T2DM patient

CHAPTER THREE

CHARACTERISTICS OF TYPE 2 DIABETES MELLITUS PATIENTS AND THEIR ASSOCIATION WITH METABOLIC SYNDROME AND CARDIOVASCULAR RISK FACTORS AT THIKA LEVEL 5 HOSPITAL IN KENYA

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3.1 Abstract

Type 2 diabetes mellitus (T2DM) is a public health problem and one of the most common life threatening conditions globally; due to its related complications that are usually very costly to treat, with increasing number of people being diagnosed with this condition each year. Presence of the metabolic syndrome (MetS) and cardiovascular risks in T2DM patients increases the risk to complications. The objective of this study was to determine characteristics of T2DM patients and their association with MetS and associated cardiovascular risk. The study employed a cross section design. Subjects with T2DM were recruited for the study from Thika Level Five Hospital in Kenya. Socio-demographic, clinical and lifestyle data were obtained using structured questionnaires. The nutrition status was determined by anthropometry. Other laboratory parameters that were determined included total cholesterol (TC), high density cholesterol (HDL-c), low density cholesterol (LDL-c), triglyceride (TG), fasting blood glucose (FBG), glycated hemoglobin (HbA1C), and blood pressure (BP). Overall 153 (40.5% men and 59.5% women) Type 2 Diabetes Mellitus (T2DM) patients aged 20-79 years were included in the study. The overall mean age of patients was 56years. The prevalence of the metabolic syndrome was 86.3% as per WHO criteria. The MetS components were elevated waist circumference (WC, 90.8%), increased waist to hip ratio (WHR, 86.9 %), elevated blood pressure (65.7% & 72.5%) and elevated triglycerides (64.8%). The prevalence of occurrence of the components of the MetS was not significantly different among male and female patients except for WC, BMI and reduced serum HDL-C where women were at a significantly higher risk than men ($P<0.001$). The current study showed that income was associated with elevated diastolic blood pressure (BP), secondary education and years lived with diabetes were associated with elevated TG, while occupation showed some association with high WHR. Additionally, Gender, marital status and type of residence were associated with elevated HDL while education, family history of diabetes and alcohol intake was associated with obesity. The prevalence of the MetS and associated cardiovascular risk among T2DM patients was high and similar among males and females. Enhanced surveillance on Mets and associated cardiovascular risk in T2DM in addition to application of preventive measures are critical in order to reduce the risk of macro vascular complications as well as increased cardiovascular risks in T2DM patients.

Keywords: Metabolic Syndrome, Type 2 Diabetes, cardiovascular risk and Patient characteristic

3.2 Introduction

Type 2 Diabetes mellitus (T2DM) is a group of metabolic disorders of multiple etiologies characterized by chronic hyperglycemia (ADA, 2018). It is further characterized by disturbances of carbohydrate, fat and protein metabolism as a result of insulin resistance and relative insulin deficiency; both of which may be present at the time that diabetes becomes clinically manifested (IDF, 2013, 2014, 2015). It is a major risk for cardiovascular diseases (CVD) and metabolic syndrome (MetS) (WHO, 1998). It is a public health problem and one of the most common life threatening conditions globally, due to its related complications that are usually very costly to treat, with more and more people living with the condition each year (IDF, 2014, 2015, 2017; WHO, 2016). It is the fourth leading cause of death in most developed countries (IDF, 2017; WHO, 2016, 2017). It is also the main cause of morbidity with a fast growing incidence due to demographic transition and changes in the population's lifestyle (IDF, 2015, 2017; WHO, 2016, 2017). Typically, this type of diabetes is diagnosed in people aged 20 years or older (IDF, 2015, 2017). Increasingly, however, it is being diagnosed in younger peoples too (IDF, 2015, 2017). Poor glycemic control in addition to presence of MetS in T2DM patients worsens the condition further due to related complications and increases the risk for development of CVD (IDF, 2014; Rhee et al., 2014; Siu & Yuen, 2014).

The MetS comprises a complex of interrelated risk factors that include abdominal obesity, dyslipidemia (low level of high density lipoprotein cholesterol (HDL-C) and /or high triglycerides level (TG)/low density lipoproteins (LDL-c), hypertension and hyperglycemia as a result of insulin resistance (Alberti et al., 2009; Hajian-Tilaki .k et al., 2014; Osei-yeboah et al., 2017; Tamang et al., 2013). It increases the risk of developing T2DM by fivefold and CVD by two folds (Alberti et al., 2009; Kaur, 2014a). MetS, T2DM and CVD risk factors are therefore closely interrelated (Hajian-Tilaki et al., 2014; Kaimuri et al., 2016; Kaur, 2014a; Kengne et al., 2012). Studies conducted on T2DM patients have shown high prevalence of MetS and associated risks (Hajian-Tilaki et al

2014; Kaimuri et al., 2016; Kengne et al., 2012; Nazaimoon et al., 2011; Ogbera, 2010; Rhee et al., 2014) This pose a greater risk to microvascular and macrovascular complications in addition to development of CVD (IDF, 2017; WHO, 2016). Furthermore, patient characteristics (socio demographic, lifestyle and clinical characteristic) have also been shown to be a strong predictor of developing MetS, T2DM and occurrence and progression of CVD (Alwan et al., 2014; Hajian-Tilaki et al., 2014; Kaur, 2014b; Ogbera, 2010). In Kenya studies on MetS status and cardiovascular risk factors have been determined in the general population in some regions and have shown a high prevalence of >50% (Kaduka et al., 2012; Kaimuri et al., 2016). However, there is very limited information on MetS prevalence and cardiovascular risk factors among T2DM patients. Therefore, the aim of this study was to determine the association of T2DM patient characteristics with MetS and cardiovascular risk factors

3.3 Methodology

3.3.1 Study design

The study applied a cross sectional design to collect baseline data that was used to determine the association between T2DM patient characteristics (demographic, economic and clinical) and their association with the MetS and associated CVD risk factors.

3.3.2 Study setting

The study was conducted at Thika Level 5 Hospital (TL5H), Kiambu County, Kenya on Type 2 Diabetes patients attending the Diabetes Comprehensive Centre (DCC).

3.3.3 Population

3.3.3.1 Study participants

The Study participants were men and women aged 20–79 years with T2DM attending care at the DCC in TL5H. They were recruited during their monthly clinic attendance while waiting to see a health professional. Recruitment was done over a period of two months from August 2016 to October 2016. Convenience sampling method was used to recruit the participants. Details of the recruitment process is given in Appendix II.

3.3.3.2 Inclusion criteria

Patients suffering from T2DM aged between 20-79 years with regular attendance at the DCC who signed an informed consent and were willing to participate in the study were included. Details of inclusion criteria are as indicated in Appendix II.

3.3.3.3 Exclusion criteria

Type 2 Diabetes mellitus (T2DM) patients with complications which included renal failure, congestive heart failure (CCF), and stroke were excluded from the study. These conditions were verified from the medical records by the Physician who was present during the recruitment process. Pregnant women and HIV patients with T2DM were also excluded.

3.3.4 Sample size

A target sample size of 153 patients calculated using the formula by Armitage et al., (Armitage, Berry, & Matthews, 2008) and Lwanga and Lemeshow (Lwanga & Lemeshow, 1991) was used for the study. Details of sample size calculation are as attached in Appendix II.

3.3.5 Data collection

3.3.5.1 Baseline data (social demographic, anthropometry, clinical and physical activity)

The demographic data and medical history were obtained using structured questionnaires. Anthropometric measurements that included weight, height, waist circumference and hip circumference were also done. Height and weight was measured using standard protocols with the participants wearing light clothing and no shoes (CDC, 2009). Weight was measured to the nearest 0.1kg using a pre-calibrated Seca scale (SECA, Hamburg, Germany model no. 786/2021994), while height was measured to the nearest 0.1cm using a stadiometer attached to the scale as per CDC protocol (CDC, 2009).The participants were requested to stand straight, with their body weight evenly distributed, both feet flat on the platform with the heels together and toes apart, the back of the head, shoulder

blades, buttocks and heels in contact with the stadiometer backboard plus their heads in the Frankfort horizontal plane. The stadiometer head piece was then lowered so that it rested firmly on top of the participant's head, with sufficient pressure to compress the hair. The participants were then requested to take a deep breath and the reading recorded while the patient released the breath. For the study participants with age ≥ 60 years, the researcher ensured that there was no hunching while standing. Additionally height as well as BMI has been used by other scholar to access nutrition status for T2DM patients with ages above 60 years. For example a studies by Ganz et al (2014) and Ladel et al (2016) assessed BMI in participants with T2DM age ≥18 years. Two readings of each (weight and height) were taken and the average recorded. Body mass index (BMI) was then calculated as weight (kilograms)/height (meters)^2 and classified as per WHO classification (WHO, 2006). A BMI of >18.5-24.9 kg/m^2 was considered normal; 25-29.9 kg/m^2 as overweight and >30 kg/m^2 as obese. The waist circumference was measured mid-way between the lower rib margin and the iliac crest with an anthropometric tape while hip circumference was measured as the maximal circumference around the buttocks posteriorly and pubic symphysis anteriorly as per WHO protocol (WHO 2008). The waist circumference and hip circumference was measured twice to the nearest 0.5 cm while the participants were standing relaxed with their feet apart and arms on the sides. If the variation between these two measurements was greater than 2cm, a third measurement was taken, and the mean calculated using the two closest measurements. Classification of WC and WHR was done as per WHO (1998) and Alberti et al (2009).

Blood pressure was measured by trained nurses on left arms with a Spengler digital sphygmomanometer (model: Autortensio® noSPG440), while the participants were in a seated position and the arm supported at heart level. There was at least a 10-minute rest period before the measurement. Two measurements were taken from all the participants at 2-min intervals, and the mean of the measurements used as the final measurement. Readings from the blood pressure machine were recorded to the nearest 2 mm Hg.

Information on physical activity pattern was collected using a modified WHO Global Physical Activity Questionnaire (GPAQ) (WHO,2010a). This was modified to ensure patients understood the question better. Accordingly, the physical activity level of the

participants was categorized using metabolic equivalent (MET) as per the WHO classification (WHO, 2010a). This classification included light physical activities that included light house work job accumulating a MET minutes per week of <600MET minute/week; moderate physical activities that included the routine productive activities of an electrician, mechanics, jogging, walking accumulating MET minutes per week of 600-1499 and heavy/vigorous physical activities that included productive activities of non-mechanized agriculture, dance, sports, aerobics digging accumulating MET minute per week of ≥1500. Participants who participated in moderate activities and accumulated ≥3000 MET minutes were also considered in the vigorous physical activity category. The average energy expenditure and duration of total physical activity per week was calculated from the questionnaire and recorded in MET minute week.

3.3.5.2 Laboratory assay

Blood samples were collected from each participant while in a seated position after fasting for at least 8-12hrs. Within 1 hour of blood collection, the samples were centrifuged and separated. Lipid profile (total cholesterol, triglycerides, high density lipoprotein cholesterol [HDL-c] and blood glucose estimation were determined using enzymatic method. Level of serum TG was determined using Glycerol Phosphate Oxidase Peroxidase GPO/POD, endpoint method (Bucolo & David, 1973), total cholesterol (TC) using Cholesterol Oxidase Peroxidase (CHOD-POD), end point method (Allain, Poon, Chan, Richmond, & Fu, 1974; Keppy, Bain, & Allen, 2009).and high density lipoprotein (HDL-c) using Phosphotungstic Acid, end Point method (Assmann, Schriewer, Schmltz, & Edgar-otto, 1983)). Serum low density cholesterol (LDL-C) was calculated using the Friedwald's formula (LDL-cholesterol (mmol/l) = Total cholesterol - (HDL+ triglycerides/2.181) (Friedewald, Levy, & Fredrickson, 1972). All parameters were read on a spectrophotometer (Dilui 240T autoanalyzer) at 510nm. Glycated hemoglobin (HbA1c) was determined by Biorad D-10 hemoglobin testing system an automated analyzer, intended for percent determination of HbA1c in human blood using high-performance liquid chromatography (Klenk et al., 1982). Fasting plasma glucose was determined by glucose oxidase method (Beach & Turner, 1958). Detailed procedures of the methods are explained in Appendix II.

3.3.6 Metabolic Syndrome Diagnosis Criteria

Metabolic syndrome in the study was defined according to WHO criteria (WHO, 1998). This criteria requires the presence of diabetes mellitus, impaired glucose tolerance or insulin resistance, and any two of the following :(1) body mass index (BMI) ≥ 30 kg/m2 and/or waist-to-hip ratio >0.90 (male), >0.85 (female); (2) blood pressure ≥140/ ≥90mmHg or on hypertension medication; and (3) triglyceride ≥ 1.7mmol/L and/or HDL-C < 0.91mmol/L (male), <1.01mmol/L (female).

3.3.7 Classification of other CVD risk factors

Glycemic status control was categorized as good glycemic control if HbA1c is<7% and poor control HbA1c is >7% as per the American Diabetes Association (ADA) guidelines (ADA, 2017, 2018). Elevated waist circumference was considered as waist circumference of ≥94 cm in males and ≥80 cm in females) (Alberti et al., 2009) and BMI was categorized as obese >30/m2 and non-obese <30kg/m2 (WHO, 2006) Elevated blood pressure was considered for participants with systolic/diastolic pressure of 130/80 mmHg or those already using hypertensive drugs (AAC, 2017; Alberti et al., 2009). Classification of lipid profiles was done as described by the ADA (ADA, 2017, 2018) and American Association of Clinical Endocrinologists and American College Of Endocrinology; AACE-ACE) (AACE & ACE 2017, 2016). These include elevated triglyceride level ≥1.7 mmol/l and/or the use of triglyceride-lowering drugs), reduced HDL cholesterol (<1.0 mmo/l in males and <1.3 mmol/l in females, elevated LDL cholesterol (>2.6mmol/l) and elevated total cholesterol(>5.2mmol/l) (AACE & ACE, 2017, 2016).

3.3.8 Statistical analysis

Statistical analysis was performed using Statistical Package for Social Sciences (SPSS, Version 20). Data was presented using mean± S.D. for continuous variables and proportions for categorical variables. Categorical variables were compared using Chi-Square test. Independent t-test was used to compare statistical difference of means for the metabolic risk factors between genders. Multivariate logistic regression analysis was

performed to determine variables associated with Mets and associated risk. A P value <0.05 was considered statistically significant.

3.3.9 Ethical approval

The study was approved by the Kenyatta National Hospital-University of Nairobi Ethics and Research Committee (Permit No. KNH-ERC/A/232) and the National Commission for Science, Technology and Innovation (NACOSTI), Permit No. NACOSTI/P/16/83452/10118. Study participants gave a written informed consent

3.4 Results

3.4.1 Demographic Characteristics

Socio demographic characteristics of the respondents are presented in Table 3.1. Overall, 153 Type 2 Diabetic patients participated in the study. Their mean age of the participants was 56 years. Over half of them (58.6%) were aged between 50-69 years. Majority (84.3%) of the participants were married while only 10.5% were single. The highest proportion (54.9%) of the study participants had attained primary education while 35.3% had attained secondary education. Additionally, less than half (41.5%) of the participants were farmers and about one third (31.3%) were engaged in business. In addition, more than half (62.1%), of the participants lived in the rural areas. Moreover, majority of the participants owned a mobile phone (96.1%), owned a house (75.8%), were married (84.3%) and lived in rural areas (62.1%).

Table 3. 1: Socio-demographic characteristics of the participants

Parameters Category		Totals n (%)
Gender	Male	62 (40.5)
	Female	91 (59.5)
Age	20-49	12 (7.8)
	40-49	29 (19.1)
	50-59	46 (30.5)
	60-69	43 (28.1
	70-79	23 (15.1)
Marital status	Single	16 (10.5)
	Married	129 (84.3)
	Separated /divorced	5 (3.3)
	widowed	3 (2.0)
Highest Education Level	Primary	84 (54.9)
	Secondary	54 (35.3)
	Tertiary	14 (9.2)
	No formal education	1 (0.7)
Occupation	formal employment	6 (3.9)
	Casual employment	10 (6.5)
	Farming	63 (41.2)
	Business	49 (32.0)
	unemployed	25 (17.1)
Location of residence	Rural	95 (62.1)
	Urban	58 (37.9)
House ownership	Own house	116 (75.8)
	Rental house/others	37 (24.2)
No of people in HH	None	24 (15.7)
	1 -2 person	56 (36.6)
	3-4 person	48 (31.4)
	5 person or more	25 (16.3)
Income	<1000	72 (47.1)
	>1000-10000	55 (35.9)
	>10000	26 (17.0)
Assets	Radio	136 (88.9)
	Television	120 (78.4)
	Mobile phone	147 (96.1)
	Bicycle	37 (24.2)
	Vehicle	23 (15.0)

n represents the number of participants while (%) represents the percentage; HH-household.

3.4.2 Clinical and Lifestyle Characteristics

As shown in Table 3.2, less than half (46.4%) of the study participants had a family history of diabetes. Of these participants who had a family history of diabetes, 35.3% had poor glycemic control. About half (47.1%) of the participants had a complication as a co-morbidity to T2DM. These complications included retinopathy (23.5%), arthritis (11.8%), lower limb extremity problems (9.8%), nephropathy (1.3%) and neuropathy (2.6%). Majority (96.1%) of the respondents did not take alcohol. Over half of the participants (53.6%) were able to meet the recommended physical activity level as per the WHO guidelines (≥600 MET/week) with only 5.9% being vigorously active (>3000MET/week) (Table 3.2).

Table 3. 2: Clinical and lifestyle characteristics of the participants

Parameter		**Total n (%)**
FHD		71 (46.4)
Complication	Retinopathy	36 (23.5)
	Foot disease	18 (11.8)
	Arthritis	15 (9.8)
	Nephropathy	4 (2.6)
	Nephropathy	2 (1.3)
Alcohol intake		6 (3.9)
PAL	Liight	71 (46.4)
	Moderate	73 (47.7)
	Vigorous	9 (5.9)
YLWD	1-4 years	89 (58.2)
	5-9 years	30 (19.6)
	10-14 years	19 (12.4)
	15-19 years	10 (6.5)
	≥20 years	5 (3.3)

n represents the number of participants while (%) represents the percentage
FHD; family history of diabetes, YLWD; years lived with diabetes, PAL; physical activity level

3.4.3 Screening, Treatment and Effect of Diabetes on the Patients Life

As shown in Table 3.3, majority (82.4%) of the respondents were on oral hypoglycemic agents as a mono-therapy; 12.4% on insulin as a mono-therapy and only 5.2% took a combination of insulin and oral hypoglycemic agents. Most (92.8%) of the study participants monitored their blood glucose level but did not do other routine examinations recommended for T2DM patients, including foot examination (125; 81.7%), eye examination (115; 75.2%), lipid profile (116; 75.8%) and HbA1c (114; 74.5%). More than half (64.1%) of the participants were unable to work as well as before and only 15.0% had not had a change in lifestyle due to diabetes.

Table 3. 3: Screening, treatment and effect of diabetes on the patient life

Parameter		**Total n (%)**
Screening		
Blood glucose monitoring		142 (92.8)
Hba1c		22 (14.4)
Lipid profile		19 (12.4)
Eye examination		23 (15.0)
Foot examination		11 (7.2)
Current treatment	Oral medication	126 (82.4)
	Oral medication and insulin injection	8 (5.2)
	Insulin injection	19 (12.4)
How the disease has affected life	Unable to work as well as before	98 (64.1)
	Unable to work completely	10 (6.5)
	Family life (I am not able to cater for the family)	20 (13.1)
	Socially (Most of the time too sick to be able to socialize)	2 (1.3)
	No change noted	23 (15.0)

n represents the number of participants while (%) represents the percentage

3.4.4 Metabolic syndrome (MetS) and associated risk factors

Prevalence of MetS, and associated cardiovascular risk factors as well as anthropometry and biochemical parameters are as shown in Table 3.4, Table 3.5 and As shown in Table 3.4, the prevalence of Mets was 86.3% as defined by WHO (1998) criteria and 88.2% as defined by Harmonized criteria (Alberti et al., 2009) with female having high prevalence that male which was significant using the albert criteria.

Table 3. 4: Prevalence of MetS based on WHO and Harmonized criteria

Mets status	Gender			χ2 (P values)
	Male n (%)	Female n (%)	Total n (%)	
MetS[a]	54 (35.3)	78 (51.0)	132 (86.3)	2.658 (0.103)
Mets[b]	50(32.7)	85(55.6)	136 (88.2)	5.785 (0.016) *

n represents the number of participants while (%) represents the percentage
Chi-square (χ2) test; statistical significance at p value<0.05
MetS[a] -as defined by WHO criteria and Mets[b] as defined Harmonized criteria

As shown in Table 3.5 majority of the participants; 90.8% and 86.9% had high WC and WHR. The prevalence of hypertension was seen in 65.7% of the participants and raised TG in 64.7%. About a third of the participants (28.8%) had reduced serum HDL cholesterol levels with the prevalence being statistically significant higher (p<0.001) among women than men. Statistically significant differences (p= 0.037 and p<00.01) were also observed among gender in prevalence's of those participants who were obese and those who had increased WC.

As shown in Table 3.6, there was no significant difference in the mean body mass index (BMI) of the participants However, there was a statistically significant difference in the WHR (P=0.001 and WC (P=0.032) among males and females participants with males having a higher mean for both measurements. There was also significant difference (p= 0.045) between the mean TG among gender with females having a higher level (2.39mmol/l) as compared to males (2.03 mmol/l). There was no significant difference in all the other parameters assayed (Table 3.6). Furthermore, comparing the metabolic risk between those who had MetS and those without MetS, participants with MetS had significant high mean WC (94.44 ± 10.02; p=0.002), HC (97.89 ± 9.60), TG (1.41 ±

10.62) and HDL (1.59 ± 0.41). However, other metabolic parameters studied were not significantly higher between those who had MetS and those without.

Table 3. 5: Prevalence of the various components of MetS and other cardiovascular disease risk factors among the participants stratified by Gender.

Parameter	Total n (%)	Male n (%)	Female n (%)	χ2 (P values)	Pvalues
BMI >30Kg/M^2	33 (21.6)	8 (5.2)	25 (16.3)	4.627	0.037
High WHR	133 (86.9)	57 (37.3)	76 (49.)	2.300	0.129
elevated TG	99 (64.7	39 (25.5)	60 (39.2)	0.148	0.700
Reduced serum HDL –c[a]	44 (28.8)	4 (2.6)	40 (26.1)	25.317 *	<0.001**
Dyslipidemia	106 (69.3)	41 (26.8)	65 (42.5)	0.487	0.485
Elevated BP [a]	100 (65.7)	41 (26.8)	59 (38.6)	0.027	0.869
Cardiovascular risk factors					
High WC	139 (90.8)	50 (32.7)	89 (58.2)	13.058	<0.001**
Reduced serum HDL-c[b]	44 (29.7)	6 (3.9)	38 (24.8)	18.524	<0.001**
Elevated BP [b]	111 (72.5)	47 (30.7)	64 (41.8)	0.555	0.046*
Elevated LDL-c	68 (44.4)	27 (17.6)	41 (26.8)	0.034	0.854
Elevated TC	64 (41.8)	24 (15.7)	40 (26.1)	0.000	0.983

n represents the number of participants while (%) represents the percentage chi-square (χ2) test; *statistical significance at p value<0.05 BMI obese >30 kg/m^2, Elevated Waist hip ratio (WHR)>0.9 for men and >1.0 for women, Elevated blood pressure [a] >140/90mmHg or treatment of previously diagnosed hypertension (WHO criteria); Elevated blood pressure [b] >130/80mmHg or treatment of previously diagnosed hypertension (ACC criteria), Reduced serum HDL cholesterol (a) <0.9 mmol/L for men or<1.0 mmol/L for women or specific treatment for this abnormality (WHO criteria); Reduced serum HDL cholesterol [b] <1.0 mmol/L for men or<1.3 mmol/L for women or specific treatment for this abnormality (ADA criteria), Elevated triglycerides (TAG) >1.7 mmol/L or specific treatment for this abnormality (both criteria), Waist circumference (WC) ≥94 cm for men or ≥80 cm for women, Elevated TC>5.2mmol/l, Elevated LDL-cholesterol>2.6mmol/l, Dysilipedimia: Elevated triglycerides >1.7mmol/l/ and or(a) <0.9 mmol/L for men or<1.0 mmol/L for women or specific treatment for this abnormality

Table 3. 6: Anthropometric, clinical and biochemical parameters of patients with T2DM stratified by gender and MetS.

Parameter	Total	Gender		P value	Presence of MetS		p value (<0.05)
		Male	Female		Yes	No	
BMI (Kg/M^2)	27.03±4.70	26.88±4.11	27.13±5.08	0.750	27.21±4.77	25.66±3.98	0.188
WC (cm)	100.84±9.58	102.85±9.03	99.47±9.76	0.032*	101.70±9.23	94.44±10.02	0.002*
HC (cm)	105.0±9.68	103.63±8.89	105.93±10.12	0.149	105.95±9.33	97.89±9.60	0.001*
WHR	0.96±0.09:	1.00±0.078	0.94±0.098	0.001*	0.96±0.097	0.97±0.069	0.735
TC (mmol/L)	4.97±1.1.22	4.80±1.22	5.09±1.231	0.171	5.00±1.26	4.81±0.94	0.540
TG (mmol/L)	2.24±1.09	2.02±0.92	2.38±1.17	0.045*	2.35±1.09	1.41±1.0.62	0.001*
HDL (mmol/L)	1.39±0.37	1.38±0.35	1.38±0.38	0.920	1.36±0.35	1.59±0.41	0.011*
LDL (mmol/L)	2.57±1.07.	2.52±1.12	2.61±1.04	0.574	2.57±1.08	2.57±0.99	0.917
HbA1c (%)	8.48±1.86	8.65±1.99	8.37±1.76	0.375	8.48±1.89	8.52±1.64	0.994
FBG (mmol/L)	11.01±3.39	11.28±3.67	10.83±3.19	0.422	10.91±3.09	11.75±5.17	0.328
DP (mmHg)	88.90±9.55	88.69±8.56	89.03±10.21	0.830	89.66±9.78	83.17±4.77	0.006*
SP (mmHg)	143.78±20.09	142.77±20.35	144.47±1999	0.609	145.80±20.16	128.67±11.47	0.001*

*statistical significance at $p<0.05$; (a) independent t test

Data are presented as mean ± standard deviation of the mean. BMI: body mass index, HC: hip circumference, WHR: waist-to-hip ratio, SP: systolic blood pressure, DP: diastolic blood pressure, LDL low density lipoprotein, TC: total cholesterol and HbA1c –glycated Hemoglobin

3.4.5 Association of Patient Characteristics with MetS with Associated Risks

3.4.5.1 Association of patient characteristics with High WHR

The association of patient characteristics with high WHR is as shown in Table 3.7. Occupation status of the participant showed significant association with High WHR. Participants who were in formal employment (OR=0.017, P=0.012), those who were farming (OR=0.037, P=0.028) and those in business (OR=0.07, P<0.01) had a reduced risk to high WHR. However, all the other participant characteristics that included gender, age, marital status, education level, type of residence, house ownership, number of dependents, income levels, family history of diabetes, complication due to T2DM, years lived with diabetes, alcohol intake as well as physical activity levels showed no significant association with MetS showed no association with High WHR

3.4.5.2 Association of patient characteristics with obesity

Association of participant characteristics with obesity is as shown in Table 3.8. Participants who had attained secondary education had a reduced odds (OR=0.144, P=0.007) to Obesity as compared to those who had primary education Additionally, participants who had a family history of diabetes (OR=6.391, P=0.003) and those drinking alcohol (OR=32.64, P=0.011) were significantly associated with increased risk to obesity (Table 3.7). Other patient characteristics that included gender, age, marital status, education level, occupation status, type of residence, house ownership, number of dependents, income, complication due to T2DM, years lived with diabetes as well as physical activity levels showed no significant association with obesity (Table 3.8).

Table 3. 7: Associations of patient characteristics with WHR

Parameter		High WHR				
		n (%)	OR	95% CI		P value
Gender	Male	57 (42.9)	Ref			
	Female	76 (57.1)	2.534	0.494	13.002	0.265
Age	20-39	11 (8.3)	Ref			
	40-49	22 (16.5)	2.833	0.071	113.376	0.580
	50-59	40 (30.1)	2.055	0.057	74.329	0.694
	60-69	39 (29.3)	1.554	0.036	67.061	0.819
	70-79	21 (15.8)	1.505	0.023	98.465	0.848
Marital status	Single	12 (9.0)	Ref			
	Married	114 (85.7)	1.380	0.119	15.967	0.796
	others	7 (5.3)	2.512	0.050	125.342	0.644
Education	Primary	72 (54.1)	Ref			
	Secondary	49 (36.8)	0.230	0.041	1.289	0.095
	Tertiary	12 (9)	0.396	0.035	4.522	0.456
Occupation	unemployed	25 (18.8)	Ref			
	Formal employment	2 (1.5)	0.043	0.001	1.633	0.090
	Casual employment	8 (6.0)	0.017	0.001	0.403	0.012*
	Farming	57 (42.9)	0.037	0.002	0.704	0.028*
	Business	41 (30.8)	0.007	0.000	0.283	0.009*
Type of residence	Rural	85 (63.9)	Ref			
	Urban	48 (36.1)	3.382	0.559	20.455	0.185
house ownership	Own house	100 (75.2)	Ref			
	Rental house &others	33 (24.9)	0.196	0.029	1.312	0.093
No. of HH members	None	19 (14.3)	Ref			
	1-2 person	50 (37.6)	0.476	0.056	4.048	0.497
	3-4 person	43 (32.3)	0.533	0.079	3.578	0.517
	5 person or more	21 (15.8)	0.766	0.107	5.504	0.791
Income (Ksh)	500-1000	65 (48.9)	Ref			
	>1000-4999	27 (20.3)	1.796	0.350	9.214	0.483
	>5000-9999	19 (14.3)	1.292	0.120	13.903	0.832
	≥10000	22 (16.5)	0.781	0.077	7.966	0.835
FHD	No	63 (47.4)	Ref			
	Yes	70 (52.6)	2.572	0.596	11.093	0.205
Complication	Yes	64 (48.1)	Ref			
	No	69 (51.9)	2.350	0.552	10.012	0.248
YLWD	1—4.99 years	69 (51.9)	Ref			
	>5-9.99 years	24 (18.0)	3.230	0.562	18.570	0.189
	>10-14.99 years	24 (19.0)	4.463	0.651	30.604	0.128
	>15-19.99 years	16 (12.0)	3.322	0.182	60.572	0.418
	≥20 years	5 (3.8)	0.000	0.000	.	0.999
Alcohol intake	No	127 (95.5)	Ref			
	Yes	6 (4.6)	0.000	0.000		0.999
PAL	Light	57 (42.9)	Ref			
	moderate	67 (50.4)	0.479	0.121	1.888	0.293
	vigorous	9 (6.8)	0.000	0.000	.	0.999

ref: refrence point; n represents the number of participants while (%) represents the percentage
OR – Odds ratio; 95% CI- 95% confidence interval; * statistical significance at p value<0.05, ** statistical significance at p value<0.01 ref -reference point
High Waist hip ratio (WHR)>0.9 for men and >1.0 for women,
FHD; family history of diabetes, YLWD; years lived with diabetes, PAL; physical activity level

Table 3. 8: Association of patient demographic characteristics with obesity

Parameter		Obesity				
		n (%)	OR	95% CI		P value
Gender	Male	8 (24.4)	Ref			
	Female	25 (75.8)	0.280	0.070	1.121	0.072
Age	20-39	2 (6.1)	Ref			
	40-49	6 (18.2)	2.053	0.166	25.317	0.575
	50-59	11 (33.3)	1.158	0.107	12.519	0.904
	60-69	9 (27.3)	0.820	0.066	10.219	0.877
	70-79	5 (15.2)	0.549	0.036	8.371	0.666
Marital status	Single	4 (12.1)	Ref			
	Married	28 (84.8)	1.379	0.186	10.239	0.754
	others	1 (3.0)	24.123	0.644	904.03	0.085
Education	Primary	15 (45.5)	Ref			
	Secondary	15 (45.5)	0.144	0.035	0.587	0.007**
	Tertiary	3 (9.1)	0.136	0.013	1.449	0.098
Occupation	unemployed	1 (3.0)	Ref			
	Formal employment	15 (45.5)	0.000	0.000	.	0.998
	Casual employment	4 (4.6)	0.569	0.020	16.228	0.741
	Farming	13 (39.4)	0.283	0.012	6.631	0.432
	Business	4 (12.1)	1.444	0.046	45.349	0.834
Type of residence	Rural	21 (63.6)	Ref			
	Urban	12 (36.4)	1.099	0.215	5.611	0.909
House ownership	Own house	26 (78.8)				
	Rental house &others	7 (21.2)	.488	0.090	2.637	0.404
No. of HH members	None	7 (21.2)	Ref			
	1-2 person	8 (24.2)	3.740	0.587	23.835	0.163
	3-4 person	13 (39.4)	.690	0.139	3.438	0.651
	5 person or more	5 (15.2)	1.605	0.240	10.756	0.626
Income (Ksh)	500-1000	14 (42.4)	Ref			
	>1000-4999	13 (39.4)	.281	0.074	1.066	0.062
	>5000-9999	4 (12.1)	1.491	0.164	13.595	0.723
	≥10000	2 (6.1)	6.806	0.501	92.527	0.150
FHD	No	21 (63.6)	Ref			
	Yes	12 (36.4)	6.391	1.889	21.623	0.003*
Complication	Yes	13 (39.4)				
	No	20 (60.6)	.551	0.175	1.738	0.309
YLWD	1—4.99 years	20 (60.6)	Ref			
	>5-9.99 years	6 (18.2)	1.597	0.368	6.937	0.532
	>10-14.99 years	5 (15.2)	1.125	0.140	9.020	0.912
	>15-19.99 years	2 (6.1)	14.514	0.884	238.228	0.061
	≥20 years	0 (0)	0.000	.000	.	0.999
Alcohol intake	No	2 (6.1)	Ref			
	Yes	31 (36.4)	32.640	2.239	475.767	0.011*
PAL	Light	20 (66.6)	Ref			
	moderate	12 (36.4)	3.334	.956	11.624	0.059
	vigorous	1 (3.0)	12.502	.814	192.020	0.070

ref: refrence point; n represents the number of participants while (%) represents the percentage
OR – Odds ratio; 95% CI- 95% confidence interval; * statistical significance at p value<0.05, ** statistical significance at p value<0.01 ref -reference point
Obesity BMI >30 kg/m^2
FHD; family history of diabetes, YLWD; years lived with diabetes, PAL; physical activity level MetS defined as per WHO criteria

3.4.5.3 Association of patient characteristics with elevated blood pressure

As shown in Table 3.9 education level, type of residence and income levels showed an association with elevated BP. Compared to participants, earning an income of KSH. 500-999 per month, participants, earning an income of KSH. 5000-9,999 and >10,000 were significantly associated with increased risk to elevated DBP (OR= 5.648, P=0.046 & OR=5.326, P=0.042) with risk reducing as income increases (Table3.9). Additionally, participant who had attained secondary education had an increased risk to elevated BP (OR=0.323, P=0.042) compared to those who had attained primary education. Moreover, participant living in the urban area also had an increased risk to elevated BP (OR=0.276, P=0.033) compared to those living in the rural areas (Table 3.9). All other patient characteristics that included gender, age, marital status, occupation status, house ownership, number of dependents, family history of diabetes, complication due to T2DM, years lived with diabetes, alcohol intake as well as physical activity levels showed no significant association with elevated BP.

3.4.5.4 Association of patient characteristics with reduced HDL

As shown in Table 3.10, gender, marital status and type of residence showed some association with reduced HDL. The female participant had a reduced odds to reduced HDL-c (OR=0.047, P<0.001) compared to the male participants. Additionally, participants who were married had a reduce odds to reduced HDL-c (OR= 0.065, p value=0.004) while participant living in the urban areas having an increased risk to reduced HDL-c (OR=0.207, P=0.037) compared to those living in the rural areas. However, other participant characteristics studied showed no significant association with reduced HDL.

Table 3. 9: Association of patient characteristic with blood pressure

Parameter		Elevated BP				
		n (%)	OR	95% CI		P value
Gender	Male	30 (40)	Ref			
	Female	45 (60)	0.815	0.313	2.122	0.675
Age	20-39	7 (9.3)				0.392
	40-49	12 (16.0)	3.170	0.435	23.086	0.255
	50-59	22 (29.3)	1.844	0.266	12.775	0.535
	60-69	26 (34.9)	1.693	0.224	12.814	0.610
	70-79	8 (10.7)	3.467	0.395	30.405	0.262
Marital status	Single	8 (10.7)	Ref			
	Married	63 (84.0)	1.513	0.311	7.373	0.608
	others	4 (5.3)	2.991	0.267	33.545	0.374
Education	Primary	38 (50.7)				0.232
	Secondary	31 (41.3)	0.323	0.116	0.902	0.031*
	Tertiary	6 (8.0)	0.513	0.085	3.103	0.467
Occupation	unemployed	2 (2.6)	Ref			
	Formal employment	5 (6.4)	0.067	0.002	1.947	0.116
	Casual employment	29 (37.2)	0.739	0.102	5.336	0.765
	Farming	25 (32.1)	0.515	0.138	1.918	0.323
	Business	17 (21.8)	0.444	0.113	1.741	0.244
Type of residence	Rural	52 (69.3)	Ref			
	Urban	23 (30.7)	0.276	0.085	0.898	0.033*
house ownership	Own house	61 (81.3)	Ref			
	Rental house &others	14 (18.7)	0.719	0.214	2.416	0.594
No of Dependents	None	11 (14.7)	Ref			
	1-2 person	29 (38.7)	1.953	0.426	8.957	0.389
	3-4 person	25 (33.3)	1.721	0.460	6.441	0.420
	5 person or more	10 (13.3)	1.186	0.319	4.415	0.799
Income (Ksh)	500-1000	36 (48.0	Ref			
	>1000-4999	12 (16.0)	2.077	0.395	10.916	0.388
	>5000-9999	9 (12.0)	5.648	1.030	30.979	0.046*
	⩾10000	18 (24.0)	5.326	1.065	26.628	0.042*
FHD	No	36 (48.0)	Ref			
	Yes	39 (52.0)	1.483	0.609	3.610	0.386
Complication	Yes	36 (48.0)				
	No	39 (52.0)	0.560	0.238	1.315	0.183
YLWD	1—4.99 years	33 (44.0)	Ref			
	>5-9.99 years	16 (21.3)	2.085	0.163	26.690	0.572
	>10-14.99 years	14 (18.7)	2.484	0.171	36.111	0.505
	>15-19.99 years	12 (16.0)	0.428	0.020	9.143	0.587
	⩾20 years	4 (3.6)	2.184	0.119	40.040	0.599
Alcohol intake	No	4 (5.3)	Ref			
	Yes	71 (94.7)	1.012	0.137	7.493	0.991
PAL	Light	33 (44.0)	Ref			
	moderate	37 (49.3)	.957	0.840	0.349	2.021
	vigorous	5 (6.7)	1.027	0.631	0.081	4.907

ref: refrence point; n represents the number of participants while (%) represents the percentage
OR – Odds ratio; 95% CI- 95% confidence interval; * statistical significance at p value<0.05, ** statistical significance at p value<0.01 ref -reference point
High blood pressure >140/90mmHg or treatment previously diagnosed hypertension
FHD; family history of diabetes, YLWD; years lived with diabetes, PAL; physical activity level MetS defined as per WHO criteria

Table 3. 10: Association of patient characteristics with HDL-c

Parameters		Reduced HDL-c				
		n (%)	OR	95% CI		P valve
Gender	Male	4 (9.1)	Ref			
	Female	40 (90.9)	0.047	0.011	.210	<0.001**
Age	20-39	5 (11.4)				0.656
	40-49	11 (25)	1.457	0.170	12.513	0.732
	50-59	14 (31.8)	2.542	0.291	22.168	0.398
	60-69	9 (20.5)	4.270	0.443	41.143	0.209
	70-79	5 (11.4)	3.494	0.247	49.417	0.355
Marital status	Single	5 (11.4)	Ref			
	Married	38 (86.4)	0.065	0.010	.422	0.004**
	Separated /divorced/widowed	1 (23)	0.373	0.017	8.155	0.531
Education	Primary	25 (56.8)	Ref			
	Secondary	16 (36.4)	0.933	0.293	2.976	0.907
	Tertiary	3 (6.8)	1.755	0.171	18.012	0.636
Occupation	unemployed	4 (9.1)				0.379
	Formal employment	3 (6.8)	0.903	0.074	11.018	0.936
	Casual employment	18 (40.9)	3.062	0.303	30.911	0.343
	Farming	10 (22.7)	1.731	0.320	9.374	0.524
	Business	9 (20.5)	4.945	0.825	29.627	0.080
Type of residence	Rural	25 (56.8)	Ref			
	Urban	19 (43.2)	0.207	0.047	.907	0.037*
House ownership	Own house	33 (75.0)				
	Rental house & others	11 (25.0)	1.465	0.365	5.872	0.590
	None	7 (15.9)	Ref			0.160
	1-2 person	20 (45.5)	1.078	0.249	4.657	0.920
Dependents	3-4 person	10 (22.7)	4.046	0.789	20.754	0.094
	5 person or more	7 (15.9)	3.127	0.441	22.148	0.254
Income (Ksh)	500-999	20 (45.5)	Ref			
	>1000-4999	11 (25)	0.401	0.110	1.466	0.167
	>5000-9999	5 (11.4)	0.643	0109	3.799	0.626
	>10000	8 (18.2)	0.189	0.028	1.297	0.090
FHD	Yes	19 (43.2)	Ref			
	No	25 (56.8)	0.789	0.290	2.144	0.642
Complication	Yes	20 (45.5)	Ref			
	No	24 (54.5)	1.621	0.559	4.702	0.374
	1—4.99 years	24 (54.5)	Ref			
	>5-9.99 years	9 (20.5)	0.215	0.014	3.387	0.274
YLWD	>10-14.99 years	6 (13.0)	2.747	0.120	63.125	0.528
	15-19.99 years	5 (11.4)	0.138	0.007	2.919	0.203
	⩾20 years	2 (4.5)	0.269	0.010	6.931	0.428
Alcohol intake	Yes	3 (6.8)	Ref			
	No	41 (93.2)	1.283	0.107	15.404	0.844
PAL	light	17 (38.6)	Ref			
	moderate	23 (52.3)	0.578	0.199	1.675	0.312
	vigorous	4 (9.1)	0.147	0.016	1.323	0.087

ref: refrence point; n represents the number of participants while (%) represents the percentage
OR – Odds ratio; 95% CI- 95% confidence interval; * statistical significance at p value<0.05, ** statistical significance at p value<0.01 ref -reference point. Reduced HDL cholesterol <1.0 mmol/L for men or <1.3 mmol/L for women or specific treatment for this abnormality. FHD; family history of diabetes, YLWD; years lived with diabetes, PAL; physical activity level MetS defined as per WHO criteria.

3.4.5.5 Association of patient characteristics with TG

As shown in Table 3.11 house ownership, years lived with diabetes as well as alcohol intake had a significant association with elevated TG. Participants who were living in a rental house had an increased odds to elevated TG (OR=13.027, P<0.001) compared to participant who owned a house (Table3.11). Additionally, participants who had lived with T2DM for more than 20 years also had an increased odds to elevated TG (OR=29.308, P value= 0.014) compared to those participant who had lived with T2DM for less than five years (Table 3.11). However, participants who were not taking alcohol had a reduced odds to elevated TG (OR=0.025, P value= 0.006) compared to those participant who were taking alcohol (Table 3.11). Other patient characteristic that included gender, age, marital status, education, occupation, type of residence, number of dependents, income, family history of diabetes, complications as well as physical activity levels showed no association with elevated TG (Table 3.11).

3.4.5.6 Association of patient characteristics with MetS

As shown in Table 3.12, only income levels of the participants that showed a significant association with MetS, with participant earning an income of >10,000 having a reduced risk to MetS (OR=0.037, P value=0.018) as compared to those earning an income of <500. All other patient characteristics that included gender, age, marital status, education level, occupation status, type of residence, house ownership, number of dependents, family history of diabetes, complication due to T2DM, years lived with diabetes, alcohol intake as well as physical activity levels showed no significant association with MetS (Table 3.12).

Table 3. 11: Association of patient characteristic with elevated TG

Parameters		Elevated TG				
		n (%)	OR	95% CI		P value
Gender	Male	39 (39.4)	Ref			
	Female	60 (60.5)	0.603	0.229	1589	0.306
Age	20-39	7 (7.1)				0.925
	40-49	20 (20.7)	0.714	0.112	4.558	0.722
	50-59	28 (28.3)	0.896	0.154	5.219	0.903
	60-69	29 (29.3)	0.653	0.098	4.349	0.659
	70-79	15 (15.2)	0.469	0.059	3.717	0.473
Marital status	Single	10 (10.1)	Ref			
	Married	83 (83.8)	1.073	0.201	5.716	0.934
	Separated /divorced/widowed	6 (6.1)	0.289	0.020	4.148	0.361
Education	Primary	59 (59.6)	Ref			
	Secondary	31 (3.3)	3.807	1.425	10.172	0.008
	Tertiary	9 (9.1)	4.594	0.770	27.389	0.094
Occupation	Formal employment	7 (7.1)	1.952	0.059	64.490	0.708
	Casual employment	39 (39.4	12.018	0.564	256.085	0.111
	Farming	31 (31.3)	4.479	0.250	80.166	0.308
	Business	17 (17.2)	3.936	0.190	81.449	0.375
Type of residence	Rural	61 (61.6)	Ref			
	Urban	38 (38.4)	0.324	0.095	1.105	0.072
House ownership	Own house	81 (81.8)				
	Rental house & others	18 (18.2)	13.207	3.268	53.368	0.000**
	None	15 (15.2)	Ref			
	1-2 person	36 (36.4)	0.440	0.115	1.688	0.231
Dependents	3-4 person	33 (33.3)	0.403	0.094	1.731	0.222
	5 person or more	15 (15.2)	1.146	0.256	5.136	0.858
Income (Ksh)	500-999	44 (44.4)	Ref			
	>1000-4999	22 (22.2)	0.772	0.249	2.399	0.655
	>5000-9999	17 (17.7)	0.312	0.067	1.450	0.137
	>10000	16 (16.2)	0.359	0.074	1.736	0.202
FHD	Yes	44 (44.4)	Ref			
	No	55 (55.6)	0.601	0.247	1.462	0.262
Complication	Yes	46 (46.5)	Ref			
	No	53 (53.5)	0.753	0.298	1.901	0.548
	1—4.99 years	46946.5)	Ref			
	>5-9.99 years	24 (24.2)	0.401	0.123	1.311	0.130
YLWD	>10-14.99 years	20 (20.2)	0.400	0.094	1.705	0.215
	15-19.99 years	9 (9.1)	0.514	0.087	3.037	0.463
	⩾20 years	1 (1.0)	29.308	1.956	439.182	0.014
Alcohol intake	Yes	98 (99.0)	Ref			
	No	50 (50.5)	0.025	0.002	.345	0.006**
PAL	light	46 (46.5)	Ref			
	moderate	3 (3.0)	1.483	0.600	3.663	0.393
	vigorous		2.514	0.409	15.469	0.320

ref: refrence point; n represents the number of participants while (%) represents the percentage
OR – Odds ratio; 95% CI- 95% confidence interval; * statistical significance at p value<0.05, ** statistical significance at p value<0.01 ref -reference point
Elevated triglycerides (TG) >1.7 mmol/L or specific treatment for this abnormality
FHD; family history of diabetes, YLWD; years lived with diabetes, PAL; physical activity level MetS defined as per WHO criteria

Table 3. 12: Association of Patient Characteristic with MetS

Parameters		MetS				
		n (%)	OR	95% CI		P value
Gender	Male	54 (40.9)	Ref			
	Female	78 (59.1)	0.716	0.190	2.692	0.621
Age	20-39	11 (8.3)	Ref			
	40-49	23 (17.4)	1.095	0.053	22.733	0.953
	50-59	40 (30.3)	0.730	0.038	13.969	0.835
	60-69	38 (28.8)	0.555	0.025	12.469	0.710
	70-79	20 (15.2)	0.823	0.030	22.587	0.908
Marital status	Single	13 (9.8)	Ref			
	Married	113 (85.6)	0.990	0.142	6.908	0.992
	Separated /divorced/widowed	6 (3.9)	1.713	0.094	31.158	0.716
Education	Primary	73 (55.3)	Ref			
	Secondary	48 (36.4)	0.696	0.173	2.809	0.611
	Tertiary	11 (8.3)	4.175	0.514	33.886	0.181
Occupation	unemployed	21 (15.9)	Ref			
	Formal employment	4 (3.0)	0.318	0.015	6.885	0.465
	Casual employment	7 (5.3)	0.080	0.004	1.512	0.092
	Farming	57 (43.2)	0.102	0.007	1.542	0.100
	Business	43 (32.6)	0.090	0.005	1.762	0.113
Type of residence	Rural	86 (65.2)	Ref			
	Urban	46 (34.8)	1.829	0.368	9.095	0.460
House ownership	Own house	102 (87.3)	Ref			
	Rental house and others	30 (22.7)	1.428	0.287	7.100	0.663
Dependents	None	18 (13.6)				
	1-2 person	49 (37.2)	0.418	0.072	2.421	0.330
	3-4 person	44 (33.3)	0.140	0.019	1.050	0.056
	5 person or more	21 (15.9)	0.383	0.060	2.457	0.311
Income (Ksh)	500-999	60 (45.5)	Ref			
	>1000-4999	29 (45.5)	0.430	0.077	2.399	0.336
	>5000-9999	18 (13.6)	0.357	0.047	2.714	0.319
	>10000	25 (18.9)	0.037	0.002	.572	0.018
FHD	Yes	61 (46.2)	Ref			
	No	71 (53.8)	2.038	0.306	13.587	0.462
Complication	Yes	60 (47.0)				
	No	72 (53.0)	0.754	0.212	2.675	0.662
	1—4.99 years	78 (59.1)	Ref			
	>5-9.99 years	25 (18.9)	1.368	0.293	6.398	0.690
YLWD	>10-14.99 years	16 (12.1)	0.965	0.141	6.615	0.971
	15-19.99 years	9 (9.0)	0.952	0.075	12.056	0.970
	≥20 years	4 (4.0)	7.234	0.320	163.386	0.213
Alcohol intake	Yes	4 (3.0)	Ref			
	No	12 (97.0)	9.871	0.904	107.718	0.060
PAL	light	58 (43.9)	Ref			
	moderate	66 (50.0)	0.408	0.102	1.624	0.203
	vigorous	2 (6.1)	0.226	0.007	7.002	0.396

ref: refrence point; n represents the number of participants while (%) represents the percentage
OR – Odds ratio; 95% CI- 95% confidence interval; * statistical significance at p value<0.05, ** statistical significance at p value<0.01 ref -reference point
MetS defined as per WHO criteria
FHD; family history of diabetes, YLWD; years lived with diabetes, PAL; physical activity level

3.5 Discussion

Type 2 Diabetes mellitus (T2DM), metabolic syndrome (MetS) and cardiovascular disorder (CVD) are prevalent chronic conditions of global importance that can be controlled with proper management (IDF, 2015; WHO, 2016, 2017). This could result to potential benefit geared toward the patient, the health care system as well economic development (IDF, 2015; Kaur, 2014a; Unadike et al., 2009). The metabolic syndrome (MetS), a cluster of risk factors which include raised blood pressure, dyslipidemia (raised TG and lowered HDL-c), raised fasting glucose, and central obesity (increased WC) has been shown to increase the risk to T2DM by 5 fold and cardiovascular disease by 2 folds (Alberti et al., 2009; Kaur, 2014a). The current study explored the association between patient characteristic and MetS and associated cardiovascular risk. Exploring these associations might aid in development of preventive measure therefore improving the quality of life of the diabetes patients.

Overall, 153 (59.5 female and 40.5 male) T2DM patients with a mean 56 years were incorporated into the study. Majority were aged between 50-59 years with an average age of 56.08 years and 56.51years for those with MetS and poor glycemic control respectively. Indeed, age has been shown to be a risk factor in T2DM, MetS and associated cardiovascular risk (Nazaimoon et al., 2011). Studies conducted on T2DM patients have reported a high prevalence of T2DM and MetS in older people (>50 years) and this is in congruent with the current study (Kengne et al., 2012; Ogbera, 2010; Otero et al., 2007; Tamang et al., 2013).

Prevalence study on MetS, MetS risk and associated CVD risk factors in T2DM patients have revealed different rates in different places, depending on definition criteria used (Alwan et al., 2014; Hajian-Tilaki et al., 2014; Osei-yeboah et al., 2017). The current study reported a high prevalence (>80%) of MetS using the WHO criteria which was comparable among gender. These results are agreement to previous studies which reported high prevalence's (>70%) of MetS in T2DM patients supported by (Alwan & Alhusuny, 2014; Patel et al., 2013). Presence of MetS in T2DM patient increases the risk of microvascular macrovascular complications in addition to cardiovascular disorders (Raman et al., 2010; Tan et al., 2013).

The high prevalence of Mets in the current study might have been due increased risk factors in the study participant. In fact, most (88.9%) of the T2DM patients who participated in this study had three or more MetS component risk factors and this, might explain the high prevalence of Mets. Similar findings were reported by Raman et al (2010) and Ogbera (2010) and are in support of the current study. Increased WC was the most prevalent component, followed by high WHR, elevated serum TG and elevated blood pressure; with most of the participants recording higher figures than the cut-off point (Table 3.5). Higher overall mean above the agreed cut off points for BMI, WC, TG, SBP, FBG, and HbA1c were noted in the current study. The male participants had statistically significantly higher mean WC, WHR and female higher statistically significantly TG. The current study is in agreement with other studies that have shown an association of dyslipidemia with obesity characterized by BMI>30kg/m2, elevated WC, high WHR, poor glycemic control and elevated BP. (Moreira et al.,2015; Rodrigues et al., 2008; Tamara, 2010; Wallace & Matthews, 2000). This association is a key risk factor to MetS, CVD as well as progression of T2DM complication. Over half of the patient had elevated TC and LDL-c key indicator of cardiovascular risk factor related to progression of MetS, Type 2 Diabetes and CVD (IDF 2015; WHO, 2016, 2017). Moreover, combination of these risk factors complicates the management thus escalating the problem further (Firouzi et al 2015; Godwill et al 2018; Hu et al., 2016; IDF, 2015; WHO, 2016).

Majority (77.8%) of the participants had poor glycemic control, with an average mean HbA1c of 8.49%. Similar findings were reported by Raman et al.(2010) and Moreira et al (2015). Poor glycemic control (HbA1c>7%) poses a major risk to T2DM patients and those with MetS. Moreover, combinations of risk factors such as increased WC, elevated TC, increased BP and reduced HDL, elevated TC, and elevated LDL-c may lead to poor glycemic control, development of cardiovascular, micro vascular and macro vascular complications in T2DM (ADA, 2018). A strong association of poor glycemic control, hypertension, dyslipidemia and central obesity with MetS as well as T2DM have been reported (Moreira et al., 2015; Rodrigues et al., 2008; Tamara et al., 2010; Wallace & Matthews, 2000). Elevated WC as well as high WHR or BMI and dyslipidemia have been associated with abdominal obesity, which is a major cause of insulin resistance; one of the important risk factors of MetS and T2DM (IDF, 2017;

WHO, 2016).The condition worsens in the presence of elevated blood pressure, one of the major complications in T2DM and key risk to CVD (Godwill et al., 2018; Hu et al., 2016; IDF, 2017; WHO, 2016).

Patient characteristics have been associated with increased risk to MetS, associated risk and CVD risk factors. Studying their association with Mets and associated risk is paramount as strategic way for preventive measures Studies have reported varying prevalence of MetS among gender, as well as other patient characteristics. A study by Kengen et al, (2012) reported a significant high prevalence of MetS in women compared to men. A study by Kaduka et al, (2012) in a general population showed significant association of MetS with age, level of education, monthly income and social economic status with advanced age, wealth quintile and higher education being strongly associated with MetS. A study by Tadewos et al., (2017) on T2DM also revealed significant association of gender, occupation, duration of diabetes and nutrition status with MetS.

Moreover, the current study showed different association of patient characteristics with MetS risk factors and selected CVD risk factors (Table 3.7 to Table 3.12) using multiple logistic regression. Studies have shown that occupation status of patient have been associated with improved social economic status that usually leads to adaptation of behavior traits that increase the metabolic risk in patient with Type 2 diabetes (Barlin & Mercan, 2016). The current study was unique as it showed some association of economic status with increased MetS risk with patient having a higher income being associated with elevated blood pressure (BP). Patient occupation status also showed some significant association with high WHR. A study by Ogunsina et al (2018) is in support of the current study as it showed that high social economic status for both men and women was associated with increased odds of overweight/ obesity. Patient with secondary education from the current study were associated with increased odds of obesity and elevated TG. However current study reported reduced risk of overall MetS as income level increased (Table 3.12) supporting the evidence that high income levels is associated with reduced risk (Mavarez-Martinez et al 2016).

Additionally, patients with a family history of diabetes and were taking alcohol were also associated with obesity. Patient who had lived with T2DM ≥15 years were also associated with elevated TG. Family history of diabetes (FHD), alcohol intake and increased years with diabetes predisposes T2DM patient to metabolic risk like obesity and dyslipidemia as well as associated complication (Gopalakrishnan et al., 2017) and this is in support of our current study. Moreover, gender, marital status and type of residence were associated with reduced HDL-c with female patient, married patient and patient living in urban areas being significantly associated with increased odds of reduced HDL-c. This might have been due to adapted behaviour by the patients.

The study had some limitations. The above study was conducted in a Hospital setup on T2DM patients visiting the clinic. Thus, the result might not represent a true sample of population, given that some diabetes patients may not be attending the clinic. To find out the true prevalence, a community-based study needs to be conducted and comparison with hospital-based studies done. However, several studies conducted on T2DM on prevalence of MetS in different countries have been done on hospital set up, hence making our result comparable.

3.6 Conclusion

A high prevalence of MetS in the current study was noted in T2DM patients using the WHO and harmonized criteria. The most prevalent components of the MetS were elevated WC, increased WHR, and elevated TG and elevated BP. The current study showed that participants with some form of occupation had attained secondary education and earned a higher income was associated with increased MetS risk factors. Income was associated with elevated diastolic blood pressure (DBP), secondary education and years lived with diabetes were associated with elevated TG, while occupation showed some association with high WHR. Additionally, Gender, marital status and type of residence were associated with reduced HDL-c while education, family history of diabetes and alcohol intake was associated with obesity. This calls for an urgent action aimed at preventing the progression of the patients to diabetes complications and cardiovascular problems. Increased surveillance on MetS in Type 2 Diabetes patients need to be hastened and preventive measures (like lifestyle and diet

intake modification, doing regular moderate to vigorous intensity physical exercises) put in place to prevent the condition from worsening

CHAPTER FOUR

RELATIONSHIP BETWEEN PATIENT CHARACTERISTICS AND HBA1C IN TYPE 2 DIABETES MELLITUS PATIENTS ATTENDING CARE THIKA LEVEL FIVE HOSPITAL, KENYA

Manuscript has been Published by AJFAND DOI: 10.18697/ajfand.87.18420; Citation Thuita AW, Kiage BN, Onyango AN and AO Makokha: Relationship between glycemic control and patient characteristics in Type 2 Diabetes patients attending Thika Level Five Hospital, Kenya

4.1 Abstract

Type 2 Diabetes Mellitus (T2DM) is a metabolic disorder characterized by hyperglycemia due to relative insulin secretion deficiency and insulin resistance. It is a global pandemic of public health concern with increasing prevalence each year. Social demographic, lifestyle and metabolic characteristics play a crucial role in development and progression of T2DM. Studies indicate that poor glycemic control worsens T2DM, leading to complications that are life threatening and very costly to treat. Therefore, this calls for a need to explore the relationship between patient characteristics and glycemic control (HbA1c). One hundred and fifty-three (153) subjects (40.5% men and 59.5% women) with T2DM aged 20-79 years and attending care at Thika Level Five Hospital were enrolled in the study. Socio-demographic, clinical and lifestyle data were obtained using structured questionnaires. Their nutritional status was determined using anthropometrical methods. Lipid profile that included total cholesterol, (TC); high density lipoprotein-cholesterol, (HDL-c); low density lipoprotein cholesterol, (LDL-c) and triglyceride, (TG,) were determined by enzymatic method while glycated hemoglobin (HbA1c) and fasting blood sugar (FBS) were determined using high-performance liquid chromatography (HPLC) and glucose oxidase methods, respectively. Blood pressure of the patients was also determined. Overall sample size was 153. The overall mean age of patients was 56. Years, and the mean age of patients with poor glycemic control (HbA1c>7%) was 57 years. The prevalence of the poor glycemic control (HbA1c>7%) was 77.8%. Participants with HbA1c > 7% showed statistically significant higher means for FBG; 11.71±3.11mmol/l vs. 8.54±3.19 (P<0.01), TC; 5.11±1.21mmol/l vs. 4.48±1.16 (P<0.01), and LDL- c ; 2.66±1.07 mmol/l vs. 2.22±1.04 (P=0.03) than their counterparts with good glycemic control The study showed a significant strong positive correlation between HbA1c and FBG (r=0.679, p<0.01); family history of diabetes, (FHD) (r=0.165, p<0.05); systolic blood pressure, (SBP) moderated with FHD (r=0.168, p<0.05); and diastolic blood pressure (DBP) moderated with FHD(r=0.181, p<0.05). In conclusion, poor glycemic control was associated with high blood pressure, high fasting blood glucose and dyslipidemia all of which are risk factors for macrovascular, and microvascular cardiovascular complications.

Key words: Type 2 Diabetes Mellitus, glycemic control, cardiovascular risk, Patient characteristic.

4.2 Introduction

Type 2 diabetes mellitus (T2DM) is a heterogeneous disorder characterized by hyperglycemia due to relative insulin insufficiency and impaired effectiveness of insulin action (ADA, 2018). It is a global public health problem and life threatening condition with increasing prevalence each year (IDF, 2017; WHO, 2016). It is estimated that about 424.9 million (8.8%) adults worldwide aged between 20-79 years had suffered from T2DM in 2017 with 4.0 million deaths (IDF, 2017). This prevalence is projected to increase to 628.6 million (9.9%) by the year 2045, if no interventions are put in place (IDF, 2017). The problem is especially worse in the West Pacific region (158.8 million) followed by South East Asia (82million) with Africa registering a prevalence of 15.9 million and a projection of 40.7 million by 2045 (IDF, 2017). In Kenya, it is estimated that 458,900 (2.0%) people had T2DM by 2017 (IDF, 2017). However, this prevalence might be higher due to high rate of undiagnosed diabetes (IDF, 2017).

In most of the developed countries, T2DM is the fourth leading cause of death. According to studies, this pandemic is now also in many developing countries including Kenya (IDF, 2017; WHO, 2016). Type 2 diabetes mellitus (T2DM) is the main cause of morbidity in developed countries, with a fast growing incidence due to demographic transition and changes in the population's lifestyle (IDF, 2017; WHO, 2016). Traditionally, T2DM was mainly diagnosed in people aged 20 years or older (IDF, 2017). Increasingly, however, it is now being diagnosed in younger patients as well, as a consequence of the growing incidence of childhood obesity (IDF, 2017).

To diagnose T2DM, there are a number of biomarkers that are traditionally used like fasting plasma glucose of ≥ 7 mmol/L, taken after at least 8 hours of no caloric intake; or by a 2-hour plasma glucose value (2 h PG) of ≥ 11.1 mmol/L, after administration of a glucose load containing an equivalent of 75 g of anhydrous glucose dissolved in water, a method referred to as the oral glucose tolerance test (OGTT). For patients with classic symptoms of hyperglycaemia a random plasma glucose of ≥ 11.1 mmol/l is

diagnostic (ADA, 2018). Furthermore, T2DM can be determined using glycated hemoglobin (HbA1c) of above 7% (ADA, 2018).

Type 2 diabetes mellitus (T2DM) results from a complex interaction between genetics, metabolic and environmental factors, among which lifestyle has an important role in its development (Gohel et al., 2012). Moreover, social, economic, and lifestyle factors are also associated with the development and progression of T2DM (Gohel et al., 2012; Hill et al., 2013; Los Angeles County Department of Public Health, 2013). Among the social and economic determinants in T2DM, income, education, employment, housing, access to nutritious food, family and social support are central to the development of T2DM (Gohel et al., 2012; Hill et al., Los Angeles County Department of Public Health, 2013). All these have also been shown to influence health behavior like adherence to medication and lifestyle choices which are fundamental to management of T2DM (Hill et al., 2013).

Glycated hemoglobin A (HbA1c) is a hemoglobin variant that is formed when glucose binds covalently to the beta-chain of hemoglobin A (HbA) which is characterized by formation of initial shift base that is subsequently arranged to a stable Amadori product, produced in the early stage of advanced glycation end products (AGEs) formation. The formation of AGEs plays an important role in the development and progression of the long term complications of Type 2 diabetes mellitus (ADA, 2018). Therefore, determination of HbA1c is key in management of patients with Type 2 diabetes mellitus as it helps in the monitoring of long-term glycemic status (2-3months) and therefore helps in evaluating the adequacy of diabetes management in addition to adjusting therapies (ADA, 2018). Glycated Hemoglobin (HbA1c) has been accepted world over as a reliable indicator in assessing chronic glycaemia in T2DM patients and its importance in the management of T2DM is well established (ADA, 2018; WHO, 2016).

Preventing T2DM and its complications are global public health priorities (IDF, 2017; WHO, 2016). Moreover, understanding the relationship between patient characteristics and HbA1c is important in T2DM prevention at different levels. Indeed, this would act as one of the key elements to support the preventive programme aimed

at ensuring good glycemic control as well as reducing T2DM related complications. Therefore, the present research aimed at exploring the relationship between patient characteristics and HbA1c in T2DM patients attending Thika Level 5 Hospitals in Kenya. The results may help in developing strategies aimed at preventing T2DM and its complications.

4.3 Methodology

This study employed a cross-sectional design to determine the relationship between patient characteristics and HbA1c. It was a hospital-based study conducted on T2DM patients aged 20-79 years who were attending Thika Level 5 Hospital Diabetes Comprehensive Care Centre (DCC). Type 2 diabetes mellitus (T2DM) patients with complications like renal failure, congestive heart failure (CCF), and stroke were excluded from the study during recruitment. The medical conditions were verified from hospital records in the presence of a physician who was present during recruitment.

The demographic data was obtained using structured questionnaires. Anthropometric measurements which included weight, height, waist and hip circumferences were measured using standard methods (CDC, 2009; WHO, 2008). Body Mass Index (BMI) was calculated as weight (kilograms)/height (meters) ^{2} and classified as per WHO classification (WHO, 2006). Systolic and diastolic blood pressure was measured by trained nurses on the left arm with a Spengler digital sphygmomanometer (model:Autortensio® noSPG440) while the subjects were in a seated position with the arm supported at heart level and recorded in mmHg. Level of serum triglycerides (TG) was determined using Glycerol Phosphate Oxidase Peroxidase GPO/POD, endpoint method (Bucolo & David, 1973) , total cholesterol (TC) using Cholesterol Oxidase Peroxidase (CHOD-POD), end point method (Keppy et al., 2009) and high density lipoprotein (HDL-c) using Phosphotungstic Acid, end Point method (Assmann et al., 1983). Serum low density lipoprotein cholesterol (LDL-C) was calculated using the Friedwald's formula (LDL-cholesterol (mmol/l)=Total cholesterol-(HDL-c+triglycerides/2.181) (Friedewald et al., 1972).Glycated hemoglobin (HbA1c) was determined by Biorad D-10 hemoglobin testing system an automated analyzer,

intended for percent determination of HbA1c in human blood using high-performance liquid chromatography (Klenk et al., 1982) and fasting blood glucose (FBG) was determined by glucose oxidase method (Beach & Turner, 1958).

4.3.1 Classification of biochemical parameters

Glycemic status was categorized as: good glycemic control (HbA1c <7%) and poor control (HbA1c >7%) as per the American Diabetes Association; ADA (2018).Elevated blood pressure was considered for participants with systolic/diastolic pressure of 130/80 mmHg or those already using hypertensive drugs (AAC, 2017). Classification of lipid profiles was done as described by the ADA (2018) and American Association of Clinical Endocrinologists; AACE and American College of Endocrinology; (2017). These include elevated triglycerides (≥1.7 mmol/l and/or the use of triglyceride-lowering drugs), reduced HDL cholesterol (<1.0 mmo/l in males and <1.3 mmol/l in female(s), elevated LDL cholesterol (>2.6 mmol/l) and elevated total cholesterol (>5.2 mmol/l) (AACE &ACE, 2017; ADA, 2018).

4.3.2 Classification of anthropometric parameters

High waist circumference was considered if the participant had waist circumference ≥94 cm in males and ≥80 cm in females (Alberti et al., 2009) and BMI was categorized as obese >30 kg/m^2 and non-obese <30 kg/m^2 (WHO, 2006).

4.3.3 Sample size determination

A minimum sample size of 139 was determined using the formula by Armitage et al (2008) and Lwanga & Lemeshow (1991). The sample size was subjected to a correction factor of 10% to cater for attrition; hence a total sample size of 153 was used. Details on sample size calculation is as indicated in Appendix II

4.3.4 Data analysis

Data analysis was performed using Microsoft windows SPSS version 20. Data were expressed as mean ± standard deviation for continuous variables or proportion and percentages for categorical variables. Categorical variables were compared using Chi-

Square test or fishers exact test. Independent-t- test was used to determine statistical differences between groups. The relationship between patient characteristic and HbA1c was first determined using Pearson bivariate correlation for continuous variables and Point biserial correlation for categorical variables. Bivariate regression analysis was performed to determine patient characteristics (social demographic, medical history, lifestyle and metabolic risk factors) associated with poor glycemic control (HbA1c >7%) in patients with T2DM. An odds ratio with a P-value of <0.05 was considered statistically significant. Multivariate linear regression analysis was performed to evaluate whether the prediction of the metabolic risk factors alone and with an interaction term (Family History of Diabetes; FHD) contributed to the risk of poor glycemic control. A standardized regression coefficient (β) with $p<0.05$ was considered significant.

4.3.5 Ethical approval

Ethical approval to conduct the research was granted by Kenyatta National Hospital and University of Nairobi Ethical Committee (Permit No. KNH-ERC/A/232) while administrative approval was granted by the National Commission for Science, Technology and Innovation (NACOSTI) Permit No. NACOSTI / P/16/83452/10118 the Ministry of Interior and Co-ordination of National Government, County Commissioner Kiambu Permit No. ED.12/1/VOL.IV/92; Ministry of Education Kiambu Permit No. KBU/CDE/HR/4/VOL.II (138); County health officials and health facility administrators

4.4 Results

The study had 153 participants with a mean age of 56 years, a mean HbA1c of 8.5% and a prevalence of 77.8% HbA1c above 7%. As shown in Table 4.1, there was a statistically significant difference in mean HbA1c between patient with a family history of diabetes (8.16±1.62%, p=0.04) compared to those without (8.77±2.00%). Additionally there was statistically significant difference in mean HbA1c between patient aged >50 years (8.70 ± 1.03, p=0.04) compared to those <50 years. When the mean HbA1c was compared between other patient characteristics, there was no statistical significant difference. However, all patients showed a mean HbA1c of above

7% in all the studied characteristics (Table 4.1). Nevertheless, bivariate logistic regression showed that there was a tendency for better glycemic control as the educational level increased, with significant Odd Ratio (OR=O.069, 95% confidence interval; C1 0.006 – 0.774 p=0.03) for participants who had attained tertiary education (Table 4.1).

Table 4. 1: Characteristics of Type 2 diabetes mellitus patients at level 5 Hospital

Parameters		Totals	HbA1c mean±sd	P value†	HbA1c >7%	HbA1c <7%	Odd ratio	95% CI	P value††
Gender	Male	62(40.5)	8.64±1.99	0.375	51(33.3%)	11(7.2%)	ref		
	Female	91(59.5)	8.37±1.76		68(44.4%)	23(15.0%)	0.538	0.173-1.674	0.28
Age	20-39	4(2.6)							
	20-39	10(6.6)	8.23±1.28	0.463	9(75%)	3(25%)	ref		
	40-49	29(19.1)	7.96±1.43		20(69%)	9(31%)	1.908	0.290-12.561	0.50
	50-59	46(30.5)	8.71±1.73		34(73.9%)	12(26.1%)	2.016	0.319-12.720	0.47
	60-69	42(27.6)	8.65±1.79		38(88.4%)	5(11.4%)	1.083	0.139-8.431	0.94
	70-79	23(15.1)	8.52±1.99		18(78.3%)	5(21.7%)	2.294	0.242-21.775	0.47
Marital status	Single	16(10.5)	7.84±1.94		10(62.5%)	6(37.5%)	ref		
	Married	129(84.3)	8.61±1.20	0.235	102(77.1%)	27(20.9%)	0.466	0.019-11.183	0.64
	Separated /divorced	5(3.3)	7.92±0.49		5(100%)		0.344	0.018 -6.648	0.48
	Widowed	3(2.0)	7.30±0.60		2(66.7%)	1(33.3%)	0.000	0.000	1.00
Education background	Primary	84(54.9)	8.41±1.95	0.889	61(72.6%)	23(27.4%)	ref		
	Secondary	54(35.3)	8.52±1.77		44(81.8%)	10(18.5%)	0.368	0.119 – 1.131	0.08
	Tertiary	14(9.2)	8.70±1.73		13(92.9%)	1(7.1)	0.069	0.006 – 0.774	0.03*
	None	1(0.7)	9.50		1(100%)		0.000	0.000	1.00
Occupation	Formal	6(3.9)	7.85±1.43	0.705	4(66.7%)	2(33.3%)	ref		
	Casual	10(6.5)	8.54±1.82		8(80%)	2(20%)	0.771	0.049–12.210	0.85
	Farming	63(41.2)	8.68±1.98		52(82.5%)	11(17.5%)	0.598	0.063 – 5.722	0.66
	Business	48(31.3)	8.25±1.61		33(68.8%)	15(31.2%)	0.683	0.136 – 3.423	0.64
	Unemployed	26(17.1)	8.57±2.10		22(84.6%)	4(15.4%)	1.689	0.354 – 8.068	0.51
Residence	Rural	95(62.1)	8.67±1.94	0.110	78(82.1%)	17(17.9%)	ref		
	Urban	58(37.9)	8.18±1.67		41(70.7%)	17(29.3%)	0.524	0.160 – 1.714	0.26
Income Levels	<1000	72 (47.1)	8.69±1.85	0.434	61(84.7%)	11(15.3%)	ref		
	>1001-5000	32 (20.9)	8.24±1.84		22(68.8%)	10(31.2%)	0.548	0.117 - 2.522	0.44
	>5001-10000	23 (15.0)	8.06±1.78		17(73.9%)	6(26.1%)	1.594	0.341 - 7.457	0.55
	>10000	26 (17.0)	8.59±1.94		19(73.1%)	7(26.9%)	1.584	0.333 – 7.539	0.56
FHD	Yes	71 (46.4)	8.16±1.62	0.041	54(76.1%)	17(23.9%)	ref		
	No	82 (53.6)	8.77±2.00		65(79.3%)	17(20.7%)	1.374	0.532	0.51
YLWD	1-4 years	89 (58.9)	8.55±1.95	0.343	66(76.4%)	21(23.5)	ref		
	>5-10years	30 (19.6)	8.28±1.73		29(80%)	6(20%)	0.408	0.035 – 4.717	0.47
	>10-15years	19 (12.4)	8.42±1.59		15(78.9%)	4(21.1%)	0.531	0.041 – 6.955	0.63
	>15-20years	10 (6.5)	9.25±1.99		9(90%)	1(10%)	0.552	0.039 – 7.916	0.66
	>20years	5 (3.3)	7.22±1.00		3(60%)	2(20%)	0.106	0.004 – 2.645	0.17
PA	Light	71 (46.4)	8.29±1.70	0.380	56(78.6%)	15(21.1%)	ref		
	Moderate	73 (47.4)	8.51±1.96		55(70.2%)	18(29.8%)	1.448	0.144–14.615	0.75
	Vigorous	9 (5.9)	9.03±2.22		22(84.8%)	4(15.4%)	3.038	0.298–31.016	0.35

n represents the number of participants while (%) represents the percentage; OR – Odds ratio; 95% CI- 95% confidence interval; * statistical significance at p value<0.05, ** statistical significance at p value<0.01 ref -reference point, PA: Physical activity; FHD: Family history of diabetes; YLWD: Years lived with diabetes; HbA1c: Glycated hymoglobin

As indicated on Table 4.2, participants with a HbA1c > 7% had statistically significant higher mean in TC (5.11±1.21 mmol/l, P<0.01) and LDL (2.66±1.07 mmol/l, P=0.03) compared to those with HbA1c <7%. However, the other metabolic parameters (BMI, WC, WHR, TG, HDL, SBP and DBP) showed no significant difference in their means between groups with HbA1c >7% and those with HbA1c<7%. Additionally, the current study reported higher means above the recommended levels in TG, HDL, SBP and DBP for participant having a HbA1c >7% (Table 4.2).

Multivariate logistic regression was used to determine the association between HbA1c and metabolic parameters of the participants (Table 4.3). The OR showed that subjects who had elevated SBP (OR=0.273; 95% CI=0.110-0.680, p value=0.005) and elevated TG (OR=0.392; 95%CI=0.16-0.95, p value=0.04) were significantly at risk of poor glycemic control compared to those with normal levels (Table 4.3). All the other metabolic parameters had no statistically significant associations (Table 4.3).

Table 4. 2: Patient characteristics and metabolic parameters of the participants categorized by glycemic control levels

Parameter	HbA1c		P values ([a])
	>7%	<7%	
	Mean±SD	Mean±SD	
Age (years)	56.79±11.61	53.56±11.78	0.111
BMI(Kg/m2)	26.97±4.88	27.23±4.08	0.774
WC(cm)	100.62±10.04	101.62±9.18	0.604
WHR	0.96±0.097	0.97±0.083	0.984
DBP(mmHg)	89.25±9.68	87.64±9.10	0.389
SBP(mmHg)	145.34±19.51	138.35±21.42	0.074
FBG(mmol/L)	11.71±3.11	8.54±3.19	<0.001*
TG(mmol/L)	2.32±1.12	1.92±0.90	0.060
HDL-c(mmol/L)	1.39±0.34	1.36±0.39	0.689
TC(mmol/L)	5.11±1.21	4.48±1.16	0.008*
LDL-c(mmol/L)	2.66±1.07	2.22±1.04	0.034*

*statistical significance at $p<0.05$; ([a]) independent t test Data are presented as mean ± standard deviation of the mean. BMI: body mass index, WC: waist circumference; WHR: waist-to-hip ratio, SBP: systolic blood pressure, DBP: diastolic blood pressure, FBG: fasting blood glucose TG: triglycerides, HDL-c: high density lipoprotein –cholesterol LDL-c low density lipoprotein- cholesterol, TC: total cholesterol and HbA1c –glycated hymoglobin

Table 4. 3: Multivariate logistic regression between HbA1c and patient cardiovascular risk factors

Parameter		HbA1c>7% n (%)	HbA1c<7% N (%)	OR	95% CI	P value
Obese	Yes	25(75.8)	8(24.2)	1.215	0.442 – 3.340	0.706
	No	94(78.3)	26(21.7)	ref		
Elevated WC	Yes	106(76.3)	33(23.7)	5.801	0.668 – 50.366	0.111
	No	13(92.9)	1(7.1)	ref		
Elevated SBP	Yes	89(83.2)	18(11.8)	0.273	0.110 – 0.680	0.005*
	No	30(65.2)	16(34.8)	ref		
Elevated DBP	Yes	91(77.8)	26(22.2)	1.430	0.514 – 3.978	0.493
	No	28(77.8)	8(22.2)	ref		
Reduced HDL	Yes	31(70.5)	13(29.5)	1.745	0.713 – 4.269	0.223
	No	88(80.7)	21(19.3)	ref		
Elevated TG	Yes	81(81.8)	18(18.2)	0.392	0.161 – 0.954	0.039*
	No	38(70.4)	16(29.6)	ref		
Elevated LDL	Yes	58(85.3)	10(14.7)	0.288	0.056 -1.478	0.136
	No	61(718)	24(28.2)	ref		
Elevated TC	Yes	54(84.4)	10(15.6)	1.562	0.287 – 8.505	0.606
	No	65(73.0)	24(27.0)	ref		

n represents the number of participants while (%) represents the percentage; *statistical significance at p value<0.05, ref: represent reference point , OR- odd ratio, 95% CI- 95% confidence interval, HbA1c- glycated Hymoglobin. Obesity: BMI>30Kg/m2; elevated WC: >90cm for men or >84cm for women; elevated SBP: >130mmhg; elevated DBP: >80mmhg; Reduced HDL cholesterol: <1.0 mmol/L for men or<1.3 mmol/L for women or specific treatment for this abnormality; elevated TG :> 1.7mmol/l; elevated LDL: >2.6mmol/l and elevated TC: >5.2mmol/l

As shown in Table 4.4, there was a significant strong positive correlation between FBG with HbA1c (r=0.679, p<0.001). Additionally, a statistical positive correlation was seen between FHD (r=0.165, p=0.045. However, all the other metabolic parameter had a positive correlation that was not statistically significant except for WC that showed a negative correlation (Table 4.4). Moreover, age of the participant also showed a positive association (r=0.102) that was not statistically significant (Table 4.4). After moderating the metabolic parameters with FHD, the current study showed a significant

positive correlation between SBP*FHD and HbA1c (r=0.168 p=0.04) DBP*FHD and HbA1c (r=0.181, p=0.03) and FBG *FHD (r=0.586, p<0.001). All the other metabolic parameters after moderating showed a positive correlation with HbA1c that was not significant except for WC*FHD that showed a negative correlation but was not statistically significant (Table 4.4).

Table 4. 4: Bivariate correlation between Glycemic controls (HbA1c) with patient characteristics

Parameter	HbA1c r	P value
WC	-0.018a	0.83
HDL	-0.016 a	0.85
TG	0.022 a	0.79
FBG	0.699 a	<0.001**
BMI	0.030 a	0.71
WHR	-0.017 a	0.83
SBP	0.041 a	0.61
DBP	0.076 a	0.35
LDL-C	0.019 a	0.82
TC	0.023 a	0.77
Age	0.102 a	0.21
Years lived with diabetes	-0.082 a	0.31
FHD	0.165b	0.045*
WC * FHD	0.138 a	0.09
BMI * FHD	0.152 a	0.06
HDL-C * FHD	0.104 a	0.06
TG * FHD	0.078 a	0.34
LDL-C * FHD	-0.109 a	0.18
TC * FHD	0.144 a	0.08
SBP * FHD	0.168 a	0.04*
DBP * FHD	0.181 a	0.03*
FBG * FHD	0.586 a	<0.001*

**Correlation is significant at the 0.01 level (2-tailed); *Correlation is significant at the 0.05 level (2-tailed). aPearson correlation analysis. bPoint biserial correlation; BMI: body mass index; SBP: Systolic blood pressure; DBP: diastolic blood pressure; HDL-: high-density lipoprotein cholesterol; LDL-C: low-density lipoprotein cholesterol; FBG: fasting blood glucose; TC: total cholesterol; TG: triglycerides; WC-waist circumference; BMI: body mass index; FHD: Family history of diabetes

Since only FBG, FHD, SBP*FHD, DBP*FHD and FBG * FHD had a significant relationship with HbA1c (Table 4), they were subjected to further analysis using linear regression $Y=\beta_0+\beta_1X_1$ ε; $Y=\beta_0+\beta_1X_1+\beta_1X_2+\varepsilon$ and

$Y=\beta_0+\beta_1X_1+\beta_2X_2+\beta_3X_2Z_1+\beta_4X_2Z_2+\varepsilon$ to determine whether they had a positive effects on glycemic control (HbA1c) in patient with T2DM (β^0 is the Y intercept /constant; β_i is the slope coefficient representing relationship of the associated of independent variable X_i where; X_1: FBG; X_2: FHD; X_2Z_1 : FHD *SBP; X_2Z_2- FHD *DBP and ε: the error term). The stepwise method was used for multivariate analysis.

As shown in Table 4.5, there was a statistically significant relationship between FBG and HbA1c ($\beta=0.0679$, $p < 0.001$), in the first model. In model 2 a significant relationship between FBG and HbA1c ($\beta=0.671$, $p <0.001$) and; FHD and HbA1c ($\beta=0.119$, $p=0.047$ was seen. After inclusion of FHD as the moderating variables, a statistically significant relationship was only seen in moderated variable (FBG*FHD) ($\beta=0.640$, $p=0.02$) with no relationship in the FBG and FHD. The R2 value was 0.462, 0.473, 0.493 and 0.488 indicating that 46.2%, 47.3%, 49.3% and 48.8% of the variations in HbA1c could be explained by FBS; FBG and FHD: FBG, FHD and FBG*FHD and FHD and FBG*FHD. The scatterplot of standardized predicted values versus standardized residuals showed that the data met the assumptions of homogeneity of variance and linearity and the residuals were approximately normally distributed. From the ANOVA analysis, the model were valid indicating that the independent variables FBG; FBG and FHD; FBG, FBG, FHD, FBG*FHD and FHD, FBG *FHD are good predictors of HbA1c [$F (1,152)=129.42$, $p <0.001$; $F (2,152)=68.00$, $p <0.001$; $F (3,152) =48.36$, $p<0.001$; $F (2,152)=71.35$, $p<0.001$].

Table 4. 5: Multivariate linear regression between HbA1c and participant characteristics

Model	Parameters	B	R squared	P value.	95% CI
1	FBGa	0.679	0.462	<0.001	0.307 – 0.436
2	FBGa	0.671		<0.001	0.303 –0.431
	FHDa	0.119	0.476	0.047	0.006 -0.874
3	FBGa	0.252		0.19	-0.070– 0.346
	FHDa	-0.317		0.11	-2.638 – 0.283
	FBG*FHDb	0.640	0.493	0.02	0.020 – 0.275
4	FHDa	-0.553		<0.001	-2.676 –1.428
	FBG*FHDb	0.988	0.488	<0.001	0.189 – 0.267

HbA1c-Glycated hymoglobin; FBS-fasting blood glucose; FHD- Family history of diabetes
β- Standardized regression coefficient, statistical significant p<0.05, 95% CI- 95 % confidence interval, a –independent variables included in the regression, b - moderated variables included in the regression

4.5 Discussion

Type 2 Diabetes Mellitus (T2DM) is a major metabolic disorder of global public health concern due to its increasing prevalence as well as related complications associated with poor glycemic control (IDF, 2017). Glycemic control can be described by either the amount of HbA1c or FBG levels (ADA, 2018). In the current study, HbA1c as defined by ADA was used to determine glycemic control (ADA, 2018). Glycated hemoglobin (HbA1c) of <7% is recommended for T2DM patients since higher levels (HbA1c>7%) are associated with increased risk to microvasucular and macrovasucular complications. Good glycemic control (HbA1c<7%) is one of the best strategies to prevent and delay the progression of T2DM complications (ADA, 2018). In fact, the ADA recommends the prevention of T2DM complications because this leads to improved quality of life (ADA, 2018).

The current study showed a high prevalence (77.8%) of inadequate glycemic control (HbA1c>7%) as well as a high mean (8.5%) above the recommended level of HbA1c<7% in T2DM patients studied. These findings are in agreement with other studies conducted in T2DM patients that showed higher rates above 8% as well as high prevalence's > 60% of poor glycemic control (HbA1c>7%) (Firouzi et al., 2015; Lima et al., 2016). This actually indicates that there seems to be poor glycemic control

amongst T2DM patients which may predispose them to complications and thus negatively impact their quality of life.

Moreover, the study results also found higher rates of poor glycemic control that were prevalent in participant aged >50years (Table 4.1). Indeed, age has been shown to be a risk factor in T2DM and associated cardiovascular risk with increased prevalence as people age (Nazaimoon et al., 2011). This might be due to increased insulin resistance and increased fat metabolism with advanced age (Suastika & Dwipayana, 2012). A study by Ekpenyong et al., (2012) reported an increased prevalence of T2DM in older patient and is in support of the current study. However, when the mean HbA1c between other patient characteristics (gender, education, marital status, occupation, income levels, residence and physical activity levels) was compared, there was no statistical difference. All the same, all participants showed a mean HbA1c of above 7% in all the studied characteristics (Table 4.1) signifying that all patients had poor glycemic control despite their characteristics.

Nevertheless, bivariate logistic regression showed that there was a tendency for better glycemic control as the educational level increased, with participants who had attained tertiary education having better control (Table 4 1). Indeed studies have shown a relationship between good glycemic control and higher education attainment (Andrade, Ribeiro, Santos, Neves, & Moreira, 2017) and the current study is in support of this.

The mean FBG, LDL, and TC were significantly higher in patient who had a HbA1C >7%. This was not surprising since studies as well as International Diabetes Federation (IDF) and World Health Organization (WHO) have shown that elevated LDL>2.6mmol/l as well as TC>5.3mmol/l in T2DM patients are indicators of dyslipidemia which is a major risk to glycemic management and related complications as well as cardiovascular risk (Hu et al., 2016; IDF, 2017; WHO, 2016). The current study reported higher means in LDL-C and TG (Table 4.2) above recommended levels in participants with a HbA1c>7%. Indeed, elevated LDL and high TC are also patients risk factors which predisposes them to insulin resistance, a key contributor to poor

glycemic control, microvascular and macrovascular complications as well as cardiovascular disorders (IDF, 2017; WHO;, 2016).

Additionally, in the current study, higher means above the recommended levels were noted in TG, HDL, SBP and DBP for participant having a HbA1c >7% (Table 4 2). This might indicate that the participants were at risk of being obese, having hyper-triglycemia as well as high blood pressure in addition to poor glycemic control. All these factors combined worsens the problem (IDF, 2017; WHO, 2016). Moreover high BMI and dyslipidemia are key indicators of obesity. In fact, obesity is a major cause of insulin resistance as well as reduced insulin sensitivity (Godwill et al., 2018). Both reduced insulin sensitivity and increased obesity are key risk factors in T2DM patients and major causes of poor glycemic control, 2016).

Additionally, when multivariate logistic regression (Table 4 3) was done, it indicated that participants who had elevated SBP and high TG were at risk of high HbA1c. Elevated (BP) defined by either an elevated SBP and/or elevated DBP (AAC,2017) as well as elevated TG are key risk factors and related complications to Type 2 diabetes (IDF, 2017; WHO, 2016). Studies as well as IDF and WHO have shown that poor glycemic control in T2DM patients have been associated with increased blood pressure as major risk factors as well as associated complications (Hu et al., 2016; IDF, 2017; WHO, 2016).

Moreover, the bivariate correlation ($r=0.766$, $p<0.001$) (Table 4 4) and multivariate linear regression results ($\beta=0.679$, $P<0.001$) (Table 4 5) showed that FBG is significant and positively related to HbA1c signifying that FBG is an important predictor to optimal glycemic control. According, Ghazanfari et al (2010), there is a significant relationship between FBG and HbA1c. Furthermore, a study by Gupta et al (2014) reported a positive correlation between FBG and HbA1c as well as higher mean HbA1c above 8% which is further in agreement with the current study.

Poor glycemic control in T2DM patient have been associated with increased blood pressure a major risk factor as well as associated complication(IDF, 2017; WHO, 2016). The current study reported a statistically significant positive relationship between HbA1c and FHD as well as SBP and DBP moderated with FHD (Table 4 5),

supporting the evidence that elevated blood pressure is a risk factor to T2DM that may worsen in the presence of a FHD (AAC, 2017; AACE and ACE, 2017; ADA, 2018). Additionally, participants with SBP>130mmhg had a significant association with HbA1c>7% and this is in support of earlier studies that reported a significant association of elevated BP and poor glycemic control (Hu et al., 2016).

Further, the current study showed that there was a strong positive correlation between FHD with HbA1c. Studies have reported that FHD have been associated with reduced insulin sensitivity and increased insulin resistance (Godwill et al., 2018; Vázquez et al., 2014). Hence, this might explain the positive correlation between FHD and HbA1c in the current study (Gopalakrishnan et al., 2017). Moreover, our findings are in support of studies that have indicated a significant association between FHD and HbA1c (Godwill et al., 2018; Vázquez et al., 2014).

4.6 Conclusion

In conclusion, the study reported a significant relationship between HbA1c with advanced age and FHD. HbA1c was also significantly associated with high BP, high FBG and dyslipidemia (TC, LDL). These metabolic factors (BP, FBG, TC, and LDL) in T2DM patient increase the risk of macrovascular, microvasucular as well as cardiovascular risk.

CHAPTER FIVE

EFFECT OF NUTRITION EDUCATION ON KNOWLEDGE LEVEL IN TYPE 2 DIABETES MELLITUS PATIENTS, "A RANDOMIZED CONTROL TRIAL"

Manuscript has been submitted for publication; Journal of Nutrition and Dietetics as Thuita A.W, Kiage B.N, Onyango A.O and Makokha A.O; Nutrition education improves knowledge scores on dietary management, physical activity and glycemic index among Type 2 diabetes mellitus patients in a Randomized control trial.

5.1 Abstract

Type 2 diabetes mellitus (T2DM) is on the increase hence the need for preventive strategies to curb this upward trajectory. Diabetes education is one of the preventive strategies that can be adapted and employed with the aim of increasing knowledge and awareness of overall management of T2DM Therefore, the aim of this study was to determine the effect nutrition education on knowledge level in T2DM patients. The study was a randomized control trial with two intervention groups; nutrition education peer to peer support (NEP) group and nutrition education (NE) group, and a control (C) group. The NE group received nutrition education alone. The NEP group received nutrition education with additional peer to peer support component. The nutrition education classes run for eight weeks 2 hrs. each. Standard care was given to the control group. A pre-test questionnaire testing knowledge on diabetes management (5 questions), diet management (10 questions), glycemic index (10 questions) and physical activity (5 questions) was administered to all the groups before the intervention and the same questionnaire was administered after the intervention, at month one, month three and month six. Mean percentage knowledge score was determined and compared between groups using Analysis of co-variance (ANCOVA). The results showed that there were no statistically significant differences in the knowledge score of the participants at baseline in all the groups. However, knowledge scores improved significantly ($p<0.01$) post intervention in the NEP +42.45% after intervention, +40.00% at month one, +34.53% at month three and +36.68% at month six post intervention after intervention. The knowledge score also improved in NE; +38.34% after intervention, +35.37% at month one, +31.12% at month three and +33.10% at month six post intervention. The greatest improvement was seen one month after the intervention in the two intervention groups. When the knowledge score differences between the groups was compared, there was a statistically significant difference ($p<0.05$) between NEP and NE at 1one month post intervention (4.33%, p<0-05) and at six month post intervention (3.58%; $p<0.05$); between NEP and C after the intervention (37.99%; $p<0.01$), at one month post intervention (35.13%; $p<0.01$) at three months post intervention (29.04%; $p<0.01$) at six month post intervention (32.57%; $p<0.01$) and between NE and C at the end of the intervention (34.16%;

p<0.01), at three months post intervention (30.80%; p<0-01), and at six month post intervention (25.91%; p<0.01), In conclusion, the finding of the study showed that the application of nutrition education in T2DM patient improved the knowledge score in diabetes management, diet management, physical activity and knowledge on glycemic index. Furthermore, the inclusion of peer to peer support improved the outcome; hence we recommend that nutrition education with peer to peer support can be adapted as a preventive strategy for type diabetes mellitus patients.

Key word: Nutrition education, Peer to peer support Type 2 Diabetes Mellitus, Physical Activity, Diet, Glycemic index

5.2 Introduction

Type 2 diabetes mellitus (T2DM) is a global health problem and is becoming a serious challenge due to its associated complications and increased cost of care (IDF, 2017). This epidemic is on the increase with a prevalence of 425 billion adults aged 20-79 years having T2DM (IDF, 2017). To combat this burden, different preventive and management approaches that aims at promoting good glycemic control and reducing complication need to be adapted (ADA, 2018, 2019; IDF, 2016, 2017). These includes among others early diagnosis and continuous monitoring of glucose level, screening for complications as well as lifestyle modification (healthy diet and physical activity) (Askariet al., 2013; Muchiri et al., 2016; WHO, 2016). Despite the importance in lifestyle modification to improved care and overall metabolic outcomes, low knowledge levels on importance of diet and physical activity, key component, in lifestyle changes have been reported (Breen et al., 2017; Odenigbo & Inya-osuu, 2012) A study Kassahun & Mekonen (2017) conducted on T2DM reported limited knowledge while a study by Maina et al (2010) in Kenya also reported poor knowledge levels in T2DM patient. Other studies have also reported poor knowledge on general management of T2DM as well as poor knowledge on management of metabolic disorder being reported to affect adherence to lifestyle changes (Alefishat, Farha, & Al-Debei, 2016; Cristina et al., 2015). Therefore, it is evident that there is poor level of knowledge in management of T2DM which translates to poor level of care hence the need for enhanced preventive strategy aimed at improving management and overall

care. These preventive strategies need to be communicated to the patient as well as the stakeholders. This can be achieved through diabetes education.

In fact, diabetes education when employed in a well-structured manner has been shown to enhance knowledge in the management of T2DM as well as improve skills in diabetes self-care (Muchiri et al., 2016). Moreover, studies have shown that application of diabetes education in management of T2DM has led to improved behavior to lifestyle change, compliance to diabetes treatment (medication, diet and exercise), better glycemic control as well improved metabolic outcome (Adachi et al., 2013; Bayat, et al., 2013; Yuan et al., 2014). Diabetes education aims at enabling and empowering the patient in active self-management through knowledge acquisition. Different strategies that include individual counseling, group education, peer to peer support and telecommunication using different health model have been used to implement diabetes education (Adachi et al., 2013; Bayat et al., 2013; Liu et al., 2015; Muchiri et al., 2016). Persons with T2DM have reported potential benefits from diabetes education which includes improved understating of diabetes as well as its management, ability to make healthy food choices as well as participating in physical activities through improved lifestyle behavior. All these benefits have been linked to improved quality of life (Breen et al., 2017; Muchiri, Gericke, & Rheeder, 2015; Muchiri et al., 2016).

Nutrition education is a main component in diabetes education and has been shown to improve dietary behavior and clinical outcomes in persons withT2DM (Muchiri et al., 2015, 2016; WHO, 2016). This has been applied using different strategies that includes peer to peer support, text message, group education session, individual counseling among others (Bayat et al., 2013; Liu et al., 2015; Mardani et al., 2010; Zhang et al., 2016). Peer to peer support nutrition education strategy applied on T2DM patient has shown improved metabolic outcome, hence, can be adapted in management of T2DM in addition to other strategies (Liu et al., 2015). Despite the importance of structured diabetes education, using different strategies being effective, very few patients receive it. Kenya as country has come up with several guidelines aimed at alleviating poor knowledge levels as well as overall diabetes management such guideline includes among other the Kenya national diabetes strategy Kenya diabetes educator manual and

diabetes prevention and management guide for community health works. However, despite the guideline being in place, implementation remains poor (WHO, 2014b). Additionally, a study by Mwavua et al (2016) also indicates that the level of care is suboptimal. Therefore, this study aims to fill this gap by providing a structured nutrition education package to T2DM and assess its effectiveness on knowledge retention.

5.3 Methodology

5.3.1 Study design

This was a randomized control trial with two intervention groups (Nutrition Education group; NE and Nutrition Education Peer to Peer support group; NEP) and one control group (C). The NEP group received nutrition education with peer to peer support, while the NE group received nutrition education alone. The control group (C) group received standard care. Nutrition knowledge was assessed before start of the intervention, at the end of the intervention, one month after the intervention, three months and six months after the intervention.

5.3.2 Study setting

The study was conducted at Thika Level 5 Hospital (TL5H), which is in Thika Sub County, Kiambu County, Kenya. Thika Level 5 Hospital (TL5H) is a referral hospital as well as a treatment site for the entire population of Thika, its environment and neighbouring counties. The hospital was purposively selected as it operates an outpatient diabetes clinic daily and has a Diabetes Comprehensive Care Centre (DCC) that was established in 2011 due to demand of a comprehensive care for T2DM. This demand arose due to increased prevalence of T2DM in the region as well as related complications. Type 2 diabetes mellitus (T2DM) patients who attend this clinic are either self or clinician refereed from the county and the nearby counties. The clinic provides a comprehensive care in a single setting hence a preference for most T2DM patients. However as reported by Mwavua et al (2016), the level of care is sub optimal with nutrition education getting little emphasis during health talk. Implementation of exiting guidelines in Kenya for management of T2DM is also poor (Shiroya et al., 2019; Subramanian et al., 2017; WHO, 2014b) This therefore, calls for a detailed

nutrition education programme aimed at improving knowledge and self-care for the participants.

5.3.3 Study participants

The study participants were T2DM patients aged between 20-79 years attending diabetes care at TL5H. Participants with T2DM aged 20-79 years, willing to attend meeting on appointment days for the six months were included in the study. The participants included in the study also signed an informed consent. Participant with T2DM aged 20-79 years and had complications, like renal failure, congestive heart failure (CCF), and stroke were excluded from the study during recruitment.

5.3.4 Sample size

The sample size was determined using a formula by Armitage et al (2008) and Lwanga & Lemeshow (1991). A sample size of 46 participants was found adequate for each group. An attrition of 10% was given hence each group had a 51 participant. Recruitment of the participants was done for 2 months between the months of August to October 2016. The recruited participants gave their contacts and this was used for contacting the participants and reminding them of their appointment days.

5.3.5 Randomization

The study participants were randomized into three groups; Nutrition education peer support group (NEP), nutrition education group (NE) and control group (C) using lottery method. After randomization, the groups were given appointment days for delivery of the intervention and control group for standard care.

5.3.6 Development of nutrition education curriculum for T2DM

The nutrition education curriculum was developed after review of studies and reports on T2DM patients employing a nutrition education model (IDF, 2017; Mohamed, 2014; Muchiri et al., 2016; Paula et al., 2015; Platkin et al., 2014). The curriculum aimed at imparting knowledge to participants on diabetes management and lifestyle modification. The education material included a component on importance of nutrition

in management of T2DM as well as an introduction to diabetes management. The goal of the education material was to provide a basic understanding of the relationship between T2DM and nutrition, to help patient improve recognition of the food groups and increase awareness of the importance of combining foods for improved glycemic control and to improve diabetic meal planning skills. Recommendations from medical nutrition therapy in management of T2DM were adapted in order to achieve this goal (ADA, 2016).

5.3.7 Intervention

The study employed the social cognitive theory (Bandura, 2012) and expected that the nutrition education could lead to knowledge acquisition on nutrition management of T2DM. Those participants who consented to participate in the study, were given appointment days. Each group had a separate day. The participants were called and invited for the study in their respective days.

Before random assignment to either control or intervention groups, all study participants received standard education in the form of lectures that review T2DM and its symptoms, treatments, and associated complications as well as overall management. The NE group received weekly nutrition education sessions for eight weeks programme (NE group). The NEP group received a weekly nutrition education session together with peer to peer support component. The nutrition education included weekly (120 minutes each) nutrition classes that were conducted over eight weeks by the researcher with the help of research assistant The nutrition education curriculum, was developed by the researcher after review of literature on studies and that have applied nutrition education in management of T2DM guidelines (ADA; American Diabetes Association, 2017; Mohamed, 2014; Muchiri et al., 2016; Muchiri et al 2011) as well as review of existing guidelines on management of T2DM in Kenya (MoPHS, 2010a, 2012). Additionally, posters from Ministry of Health as well as Norvo No – disk were also used in the education sessions. The study lasted eight weeks based on experience of other researchers whose intervention lasted the same period, and the period was adequate (Asaad et al., 2016; Askari et al., 2013; Muchiri et al., 2015).

The curriculum was presented in eight sessions and focused on nutrition in relation to diabetes, on food portion control for weight reduction, and use of healthier food choices, an individualized meal planning and glycemic index control. Participants learned about the basics food groups, the difference between simple and complex carbohydrates and their relation to the glycemic index, fibre content of the foods, the difference between saturated and unsaturated fats and its relation to cholesterol and atherosclerosis; food sources of protein and the different fat content of each; hidden calories contained in beverages; and the micronutrient and fibre values of fruits and vegetables.

The first session covered the principle of health eating, importance of variety in T2DM management as well as importance of cereals, roots and tubers group in management of T2DM. Legumes group, nuts and seed group and their role in T2DM management was covered in session 2, week 2; while importance of meat and daily group in management of T2DM in session three, week three; importance of Vegetable and fruit group in management of T2DM in session 4, week four and importance of fat and oil in management of T2DM in session five, week five. Meal planning, portion control and meal frequency was covered in session ix week six while importance of glycemic index, glycemic load and nutrition fact and labels in management of T2DM in session seven week seven. The curriculum also had a lesson on types of physical activity as well as its importance in T2DM management that was covered in session 8, week eight.

The nutrition education curriculum was first tested in a subgroup (10% of sample) of patients not involved in the study before the actual implementation. The physical activity curriculum was adapted from the WHO Global strategy on diet and physical activity and health (WHO, 2006b), WHO Global recommendation on physical activity for health (WHO; World Health Organization, 2010b) as well as from ADA position statement in exercise (Colberg et al., 2016) and Mikusova et al (2009) which was modified by the researcher with the help of a physiotherapist to suit the study participants. Details of physical activity lesson are as per Appendix XII, Session 8.

Previous studies have highlighted the importance of peer support (Bahun & Savic, 2011; Boothroyd, et al., 2014; David Simmons et al., 2013). Participants in the NEP

intervention group were grouped in small support group of 5-10 participants each depending on the location they come from as well as age cohort. They were encouraged to set and share with other each other weekly goals for specific changes in their eating and physical activity behaviour aimed at making healthy food choices, reduction of portion sizes and being active. Participants then reported on their progress at the beginning of the next session. After the eight weeks training sessions the peer to peer support continued and the participants presented their goal to other members on monthly basis for six month. The goals were re-evaluated and if not met problem that affected implementation of the goal identified and the goal reset. The aim of the peer to peer support was to enhance appraisal and information support, mutual reciprocity and shared problem solving as well as emotional support. The peer to peer support strategy was adapted from De Vries et al (2014) and Heisler (2010) The researcher helped the patient review their goals and if there was any adjustment required done. Also group counselling was given on each visit. More details in Appendix II.

5.3.8 Delivery of the nutrition education content

The nutrition education content was delivered to the two intervention groups (NE and NEP) and included weekly (120 minutes) nutrition classes conducted over eight weeks by the researcher. The nutrition education was presented in the form of group enabled sessions. Different methods were used for delivery that included lectures, role play, demonstration, group assignment among others. These delivery methods aimed at giving direct, interactive and experimental approach to delivery of information. The language of communication used in the study was Kiswahili and English as the participants were a combination of different tribes. This is because Thika is a Cosmo-political town. Local language Kikuyu was also used as a third language for patients of Kikuyu origin who could not understand using Kiswahili and English.

Demonstration of food groups was done using the locally available foods. Lessons on different serving sizes using local foods, was done and participants were requested to demonstrate servings of different sizes to their group members. Household utensils that included different plate sizes, cups, glasses, serving spoons of different sizes were used during the demonstrations. Ready to eat food was also used for demonstrations.

The foods used were sourced from the TL5H hospital kitchen. Emphasis on colour selection using the signal system was given and demonstrated during serving. Different serving sizes as per the food groups guide using cooked food and row food was given. Different portion size methods that included the plate mode l and Zimbabwe hand jive were used during demonstrations. Participants performed role plays by putting emphasis on the importance of nutrition in diabetes management. Lessons on menu planning using samples of different menus and label reading were also given. Participants shared their local recipes and the PI and the research assistants assisted them to improve into healthy menu plans. Portion control was emphasized during menu planning.

Additionally, the researcher gave participants foods with different labels and gave them time to study them and communicate to their group members what was contained in the labels. This aimed at assisting participants to make informed decisions before purchasing any food products. Glycemic index of different foods were also given. Locally available foods were used while communicating the glycemic indices of different foods. The participants were encouraged to form groups and classify food samples given to high, low or medium glycemic index using the signal system. Moreover, differences between glycemic load and glycemic index were given and demonstrations done. Participants were also given a chance to practice. A one-day lesson on physical activity was given that included importance of exercise in T2DM, types of exercise recommended, and time for exercises. The physical activity pyramid was used to demonstrate different physical activity levels Demonstrations of different exercises were given by the PI together with a physiotherapy trained on diabetes management. During these sessions, participants were requested to dress ready for exercise. They were also encouraged to achieve at least 30 minutes of moderate activity daily for at least five days a week.

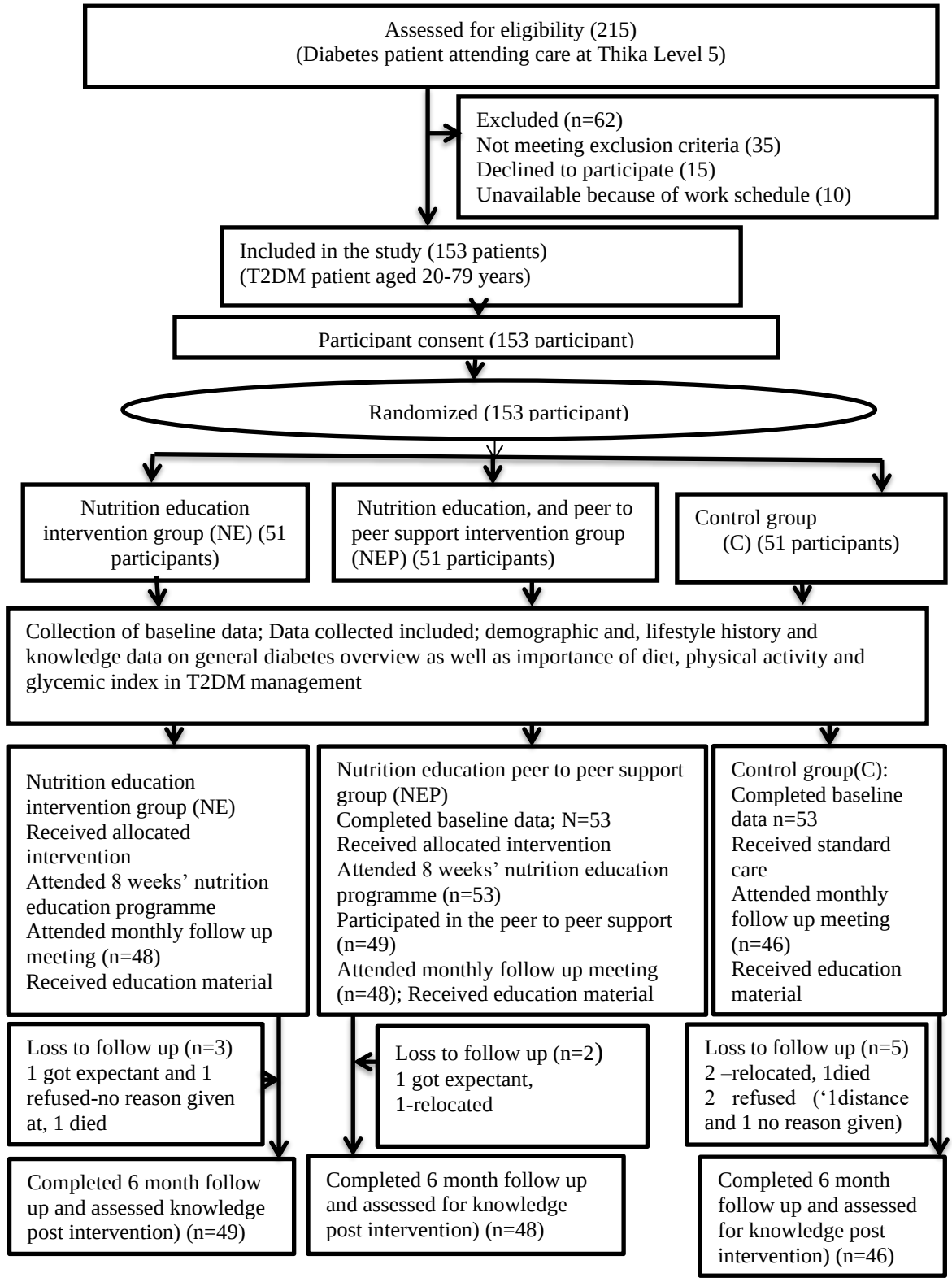

Figure 5. 1: Randomization and flow of participants throughout the study

5.3.9 Standard care

The standard care was provided to the participant in the control group. The standard care during the study included registration of the participants in the clinic in the morning on arrival, and after registration a general health talk on diabetes management was given at the DCC. After the health talk patient care profile was taken that included blood pressure, fasting blood glucose and nutrition status (weight, height and BMI computation, WC and HC). For those participants requiring clinical intervention they were examined by a clinician and treated accordingly. This continued during the study period. After six month of follow up the Control group was taken through the nutrition education sessions given to the NE group.

5.3.10 Follow up

Weekly meetings during intervention period were held for the intervention groups. Monthly follow up meetings were done for all the groups and data on knowledge collected immediately after the intervention, at month 1 post intervention, month 3 post intervention and month 6 month six post intervention for all the groups. In order to minimize drop-out, the PI made a phone call to all participants 3 days prior to each weekly meeting and reminded them on the day before the meeting. Similarly, they were called one week prior to each monthly meeting and reminded the day before the meeting. Other strategies applied included; active participation, allowing participants to choose appropriate day and time for the meetings and providing snacks during the meetings. The participants requiring treatment and other hospital services were supported by the clinicians and any problem encountered during their clinics visit was addressed. Other details of follow up are in Appendix II.

5.3.11 Data collection

Data was collected using a pretest and posttest questionnaire to test knowledge delivery as well as examining whether delivery method used was adequate. Before implementation of the curriculum, a pretest questionnaire was given to all participants in all the groups. The PI took participants through the question before they started answering to ensure they understand what was being asked. The questionnaire had

questions on general management of diabetes (5), health diet (10), physical activity (5) and glycemic index (5). The same questionnaire was given at the end of the intervention, at one-month post intervention, at 3 months' post intervention and at six months' post intervention. The average score of the questions was used to compute the total pretest and posttest score. The posttest evaluation was done after the intervention, month1 post intervention, month 3 post intervention and at month 6 post intervention. Finally, grading of the education session delivery was done only for the intervention groups; hence a sample size of 102 participants was used for the analysis.

5.3.12 Data analysis

Data was analyzed using Statistical Package for Social Science (SPSS) Version 20. Nutrition education delivery assessment was presented as frequency and statistical significance using chi square test was set at $p<0.05$. Pre and post test data between the groups was analyzed using analysis of co-variance (ANCOVA) while controlling for baseline characteristic (age, gender, marital status, education level, years lived with diabetes and family history of diabetes). The data was presented as mean (Standard error; SE) and statistical significance set at $p<0.05$.

5.4 Results

5.4.1 Baseline characteristics

As shown in Table 5.1, the mean age of the participants was 56 years with more than half having attained primary education in all the groups; 54.9% in NEP group, 52.9% in NE group and 56.9% in C group. Majority (85%) of the participants had received information about including vegetables in their meals, while only 45.8% had been told to take plenty of water. Other information given to the participant before the start of the study included information of including vegetables in their meals, avoiding alcohol, eating a low fat diet, eating non-refined carbohydrates as well as use of the plate method in portion control as shown in Table 5.1

Table 5. 1 : Baseline characteristic of the participants

Parameters		NEP Mean±SD or n (%)	NE Mean±SD or n (%)	C Mean±SD or n (%)	Total Mean±SD or n (%)	P value
Age		56 ±11.67	57±10.88	55 ±12.34	56±11.97	0.76
Education level	**No education**	0(0)	0(0)	1(2)	1(0.7)	0.7
	Primary	28(54.9)	27(52.9)	29(56.9)	84(54.9)	
	Secondary	20(39.2)	18(35.3)	16(31.4)	54(35.3)	
	Tertiary	3(5.9)	6(11.8)	5(9.8)	14(9.2)	
Nutrition information	**Include vegetable in meals**	42(82.4)	42(82.4)	46(90.2)	130(85)	0.44
	Take plenty of water	22(43.1)	20(39.2)	28(54.9)	70(45.8)	0.25
	Include protein in meal	27(52.9)	19(37.3)	19(37.3)	65(45.2)	0.18
	Eat non-refined carbohydrates	5(9.8)	4(7.8)	1(2.0)	10(6.5)	0.25
	Avoid alcohol	3(2.0)	1(2.0)	5(9.8)	9(5.9)	0.24
	Use plate model in portion control	5(9.8)	2(3.9)	5(9.8)	12(7.8)	0.44
	Consume low fat diet	11(21.6)	9(17.6)	8(15.7)	28(18.3)	0.74
Place where information was received	**Hospital**	45(88.2)	43(84.3)	40(78.4)	125(82.4)	0.49
	Media	3(5.9)	4(7.8)	3(5.9)	10(635)	
	church	1(2.0)	3(5.9)	4(7.8)	8(5.2)	
	Others (from friends and group gathering)	2(3.9)	1(2.0)	4(7.8)	7(4.6)	
Source of nutrition information	**Doctor**	2(3.9)	7(13.7)	4(7.8)	13(8.5)	0.17
	Nutritionist	44(86.3)	38(74.5)	41(80.4)	123(80.4)	
	media	3(5.9)	4(7.8)	3(5.9)	10(6.5)	
	Relative/friend/group gathering	2(3.9)	2(3.9)	3(5.1)	7(4.6)	

Data presentment as proportion (n) and Percentage (%) or Mean (SD; Standard deviation); NEP: Nutrition education peer to peer support group; NE: Nutrition education group and C: Control group.

χ^{2-} chi square

significant level =$p<0.05$

5.4.2 Knowledge score of the participants

As shown in Table 5.2 there was no statistically significant difference in knowledge score of the participants at baseline in all the groups. However, knowledge score improved significantly post intervention in the NEP group; +42.45% at the end of intervention, +40.00% at month one post intervention, +34.53% at month three post intervention and +36.68%, at month six post intervention (Table 5.2). There was also improvement of overall knowledge in NE group; +38.34% after intervention, +35.37% at month one post intervention, +31.12% at month three post intervention and +33.10% at month six post intervention (Table 5.2). The greatest improvement was seen one month after the intervention in both intervention groups (NEP and NE) (Table 5.2). Comparison of knowledge score differences between the groups was statistically significant ($p<0.05$) between NEP and NE (4.33 %,) and at month 1 post intervention and (3.59 %, $p<0.05$) six-months post intervention. Statistically significant mean percentage difference was also seen between NEP and C after intervention (37.99%), at month one post intervention (35.13%), at month three post intervention (29.04%) and at month six post intervention (32.57%). Additionally, statistically significant difference was also seen between NE and C ($p<0.01$) after intervention 34.16%, at month one post intervention (30.80%), at month three post intervention (25.91%) and at month six post intervention (28.98%) (Table 5.2).

Table 5. 2: General Diabetes Percentage Knowledge Score of the Participants Before the intervention, at the end of the Intervention, at Month 1, at Month3 and at Month 6 Post Intervention

Months	NEP Mean(SE)	NE Mean(SE)	CMean(SE)	P value	NEP-NE Mean(SED)	NEP-C Mean(SED)	NE-CMean(SED)
Pretest KS	45.38(1.18)	45.22(1.17)	44.41(1.16)	0.82	-0.29(1.51)	0.66(1.50)	0.94(1.49)
Posttest KS (After intervention)	86.61(1.13)	82.78(1.12)	48.62(1.11)	<0.001	3.38(1.60)	37.99(1.59)**	34..16(1.57)**
Posttest KS Month1 post intervention	84.15(1.15)	79.82(1.15)	49.02(1.14)	<0.001	4.33(1.64)*	35.13(1.63)**	30.80(1.61)**
Posttest KS Month3 post intervention	78.61(1.20)	75.61(1.20)	49.70(1.19)	<0.001	3.13(1.71)	29.04(1.70)**	25.91(1.68)**
Posttest KS Month6 post intervention	80.98(1.04)	77.38(1.02)	48.40(1.06)	<0.001	3.59(1.17)*	32.57(1.16)**	28.98(1.15)**
Percntage Knowledge change of the participants							
Changes in KS post intervention	42.45(1.51)	38.34(1.50)	5.12(1.49)	<0.001	4.12(2.14)	38.34(2.14)**	33.22(2.12)**
Change in KS at month 1 post intervention	40.00(1.52)	35.37(1.53)	5.52(1.51)	<0.001	4.63(2.17)*	34.47(2.16)**	29.84(2.14)**
Change in KS at month 3 post intervention	34.53(1.64)	31.12(1.65)	6.20(1.66)	<0.001	3.41(2.34)	28.33(2.35)**	24.92(2.33)**
Change in KS at month 6 post intervention	36.68(1.30)	33.10(1.28)	5.07(1.32)	<0.001	3.58(1.84)	31.61(1.87)	28.03(1.84)

KS- Knowledge score in percentage

Data represented in percentage (%) mean (Standard error; SE) or percentage (%) Mean (SED; Standard error of difference. Baseline (n=51 in all the groups,); month1 (n= 51 in NEP group, n=5 in NE group, n=50 in C group); month3 (n=51 in NEP group, n= 50 in NE group and n=48 in C group); month6 (n=48 in NEP group, N=49 in NE group and n=46 in C group); Knowledge score presented as a percentage; *Statistical significance at p<0.05, ** statistical significance at p<0.01. Data analyzed using analysis of Co- variance (ANCOVA); all data was adjusted for baseline characteristics (age, gender, marital status, education level of the participants' family history of diabetes. and years lived with diabetes

The study reported an average knowledge score of less than 50% general diabetes management. Specifically, the score was 42.78% in NEP group, 43.38% in NE group and 42.95% in C group (Table 5.3). For dietary management it was 44.33% in NEP group, 45.01% in NE group and 43.34% in C group (Table 5.3). Additionally, knowledge on glycemic index and physical activity was also below 50% for all the groups at baseline (Table 5.3). Nevertheless, the Knowledge score percentage for general management of diabetes improved significantly ($p<0.001$) after the intervention 88.08% at month one (85.02%), at month three (79.07%) and at month post intervention (82.05%) in the NEP group.

Additionally, there was also improvement in knowledge score percentage in diet management knowledge; after the intervention (88.37%), at month one post intervention (85.28%), at month three post intervention (79.07%) and at month six post intervention (82.05%). Glycemic index knowledge (84.25%, 82.44%, 78.58% and 78.69%) and physical activity knowledge score (85.75%, 83.84%, 79.68% and 81.68%) also showed significant improvement ($P< 0.001$) after intervention, at month one post intervention, at month three post intervention and at month six post intervention (Table 5.3). The NE group also reported significant improvement ($P<0.001$) for general diabetes management knowledge score (84.27%, 80.96%, 75.34%, 77.75%); for diet management knowledge (84.24%, 80.95%, 76.35% and 78.41%) for glycemic index knowledge (80.59%, 78.01%, 74.51% and 76.31%) and physical activity knowledge (82.02%, 79.36%, 76.25% and 77.06%) after the intervention, at month one post intervention, at month three post intervention and at month six post intervention (Table 5.3). Notably, the greatest improvement of above 80% in all parameters studied was seen at month one post intervention for both NEP and NE group (Table 5.3). Additionally, the NEP group showed the greatest improvement in all parameters studied in all the months (Table 5.3).

5.4.3 Nutrition content delivery

As shown in Table 5.4, majority (66.7% in NEP and NE) of the participants felt that the content delivered during the intervention was very good, with only 18.6% (17.6% in NEP group and 19.6% in NE group) and 14.7% (15.7% in NEP group and 13.7% in NE group) feeling that it was good and moderate, respectively. In terms of time allocation, majority 94.1% (96.1% in NEP group and 92.2% in NE group respectively) felt that the 2 hours allocated for the education session was adequate. Additionally, majority of the participants; 94.1% and 90.2% in NEP group and 96.1% and 94.1% in NE in group, felt that the intervention was important and that the teaching materials were relevant and can be adapted and used as a reminder (Table 5.4). Furthermore, majority of the participants felt the teaching methods used were appropriate and only 2.9% (3.9 in NEP and 2.0% in NE) felt that it needed revision (Table 5.4).

Table 5. 3 : Specific Percentage Knowledge Score Levels of the Participants Before the intervention, at the end of the Intervention, at Month 1, at Month3 and at Month 6 Post Intervention

	NEP Mean(SE)	NE Mean(SE)	C Mean(SE)	P value	NEP-NE Mean(SE)	NEP-C Mean(SE)	NE-C Mean(SE)
Percentage General diabetes knowledge							
Pretest KS	42.78(1.36)	43.38(1.35)	42.95(1.35)	0.949	-0.60(1.93)	-0.17(1.92)	0.43(1.90)
Posttest KS post intervention	88.08(1.22)	84.27(1.21)	49.32(1.21)	<0.001	3.81(1.74)	38.77(1.72)**	34.96(1.71)**
Posttest KS at Month1 post intervention	85.02(1.23)	80.96(1.23)	49.14(1.12)	<0.001	4.06(1.75)	35.87(1.74)**	31.82(1.72)**
Posttest KS at Month3 post intervention	77.63(1.39)	75.34(1.39)	48.00(1.37)	<0.001	2.28(1.97)	29.62(1.96)**	27.34(1.94)**
Posttest KS at Month6 post intervention	81.49(0.99)	77.75(0.98)	47.82(0.98)	<0.001	3.74(1.40)*	33.68(1.40)**	29.94(1.40)**
Percentage Knowledge on diet							
Pretest KS	44.31(0.99)	45.01(0.98)	43.34(0.97)	0.477	-0.70(1.40)	0.97(1.39)	1.67(1.38)
Posttest KS post intervention	88.37(1.22)	84.25(1.21)	49.15(1.20)	<0.001	4.12(1.73)	39.22(1.72)**	35.10(1.70)**
Posttest KS at Month1 post intervention	85.28(1.21)	80.95(1.21)	49.58(1.20)	<0.001	4.33(1.73)*	35.70(1.72)**	31.37(1.70)**
Posttest KS at Month3 post intervention	79.07(1.28)	76.35(1.28)	50.59(1.27)	<0.001	2.73(1.82)	28.49(1.81)**	25.76(1.79)**
Posttest KS at Month6 post intervention	82.05(1.01)	78.41(1.00)	48.86(1.00)	<0.001	3.65(1.44)*	33.20(1.43)**	29.52(1.41)**
Percentage Knowledge on glycemic index							
Pretest KS	44.85(1.14)	44.66(1.13	44.03(1.12)	0.867	0.19(1.62)	0.82(1.61)	0.63(1.59)
Posttest KS post intervention	84.25(1.21)	80.58(1.12)	46.63(1.19)	<0.001	4.12(1.73)	39.22(1.72)**	35.10(1.70)**
Posttest KS at Month1 post intervention	82.44(1.23)	78.01(1.24)	47.74(1.22)	<0.001	4.43(1.76)*	34.70(1.75)**	30.27(1.73)**
Posttest KS at Month3 post intervention	78.58(1.32)	74.51(1.32)	49.84(1.31)	<0.001	4.07(1.88)	28.74(1.87)**	24.67(1.85)**
Posttest KS at Month6 post intervention	78.69(0.90)	76.31(0.89)	48.63(0.89)	<0.001	2.39(1.27)	30.07(1.27)**	27.68(1.25)**
Percentage Knowledge on physical activity							
Pretest KS	44.71(1.12)	44.73(1.11)	43.70(1.11)	0.752	-0.27(1.59)	1.01(1.58)	1.04(1.56)
Posttest KS post intervention	85.75(1.12)	82.02(1.12)	49.39(1.11)	<0.001	3.73(1.60)	36.33(1.59)**	32.63(1.57)**
Posttest KS at Month1 post intervention	83.84(1.17)	79.36(1.17)	49.63(1.15)	<0.001	4.49(1.66)*	34.22(1.65)**	29.73(1.64)**
Posttest KS at Month3 post intervention	79.68(1.32)	76.25(1.32)	50.37(1.30)	<0.001	3.43(1.88)	29.31(1.87)**	25.88(1.85)**
Posttest KS at Month6 post intervention	81.68(1.07)	77.06(1.06)	48.31(1.06)	<0.001	4.62(1.52)*	33.37(1.51)**	28.75(1.50)**

Data represented in mean (Standard error; SE) Or Mean (SED; Standard error of difference). Baseline (n=51 in all the groups,); month1 (n= 51 in NEP group, n=5 in NE group, n=50 in C group); month3 (n=51 in NEP group, n= 50 in NE group and n=48 in C group); month6 (n=48 in NEP group, N=49 in NE group and n=46 in C group). All data adjusted for baseline characteristics (age, gender, marital status, education level of the participant's family history of diabetes. and years lived with diabetes. *Statistical significance at p<0.05, ** statistical significance at p<0.01. Data analyzed using analysis of Co- variance (ANCOVA); KS-Knowledge score presented as a percentage (%).

Table 5. 4. Grading of the nutrition education session by the participants

Grading of the nutrition education session	NEP (n=51)	NE(n=51)	Total (n=102)	χ^2 value	P value
Content delivery					
Very good	34(66.7)	34(66.7)	68(66.7)	0.119	0.942
Good	9(17.6)	10(19.6)	19(18.6)		
Moderate	8(15.7)	7(13.7)	15(14.7)		
Time allocation					
Adequate	49(96.1)	47(92.2)	96(94.1)	0.708	0.400
Inadequate	2(3.9)	4(7.8)	6(5.9)		
Importance of the intervention					
Information is important and act as a reminder	48(94.1)	49(96.1)	97(95.1)	0.210	0.647
Information need review	3(5.9)	2(3.9)	5(4.9)		
Teaching method used					
Appropriate	45(88.2)	47(92.2)	92(90.2)	0.520	0.771
Good	4(7.8)	3(5.9)	7(6.9)		
Need to be revised	2(3.9)	1(2.0)	3(2.9)		
Teaching materials					
Relevant and can be adapted	45(90.2)	48(94.1)	94(92.2)	0.543	0.461
Undecided	5(9.8)	3(5.9)	8(7.8)		

Data represented in portion (n) and percentage (%); Statistical significance at $p<0.05$

5.5 Discussion

Studies have shown that lack or insufficient knowledge on diabetes management is associated with, poor dietary choices and poor self-care leading to poor glycemic control and increased metabolic disorders in T2DM patients (Alefishat et al., 2016; Breen et al., 2017; Odenigbo & Inya-osuu, 2012). Therefore, strategies geared towards improving knowledge levels in diabetes management and support are recommended as one of the preventive measure for T2DM (ADA, 2018, 2019). Such strategies include among others diabetes education. Diabetes education has been shown to be the key in improving knowledge levels and management of T2DM as well as self-care management and glycemic control (Liu et al., 2015; Muchiri et al., 2015, 2016; Yuan et al., 2014). Importance of lifestyle modification is components that need to be in cooperated in diabetes education (Makrilakis et al., 2012b; Mohamed, 2014). However, despite the importance of diabetes education there is low knowledge level on general management of T2DM reported in patients (Breen et al., 2017; Kassahun & Mekonen, 2017; Obirikorang et al., 2016; Odenigbo & Inya-osuu, 2012). It is no wonder that this study also reported a knowledge level of below 50 % at baseline.

Nutrition education applied alone as a component of diabetes education or with other strategies like peer support and exercise programmes using different health models in T2DM, have been shown to increase nutrition knowledge, self-care as well as good glycemic and metabolic control in some studies (Muchiri et al., 2015, 2016; Yuan et al., 2014). The current study employed a nutrition education programme with peer to peer support using the social cognitive theory and determined its effect on knowledge retention. Our study showed an improved level in knowledge in diabetes management, dietary management of T2DM, glycemic index and physical activity in the intervention groups (Table 5.2 and Table 5.3).

The results of the study is supported by findings of a South Africa study that showed improved knowledge, behavior and clinical outcomes after application of a nutrition education programme (Muchiri et al., 2016). Another study in Egypt employing nutrition education is also in support of our study (Mohamed, 2014).

Peer to peer support in T2DM management is reported as one of the preventive strategies in T2DM management (Thankappan et al., 2018; Yin et al., 2015b). This is especially true when combined with nutrition education and diabetes self-management. A study by Taheri et al (2019) that used peer assisted learning (PAL) education in T2DM patients reported an increased knowledge scores as well as better metabolic outcomes. Indeed, inclusion of peer to peer support in our study improved knowledge scores post intervention which was significantly higher than the use of nutrition education alone. This therefore indicates that, peer support can be used in nutrition education and diabetes education and hence can be a good intervention strategy for T2DM patients' management.

Additionally, the current study showed a higher nutrition score immediately after the intervention with a drop as time progressed in all the components. For this reason, it is clear that knowledge retention was higher at the onset of and declined as time elapsed after the intervention. This therefore suggests that for nutrition education to be effective continuous update needs to be given to the patients after initial to ensure that they retained the knowledge. Moreover, knowledge scores for diabetes management and diet management recorded higher levels post intervention. However, knowledge on glycemic index was lower compared to others indicating. This gives an indication that the patient had good retention on diabetes management and diet management compared to glycemic index and physical activity knowledge.

5.6 Conclusions

Application of nutrition education in T2DM patient improved the knowledge score in diabetes management, diet management, physical activity and knowledge on glycemic index. Consequently, inclusion of peer to peer support improved the outcome further; hence nutrition education with peer to peer support can be adapted as a preventive strategy for type diabetes mellitus patients.

CHAPTER SIX

EFFECT OF A NUTRITION EDUCATION PROGRAMME ON THE METABOLIC SYNDROME IN TYPE 2 DIABETES MELLITUS PATIENTS AT A LEVEL 5 HOSPITAL IN KENYA: "A RANDOMIZED CONTROLLED TRIAL"

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6.1 Abstract

Type 2 diabetes mellitus (T2DM), is a life-threatening condition of global public health concern. It worsens in the presence of the metabolic syndrome (MetS), a complex disorder characterized by co-occurrence of at least three of such factors as hypertension, obesity, and dyslipidemia and insulin resistance. However, lifestyle interventions reduce the risk of both MetS and T2DM, and nutrition education can empower individuals on the appropriate, lifestyle changes. The aim of the current study was to evaluate the effect of a nutrition education programme, with and without inclusion of peer to peer support, on MetS in T2DM patients. This was a randomized controlled trial with two intervention groups and one control. One of the intervention groups involved a nutrition education programme with peer-to-peer support (NEP); the other involved only the education program, while the control received standard care. Each group had 51 participants. The nutrition education programme was conducted for 2h per week for 8 weeks. In addition, the NEP had weekly peer-to-peer interactions for 8 weeks. All groups had follow-up sessions for 6 months. Data on MetS risk factors as well as food intake patterns and physical activity levels were taken at baseline and at different time points during the study. Analysis of Co-variance and regression were used in the analysis. The MetS prevalence improved in the NEP (90% to 52%) and NE (86% to 69%), while it worsened in C (88% to 91%). There was improvement in the mean values of the anthropometric parameters in the NEP and NE which worsened in the control group. There was a general improvement in mean values of blood lipids, fasting blood glucose and HbA1c in all the groups, with NEP showing the greatest improvements, followed by NE, except for triglycerides and HDL where the control group had better improvement than the NE. Changes in the anthropometric and metabolic indicators mirrored the changes in food intake patterns and physical activity, where the greatest improvements occurred in the NEP. In conclusion nutrition education with inclusion of peer to peer support was of clinical benefit in improving metabolic outcomes and reducing MetS in T2DM patients.

Trial registration

The study has been registered retrospectively by Pan African Clinical Trial Registry; Registration No: PACTR201910518676391

Key words: Metabolic Syndrome, Type 2 Diabetes mellitus and cardiovascular risk

6.2 Introduction

Type 2 Diabetes mellitus (T2DM) is a metabolic disorder, characterized by poor glycemic control due to insulin insufficiency and insulin resistance (IDF, 2015). It is a global public health problem whose prevalence is increasing worldwide and especially in developing countries (Alberti et al., 2009; IDF, 2013, 2014, 2015). It is aggravated in the presence of the metabolic syndrome (MetS); a cluster of interrelated clinical factors, that include insulin resistance, dyslipidemia, excess weight and elevated blood pressure (Neill & Driscoll, 2015; Saboya et al., 2016; Thang & Mike, 2016).

Due to increased prevalence of obesity, surplus energy intake and sedentary lifestyle, Mets in Type 2 Diabetes mellitus patients is becoming a worldwide epidemic (Misra & Khurana, 2018). A high prevalence of between 50-80% of MetS in Type 2 Diabetes mellitus patients, using different definitions, has been reported in different parts of the world (Kengne et al., 2012; Osei-yeboah et al., 2017; Raman et al., 2010; Shehu et al., 2015; Tamang et al., 2013; Unadike et al.,2009). Similar high prevalence has been reported across the globe in the general population (Ford et al.,2002; Hydri et al., 2008; Kaduka et al., 2012; Nazaimoon et al., 2011; Raman et al., 2010) Presence of MetS in T2DM patients leads to an increase in microvascular and macrovascular complications (Kaduka et al., 2012; Kaur, 2014a; Nazaimoon et al., 2011; Neill & Driscoll, 2015; Patel et al., 2013; Ricci et al., 2017; Saboya et al., 2016; Thang & Mike, 2016).

Unhealthy lifestyle has been associated with faster progression of T2DM as well as MetS in T2DM patients (Mohamed, 2014; Muchiri et al., 2015; Yamaoka & Tango, 2012). However, this can be improved through lifestyle interventions such as improved nutrition and increased physical activity (Makrilakis et al., 2012a; Mohamed, 2014; Muchiri et al., 2015; Yamaoka & Tango, 2012). Unfortunately, achieving these

lifestyle modifications is usually very challenging due to poor self-control, lack of information, financial constraints among others. For this reason, well designed health education advocacy and awareness creation programmes on positive lifestyle changes should be promoted (Askari et al., 2013; Muchiri et al., 2015).

Peer to peer social and emotional support has been shown to help people apply disease management or prevention plans in daily life, and links individuals with clinical, community, and other resources (Fisher et al., 2014; Sanee et al.,2017; WHO, 2008a). Additionally, studies have shown that the effectiveness of diabetes education on lifestyle modification can be enhanced through inclusion of peer to peer support (Kazemi et al., 2016; Liu et al., 2015; Pan et al., 2016; Sanee et al., 2017; David et al., 2015; Werfalli et al., 2017). However, despite the established role of lifestyle intervention and peer to peer support in improving T2DM and MetS, its contribution to T2DM and MetS management in Africa, including Kenya, is not well established. Moreover, data on the existence of MetS in T2DM population, as well as, intervention to address MetS in Type 2 diabetes mellitus in in Kenya have not been reported. Therefore, the purpose of the present study, was to implement a nutrition education (NE) programme with peer to peer support, and evaluate its effect on the MetS and MetS risk factors in adults with T2DM

6.3 Methodology

6.3.1 Study setting

The study was conducted at Thika Level 5 Hospital (TL5H) in Kiambu County, Kenya at the Diabetes Comprehensive Care Clinic (DCC). The clinic attends to approximately one hundred patients per week. The DCC is an out-patient clinic that operates on a daily basis. Diabetic patients from Kiambu County and nearby areas attend the clinic on appointment days for routine monitoring of blood glucose, blood pressure and nutrition status (body mass index; BMI), as well as for treatment and collection of medication. Newly diagnosed patients with either Type 1diabetes mellitus (T1DM) patients or T2DM patients are also referred here from neighboring health facilities for further management. The clinic serves both male and female patients with T1DM and T2DM. The patients are mainly from low and middle income backgrounds.

6.3.2 Study design and ethics

This was a randomized controlled trial, with two intervention groups (nutrition education; NE and Nutrition education with peer to peer support; NEP) and a control group (C). The study was approved by the Kenyatta National Hospital-University of Nairobi Ethics and Research Committee (KNH-UoN-ERC), Permit No: KNH-ERC/A/232, and, the Kenya National Commission for Science, Technology and Innovation (NACOSTI); Permit No: NACOSTI/P/16/83452/10118. Study participants gave a written informed consent before the start of the study as attached in Appendix 7.

6.3.3 Study participants

Study participants were men and women, aged 20–79 years, with T2DM attending care at the Diabetes Comprehensive Care (DCC) clinic at TL5H. They were recruited during their daily clinic attendance while waiting to see a health professional. Recruitment was done over a period of 2 months from August 2016 to October 2016. All patients who met the following criteria were selected: patients suffering from T2DM aged between 20-79years, regular attendance at the DCC; not planning to move from the study area during the study period; not pregnant; with no complications such as renal failure, congestive heart failure, or stroke. A total sample size of 153 patients was recruited for the study.

6.3.4 Sample size determination

To confer 90% power at 5% level of significance, and to detect an absolute effect size of 30% improvement on metabolic syndrome (MetS) in T2DM patients (i.e. a decline from 86% to 56% Mets prevalence with intervention), 46 study participants need to be included in each study arm. The sample size was calculated using the formula by Armitage et al (2008) and Lwanga and Lemeshow (1991). The sample size was subjected to a correction factor of 10% to cater for attrition, thus each arm had 51 participants making a total sample size of 153 patients. Sample size calculation is as shown in Appenix II

6.3.5 Randomization

The study consisted of two intervention groups and a control group. The Nutrition Education (NE) group received nutrition education; the Nutrition Education with Peer-to Peer support (NEP) group received nutrition education with peer to peer support; while the control group (C) received standard care. Participants were randomized to either NE or NEP or C groups by use of random numbers as shown in Figure 6.1. To allow equal chances for participants, randomization was stratified on the basis of sex and age. Sealed sequentially numbered opaque envelopes per each stratum (1-3), mixed using the lottery method were used. The participants were requested to pick an envelope each and join their groups (1-3). A volunteer from each group was then requested to move forward and pick another envelop each, that contained their treatment allocation (NE, NEP and C). Upon confirmation of the treatment allocation, the participants were allocated to their treatment group by the researcher, and the group members recorded. Each group was assigned 51 participants. After randomization baseline data was collected from all the participants. Randomization and flow of the participants throughout the study is as shown in Figure 6.1.

6.3.6 Intervention

Before random assignment to control or intervention groups, all study participants received standard education that covered content on diabetes pathophysiology, risk factors, symptoms, complications, hyperglycemia and hypoglycemia symptoms and foot care treatment goals and modalities. This was done by the principal investigator (PI) together with a clinician who runs the clinic (Registered Clinical Officer with a Bachelor of Science degree in Clinical medicine). The Standard Education relied on pictorial flip charts and additional learning material with diabetes management information. These were adapted from the diabetes prevention and management guidelines from the Ministry of Public Health and Sanitation (MoPHS)(2010), the NorvoNodisk Changing Diabetes poster, as well as diabetes posters from the Ministry of Health (MOH), Kenya, with supplementary information provided by the researcher obtained by a review of different literature. Different teaching methods including lectures, discussions, demonstrations, role plays and group work were used to deliver

the information. The participants also received standard care that included blood glucose and blood pressure monitoring, treatment for those with problem as well as education on diabetes care by a clinician on monthly basis.

After the standard education, the intervention groups (NE and NEP) underwent a nutrition education programme for 8 weeks, which also covered the importance of physical activity (NE group). The curriculum for this programme is provided in the Appendix.XII In addition, the NEP group was trained on peer-to-peer support. The nutrition education given to the NE and NEP intervention groups included weekly (120 minutes each) nutrition classes conducted over eight weeks by the PI. The nutrition education curriculum was developed by the PI after review of related literature on nutrition management of T2DM. The researcher also applied her experience gained from practice as a nutritionist. The NE curriculum was written in English and supplemented by photos and illustrations to help the patient understanding the content better. It focused on nutrition in relation to diabetes; food portion control for weight reduction; healthier food choices; individualized meal planning, glycemic index and glycemic loads of different food and their importance in blood glucose control; the food pyramid, and its use together with food exchange list in meal planning.

Patients also learnt about the food groups, the difference between simple and complex carbohydrates and their relation to glycemic index and glycemic load, fibre content of different cereals and starches, the difference between saturated and unsaturated fats and their relation to diabetes management; sources of protein and the different nutrient content of each, hidden calories contained in beverages, and the micronutrient and fiber values of fruits and vegetables.

The nutrition education content was presented using lectures, demonstrations, discussions, and other participatory methods. The nutrition education curriculum was first tested in a subgroup (10% of sample) of patients not involved in the study before the actual implementation. The physical activity lesson was given to the intervention groups (NE and NEP group) in the last week of the education programme. The aim of the physical activity was to ensure that patients accumulate a minimum of 150 min of moderate intensity exercise each week from personal activity at home that includes

walking, digging, jogging, cycling, house hold duty, aerobics and sport activities. The participants were encouraged to perform the exercise at least 3 days each week with no more than two consecutive days without exercise. During the physical activity lesson, the patients were led through the importance of physical activity in management of T2DM. Additionally, demonstrations on activities they can do at home were done by a physiotherapist experienced in diabetes management. The participants were encouraged to continue with the exercises at home in addition to normal routine work.

Participants in the NEP group were divided into small support groups (5-10 participants); depending on the location they came from as well as their age. After each education session, members of the support groups were encouraged to set and share with one another other weekly goals for specific changes in their eating and physical activity behavior. The goals were aimed at making healthy food choices, reduction of portion sizes and being active. The participants reported on their progress to the group members at the beginning of the next session. After the eight-week training, participants were followed monthly, and they presented their progress and new goals to the group members, for a period of six months. A trained peer educator living with diabetes for 13 years from Kenya Defeat Diabetes Association (KDDA) joined the PI during the monthly meetings and encouraged the participants in the peer support groups by sharing his experiences. Together with the PI he also assisted them review and adjust their goals during monthly meetings. Also, group counseling was done on each visit for participants requiring more support.

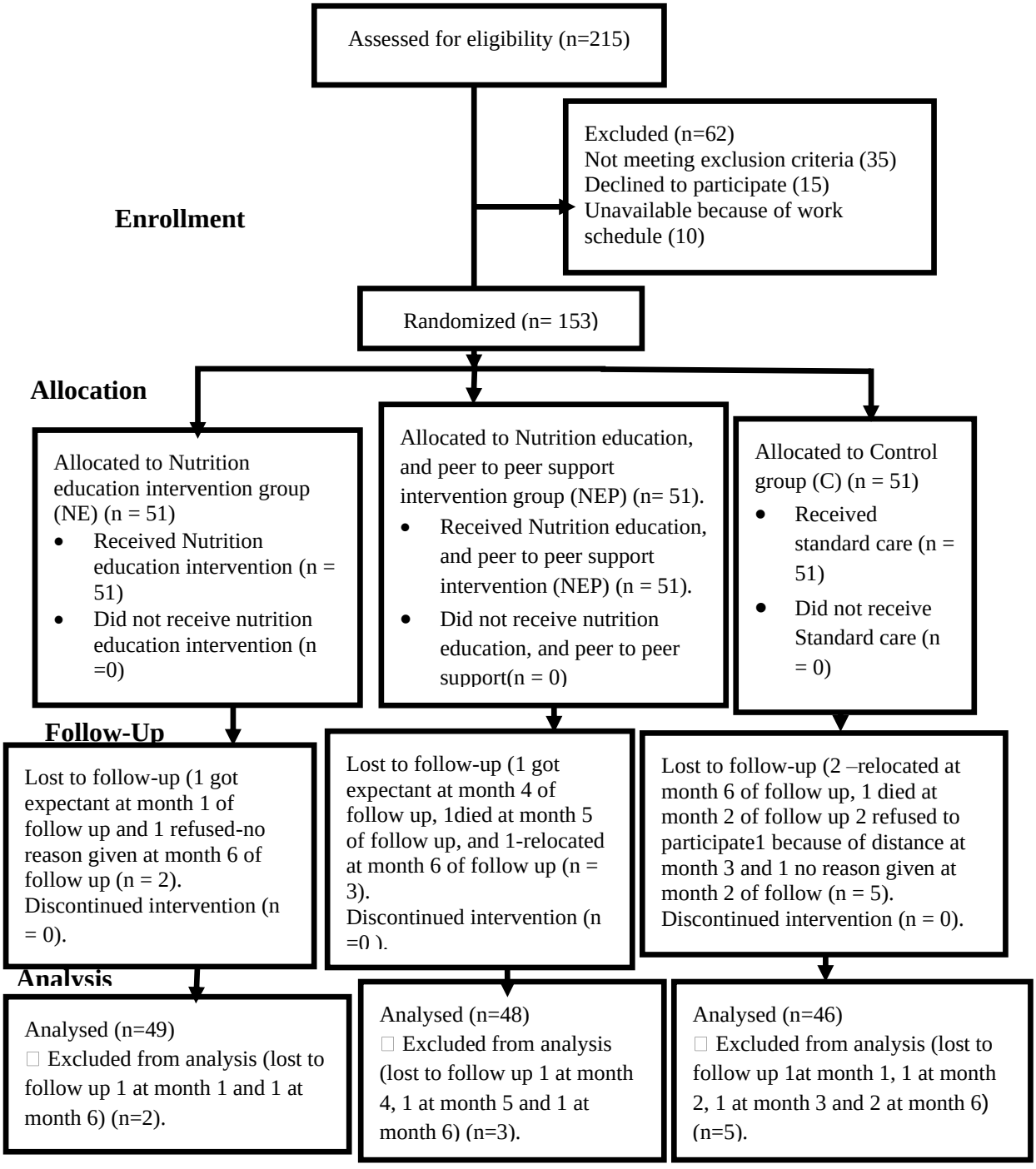

Figure 6. 1: Flow of the participants throughout the study

6.3.7 Follow up

The follow up was done monthly after the intervention period. After the end of the eight weeks' intervention the patient were requested to be coming to the hospital monthly on selected days for follow up. At the start of the study the patients were given appointment cards developed by the researcher indicating the day they were supposed to come for the appointment. The Researcher also recorded phone numbers for the participants which assisted in follow up. A call was given to the participant reminding them of the appointment day one week to the appointment day and two days to the appointment day to ensure they availed themselves. Those who did not turn up would be given another day and be reminded again of their appointment. For those who could not make to come after second reminder, they were visited in their home and requested to come for the appointment. This prevented high rate of loss to follow up. Patient in the NEP group continued with peer to peer support during the follow up period. During monthly meeting each peer group reviewed their goals with the guidance of the peer group leader, the researcher and Peer educator. The participant in the NEP group also assisted each other through group discussion. They could remind each other key principle in health eating as well as important of exercise in T2DM management in their peer groups as well as do physical activity together. More details on follow up is as explained in Appendix II.

6.3.8 Measurements

Measurements were taken on anthropometry and clinical data, blood pressure, blood glucose and lipid profile, as well as physical activity levels and food intake. A physician and clinical officer were also present during the study period to manage any patient requiring medical treatment.

6.3.8.1 Anthropometry and clinical data

Anthropometric measurement that includes weight, height, waist circumference and hip circumference were collected using standard protocols (WHO, 1995, 2008b) at baseline, during monthly follow up and post evaluation after six months. Height and weight were measured using standard methods with the participants wearing light

clothes and no shoes (WHO, 1995, 2006). The weight was determined to the nearest 0.1 kg using a calibrated electronic weigh scale (Seca model) and height to the nearest 0.1 cm using a stadiometer attached to the weighing scale. Body mass index (BMI) was then be calculated as weight (kilograms)/height (meters)^2 and classified as per WHO classification(WHO, 1995, 2006) For the elderly patient with age >60 years the researcher ensured that they stood straight without hunching. Additionally, among all the patients included in the study, all of them could stand and walk well and there was no patient who was stooping. The waist circumference and hip circumference were measured according to standard guideline (WHO, 2008b). Waist circumference was measured mid-way between the lower rib margin and the iliac crest with flexible anthropometric tape to the nearest 0.5 cm while hip circumference was measured as the maximal circumference around the buttocks posteriorly and pubic symphysis anteriorly.

6.3.8.2 Blood pressure

Blood pressure of the patients was also taken monthly. It was measured in the supine position using, a mercury sphygmomanometer (model: Autortensio® noSPG440) by trained nurses with at least a 10-min rest period before the measurement.

6.3.8.3 Laboratory assay

Blood samples were collected from each participant while in a seated position after fasting for 8-12hrs for determination of serum triglycerides (TG), total cholesterol (TC), high density lipoprotein (HDL-c), low-density lipoprotein cholesterol (LDL-c), glycated hymoglobin (HbA1c) at baseline and 6 months' post intervention. Fasting blood glucose was determined monthly. Levels of serum triglycerides(TG), total cholesterol (TC), high density lipoprotein (HDL-c), low-density lipoprotein cholesterol (LDL-c), were determined by enzymatic method (Allain et al., 1974; Assmann et al., 1983; Bucolo & David, 1973; Friedewald et al., 1972; Robinet et al., 2010; Stępień & Gonchar, 2013; Wu et al.,1989). Glycated Hemoglobin (HbA1c) and blood glucose were determined using high-performance liquid chromatography and glucose oxidase method respectively (Beach & Turner, 1958; Klenk et al., 1982).

6.3.9 Metabolic syndrome (MetS) definition

Metabolic syndrome in the study was defined according to the definition of WHO (1998) and "Circulation for Harmonizing the Metabolic Syndrome" criteria (Alberti et al., 2009). The latter requires the presence of at least three of the following five components: Fasting blood sugar of 100 mg/dl or 5.6 mmol/l or drug treatment of elevated glucose, central obesity for Africans (waist circumference ≥94 cm in males and ≥80 cm in females), elevated triglycerides (≥1.7 mmol/l or 150 mg/dl and/or the use of triglyceride-lowering drugs), reduced HDL cholesterol (<1.0 mmo/l or <40 mg/dl in males and <1.3 mmol/l or 50 mg/dl in females) and elevated blood pressure (systolic blood pressure ≥130 mmHg and/or diastolic blood pressure ≥85 mmHg and/or the use of antihypertensive drugs).

World Health Organization (WHO) criteria also requires the presence of T2DM, impaired glucose tolerance or insulin resistance, and any two of the following:(1) body mass index (BMI) ≥ 30 kg/m^2 and/or waist-to-hip ratio >0.90 (male), >0.85 (female); (2) blood pressure ≥140/≥90 mmHg or on hypertension medication; and (3) triglyceride ≥ 1.7 mmol/Land/or HDL-C < 0.91 mmol/L (male), <1.01 mmol/L (female).

6.3.10 Physical activity

Physical activity data was collected using a modified physical activity questionnaire adapted from Global physical activity questionnaire(WHO; World Health Organization, 2010a). It included questions asking the participants the type of activities they did, the time spent on each activity and number of days per week on each activity. The metabolic equivalent for each physical activity was tabulated and recorded. This was done at baseline, month 1, month 3 and month 6 post interventions.

6.3.11 Dietary intake

Dietary intake was determined by asking the participants 12 questions on healthy dietary choices adapted from perceived dietary adherence questionnaire (PDAQ) (Musee et al., 2016), dietary approach to stop hypertension questionnaire (DASH)

(NIH & NHLBI, 2006) and medical nutrition therapy (MNT) (Evert, 2014; Morris & Wylie-Rosett, 2010) (Table 6.8). These questions sought to inquire whether the participants followed their recommendation of; health diet plan, diet rich in fruits and vegetables, complex carbohydrates high in fibre, low glycemic index food that included whole grains, reduced intake of saturated fat and overall fat, included fish or fish products in their meal, reduced intake of sugars and sugar sweetened products, spaced carbohydrate intake, reduced intake of salt, included low fat food in the meal as well as, uptake of monounsaturated and polyunsaturated fat. The responses to the questions were based on a 7 Likert scale (consumption of food within 7 days of a week).

6.3.12 Data analysis

The data was analyzed using statistical package for social science (SPSS version 20). Data are present as means ± SD or SE for continuous variables and percentages for categorical variables. Chi square test and multinomial regression was used to compare groups for categorical variables and Analysis of Co-variance (ANCOVA) was used to compare difference of means between groups. Statistical significance was considered for p value <0.05.

6.4 Results

6.4.1 Participants

One hundred and fifty-three participants (153; 40.5% male and 59.5% female) were included in the study. As shown in Table 6.1, there was no significant difference in the baseline characteristics of the study participants. A total number of 143 (93.5%) participants completed the study and were used for final analysis. The losses to follow up included 3 participants in NEP, 2 participants in NE group and 5 participants in the control group as indicated in the flow diagram 6.1. The mean age of the participants was 56 years; with 46.4% of the participant having a family history of diabetes; 77.8% having poor glycemic control (HbA1c>7%) and 58.2% had lived with diabetes for 1-5 years prior the study. The prevalence of MetS was 86.3% and 88.2% as per WHO and Harmonized criteria respectively at baseline.

Table 6. 1: Baseline characteristics of the study participants

Parameter		NEP	NE	C	P Value
		Mean±SD or n (%)	Mean±SD or n (%)	Mean±SD or n (%)	
Age in years⁂		57.0 ±10.88	55.0±12.34	56.0±11.97	0.76
YLWD⁂		6.0 ± 7.10	7.0 ± 6.93	7.0 ± 6.63	0.63
Gender	Male	17(33.3)	24(47.1)	21(41.2)	0.37
	Female	34(66.7)	27(52.9)	30(58.8)	
Marital† status	Married	45(88.2)	43(84.3)	41(80.4)	0.53
	Divorced/separated/ windowed	6(11.8)	8(15.7)	10(19.6)	
Income†	<1000	26 (51.0	21 (41.2)	25 (49.0)	0.17
	1001-5000	13 (25.5)	7 (13.7)	12(23.5)	
	5001-10000	5 (9.8)	9 (17.6)	9 (17.6)	
	>10000	7 (13.7)	14 (27.5)	5(9.8)	
Occupation†	Formal employment	2(3.9)	1(2.0)	3(5.9)	0.75
	Casual employment	1(2.0)	4(7.8)	5(9.8)	
	Farming	22(43.1)	21(41.2)	20(39.2)	
	Business	15(29.4)	18(35.3)	15(29.4)	
	Unemployed	11(21.6)	7(13.7)	8(15.7)	
Complication†	Foot disease	5(9.8)	7(13.7)	5(9.8)	0.77
	Eye problem	13(25.5)	12(23.5)	11(21.6)	0.88
	Kidney problem	0(0)	2(3.9)	0(3.9)	0.11
	Neuropathy	1(2.0)	0(0)	3(5.9)	0.11
	Arthritis	6 (11.8)	7(13.7)	5(9.8)	0.83
FHD†	Yes	28 (54.9)	22(43.1)	21(41.2)	0.32
	No	23 (45.1)	29(56.9)	30(58.8)	
Medicaltion†	Oral	45 (29.4)	37 (25.2)	44(28.8)	0.08
	Insulin	9 (5.9)	6(3.9)	4(2.6)	0.32
	Oral plus insulin	2 (1.3)	3 (2.0)	3 (2.0)	0.88

⁂ data presented as mean±SD

†Data presented as proportion (n) and percentages%

Statically significance at $p<0.05$; chi ($\chi 2$) square test

n for all the groups (NEP, NE and C) =51

YLWD- years lived with diabetes

FHD – family history of diabetes

As shown in Table 6.2, there was no significant difference between the groups in the anthropometric (weight, BMI, WC, HC, WHR), clinical (SBP, DBP) and biochemical variables (HbA1c, TC, TG, HDL, LDL and FBS) at baseline. Furthermore, as shown in Table 6.2, NEP group showed greatest significant reduction in weight (-6.27 (0.87) kg; p<0.01), BMI (-2.37kg/m (0.34); p<0.01), WC (-14.51(1.34) cm; p<0.01, HC (-6.16 (1.28) cm; p<0.01) and WHR (-0.027 (0.008); p=0.01) six months' post intervention (Table 6.2). Moreover, Bonferroni post hoc comparison between groups showed that there was a significant difference (p<0.01) between NEP and C in weight lost (6.89 kg), BMI (2.26 kg/m^2) reduction, WC reduction (16.45cm) and HC reduction (10.20 cm) six months' post intervention. Additionally, significant difference (P<0.01) was also seen between NEP and NE in weight lost (4.99 kg), BMI reduction (1.89 Kg/m^2) and WC reduction (9.73 cm) as well as between NE and C in WC reduction (6.72 cm) and HC reduction (9.24 cm) (Table 6.2).

Significant increase in HDL +0.34 (0.07) mmol/l; p=0.1 was also seen in the NEP group, six months' post intervention. Further, Bonferroni post hoc comparison between groups showed a significant difference between group in HDL levels; -0.28 mmol/l between NEP and NE and +0.25 mmol/l between NE and C. Moreover, significant reduction in DBP -5.17 (1.92) mmHg was also seen in the NE group six-month post intervention (Table 6.2). Bonferroni post hoc comparison between group in DBP reduction showed a difference 7.57 mmhg between NE and C that was significant (P<0.05). Additionally, Bonferroni post hoc comparison between groups showed a significant difference in TC levels (0.69 mmol/l, p<0.05) between NEP and C as well as in HbA1c levels (1.30 %) between NEP and C. Moreover, post hoc comparison between groups was also significant in LDL levels between NEP and C (0.86 mmol/l) as well as between NE and C (0.71 mmol/l), Table 2. There was no significant mean difference for the other metabolic parameters between the intervention groups (NEP and NE) and C group (Table 6.2).

As shown in Table 6.3, there was no significant difference in MetS prevalence and metabolic risk factors (increased WC, high WHR, high FBS, elevated BP, elevated TG, reduced HDL, elevated TC, elevated LDL) as well as in high BMI (>25 kg/m^2) between group at baseline. However, the NEP intervention group significantly reduced

MetS (Odd Ratio; OR=0.08, Confidence Interval; CI=0.02-0.28, P<0.01 and OR=0.20, CI=0.06-0.68, P<0.01) as defined by harmonized and WHO criteria respectively compared to control (C) group (Table 6.3). Additionally, comparison of NE and C, six-month post intervention, also showed a significant reduction in MetS[b] prevalence (as defined by WHO criteria) in the NE group (OR=0.20, CI=0.06-0.68, p=0.01) (Table 6.3).

Additionally, comparison of NEP and C six month post intervention showed a significant reduction in prevalence of participants having increased WC (OR=0.03, CI=0.003-0.22, p<0.01), increased WHR (OR=0.09, CI=0.01-0.93, p=0.043) elevated BP as per harmonized and WHO criteria respectively (OR=4.17, CI=1.59-10.91, p<0.001 and OR=4.29, CI=1.67-11.03, P<0.01), increased TG (OR= 0.3, CI=0.13-0.75, p=0.01) as well as reduced HDL (OR=17.55, CI=2.05-150.37, p<0.01) respectively (Table 6.3).

Similarly, comparison of NE and C six months' post intervention showed a significant reduction in elevated BP as per harmonized criteria (OR=0.40, CI=0.16-0.97, p=0.04) as well as WC (OR=0.09, CI=0.01-0.07, p=0.02) (Table 5.3). Moreover, in comparison to C group, a significant increase was seen in participants having a BMI of 18.5-24.9 kg/m2 six months' post intervention in the NEP group (OR=4.62, CI=1.32-16.20, p=0.017) as well as in the NE group (OR=4.25, CI=1.09-16.59, p=0.038) (Table 5.3). Furthermore, compared to C group the NEP and NE group also showed a significant increase in participants having less than 3 MetS risk factors as per harmonized criteria definition (OR=24.03, CI=5.78-99.88, P<0.01 and OR=5.63, CI=1.63-21.77, p<0.01).

Additionally, a reduction in prevalence of participants having dyslipidemia was also seen in NEP group six-month post intervention (OR=0.30, CI=0.13-0.7, p<0.01) in comparison to control (Table 6.3).

Table 6. 2: Changes in metabolic outcomes and differences between groups six-month post intervention

Parameter	Baseline data				Changes in clinical parameters six-month post intervention++				Differences between groups post intervention		
	NEP (n=51) Mean ±SD	NE (n=51) Mean ±SD	C(n=51) Mean ±SD	P value	NEP (n=48) Mean (SE)	NE(n=49) Mean (SE)	C(n=46) Mean (SE)	P value	NEP-NE	NEP-C	NE-C
Weight	72.06±14.42	69.61±10.22	71.91±12.09	0.52	-6.27(0.87)	-1.27(0.84)	+0.63(0.87)	<0.01	4.99**	6.89**	1.89
BMI(Kg/m2)	27.64±5.72	26.34±4.16	27.11±4.04	0.38	-2.37(0.34)	-0.48(0.33)-	+0.29(0.34)	<0.01	1.89**	2.26**	0.77
WC (cm)	101.92±9.51	98.90±9.71	101.71±10.20	0.23	-14.51(1.34)	-4.78(1.29)4	+1.944(1.35)	<0.01	9.73**	16.45**	6.72**
HC (cm)	106.16±7.14	102.69±11.90	106.17±7.74	0.09	-6.16(1.28)	-5.2(1.24)	+4.04(1.29)	<0.01	0.96	10.20**	9.24**
SBP (mmHg)	145.33±21.33	146.04±19.50	139.98±18.66	0.25	-13.39(3.53)	-14.77(3.430	-5.30(3.56)	0.14	-1.38	8.09	9.47
DBP (mmHg)	87.88±10.37	90.69±8.79	88.12±9.15	0.26	-1.58(198)	-5.17(1.92)	+2.41(1.99)	0.03	-3.58	3.99	7.57*
HbA1C (%)	8.81±1.94	8.37±1.81	8.28±1.81	0.31	-2.04(0.39)	-1.48(0.39)	-0.73(0.40)	0.09	0.56	1.30*	0.75
FBG (mmol/l)	11.12±2.73	11.41±4.40	10.50±2.77	0.38	-2.59(0.66)	-2.95(0.64)	-1.55(0.68)	0.31	-0.36	1.04	1.40
TC (mmol/l)	5.23±1.43	4.77±1.07	4.91±1.13	0.12	-0.38(.24)	+0.13(0.23)	+0.30(0.24)	0.12	0.51	0.69*	0.17
TG (mmol/l)	2.32±1.37	2.00±0.92	2.39±0.89	0.16	-0.67(0.18)	-0.15(0.18)	-0.58(0.18)	0.10	0.52	0.09	-0.43
HDL (mmol/l)	1.30±0.29	1.55±0.39	1.31±0.31	0.07	+0.34(0.073)	+0.06(0.071)	+0.31(0.074)	0.01	-0.28*	-0.03	0.25*
LDL (mmol/l)	2.45±1.48	2.37±1.21	2.05±1.14	0.24	+0.38(0.24)	+0.53(0.23)	+1.23(0.24)	0.04	0.15	0.86*	0.71*
WHR	0.96±0.07	0.98±0.08	0.95±0.09	0.23	-0.027(0.008)	+0.002(0.007)	+0.008(0.008)	0.01	0.30*	0.36*	0.01

Data are presented as mean ± standard deviation or SE of the mean. ANCOVA was used for between-groups comparisons, with a significance level of P* < 0.05 and p**<0.01. BMI: body mass index, WC: waist circumference, HC: hip circumference, WHR: waist-to-hip ratio, SBP: systolic blood pressure, DBP: diastolic blood pressure, FBG: fasting blood glucose, HDL: high density lipoprotein, LDL: low density lipoprotein, TG: triglycerides, TC: total cholesterol and HbA1c –glycated hymoglobin. NEP: Nutrition education peer to peer support group, NE: Nutrition education intervention group, C: control group
Kg=kilogram/metre2, Cm=centimeter, mmhg- Millimeters of mercury, mmol/l= milimmole per litre
Adjusted for age, gender, marital status, education level, family history of diabetes, years lived with diabetes, complications and medication use.

Table 6. 3: Prevalence of MetS risk factors at baseline and six-month post intervention

Parameter		Before the Intervention					Six-month Post intervention						
		NEP n (%)	NE n (%)	C n (%)	χ^2	P value	NEP n (%)	NE n (%)	C n (%)	NEP		NE	
										Odd ratio [a] (95% CI	P value	Odd ratio [b] (95% CI	P value
High HbA1c		43(84.3)	38(74.5)	38(74.5)	1.89	0.39	23(47.9)	24(49.0)	16(34.8)	2.08(0.85-5.09)	0.111	2.04(0.84-4.92	0.114
High FBS		51(100.0)	51(100)	51(100)			38(79.2)	41(83.7)	42(91.3)	2.91(0.82-10.36)	0.100	2.30(0.56-7.34)	0.114
High WHR		45(88.2)	48(94.1)	40(78.4)	5.64	0.06	42(87.5)	46(93.9)	45(97.5)	0.09(0.01-0.93)	0.043*	0.28(0.03-3.00)	0.294
BMI	**>18.5-24.9**	18(35.3)	18(35.3)	17(33.3)	11.10	0.09	29(60.4)	19(38.8)	13(28.3)	4.62(1.32-16.20)	0.017*	4.25(1.09-16.59)	0.038*
	>25-29.9	15(29.4)	27(52.7)	25(49.0)			13(27.1)	26(53.1)	22(47.8)	1.08(0.31-3.81)	0.915	3.13(0.85-11.51)	0.086
	>30-34.9	23(45.3	9(10.8)	11(17.6))			8(12.5)	4(8.2)	13(23.9	Reference			
Elevated WC		47(92.2)	45(88.2)	47(92.2)	0.629	0.73	28(58.3)	42(85.7)	46(97.8)	.0.03(0.003-0.22)	0.001**	0.09(0.01-0.72)	0.024
Elevated BP[a]		37(72.5)	45(88.2)	37(72.5)	4.84	0.089	24(50.0)	24(49.0)	37(80.4)	4.17(1.59-10.91)	0.004**	4.29(1.67-11.03)	0.002**
Elevated BP[b]		34(66.7)	38(74.5)	28(54.9)	4.388	0.11	23(47.9)	21(42.9)	32(69.6)	0.395(0.16-0.97)	0.043*	0.33(0.14-0.78)	0.412
Elevated TG		32(62.7)	28(54.9)	39(76.5)	4.083	0.130	17(35.4)	31(63.3)	30(65.2)	0.31(0.13-0.75)	0.010 *	0.59(0.37-2.10)	0.785
Reduced HDL-C[a]		19(37.3)	11(21.6)	14(27.5)	3.126	0.21	1(2.1)	5(10.2)	10(21.7)	17.55(2.05-150.37)	0.009**	2.66(0.80-8.53)	0.111
Reduced HDL-C[b]		8(5.7)	5(9.8)	5(9.8)	1.333	0.567	1(2.1)	1(2.0)	1(2.2)	0.59(0.03-11.32)	0.730	0.91(0.05-16.9)	0.949
Dyslipidemia		35(68.6)	32)(62.7)	39(76.5)	1.700	0.32	18(36.7)	31(61.3)	30(65.2)	0.30(0.13-0.74)	0.008	0.89(0.37-2.11)	0.788
Elevated TC		26(51.0)	16(31.4)	22(43.1)	4.083	0.13	15(31.2)	18(36.7)	23(50.0)	2.45(0.99—6.04)	0.051	0.96(0.41-2.25)	0.918
LDL		29(59.9)	15 (29.4)	24(47.1)	7.994	0.244	25(52.1)	35(71.4)	31(67.4)	1.96(0.805-4.75)	0.14	0.87(0.35-2.16)	0.77
MetS[a]		46(90.2)	44(86.3)	45(88.2)	0.378	0.828	25(52.1)	34(69.4)	42(91.3)	0.82(0.02-0.28)	<0.001**	0.20(0.06-0.68)	0.01*
MetS[b]		46(90.2)	45(88.2)	41(80.2)	2.318	0.31	28(58.3)	38(77.6)	41(89.1)	0.20(0.067-0.57)	0.003**	0.50(0.17-1.52)	0.22
MetS risk factors[a]	**1-2**	4(7.8)	7(13.8))	6(11.8)	13.323	0.101	20(41.7)	11(22.4))	5(10.8)	24.03(5.78-99.88)	<0.001 **	5.63(1.63-21.77)	0.007**
	3	10(19.6)	21(41.2)	13(25.5)			20(41.2)	27(55.1)	28(60.8	3.32(11.10-99.60)	0.033*	1.48(0.59-3.74)	0.404
	4-5	37(62.7)	23(45.1)	32(63.3)			8(16.7)	12(26.4)	20(43.5)	reference			
MetS risk factors[b]	**1-2**	5(9.8)	6(11.8)	10(19.6)	2.492	0.65	20(41.7)	11(22.4)	5(10.8)	10.37(2.72-39.53)	0.001**	2.75(0.79-9.57)	0.011*
	3	25(49.0)	26(51.0)	22(43.1)			20(41.2)	27(55.1)	28(60.8)	2.92(0.94-9.10)	0.65	1.73(0.67-4.45)	0.258
	4-5	21(41.2)	19(37.3)	19(37.3)			8(16.7)	11(22.4)	13(28.3)	reference			

Data are presented as proportion; n (percentages; %) chi-square ($\chi 2$) test; *statistical significance at p value<0.05 BMI obese >30 kg/m2, Elevated Waist hip ratio (WHR)>0.90 for men and >0.85 for women, Elevated blood pressure [a] >140/90mmHg or treatment of previously diagnosed hypertension (WHO criteria); Elevated blood pressure [b] >130/85mmHg or treatment of previously diagnosed hypertension (harmonized criteria), Reduced serum HDL cholesterol (a) <0.9 mmol/L for men or<1.0 mmol/L for women or specific treatment for this abnormality (WHO criteria); Reduced serum HDL cholesterol [b] <1.0 mmol/L for men or<1.3 mmol/L for women or specific treatment for this abnormality(harmonized criteria), Elevated triglycerides (TAG) >1.7 mmol/L or specific treatment for this abnormality (both criteria), Waist circumference (WC) ≥94 cm for men or ≥80 cm for women, Elevated TC>5.2mmol/l, Elevated LDL-cholesterol>2.6mmol/l, Dyslipidemia- reduced HDL(<0.9 mmol/L for men or<1.0 mmol/L for women or specific treatment for this abnormality) or /and elevated TG(>1.7mmol/l) MetS[a] :Harmonized criteria; MetS[b]: WHO criteria, NEP; Nutrition education peer to peer support group, NE; Nutrition education group, C; control group,$\chi 2$**;** chi square Odd ratio[a] –comparison MetS parameters of NEP and C, Odds ratio[b]-comparison of MetS parameters of NE and C, CI; confidence interval
Adjusted for age, gender, education level, marital status, years; lived with diabetes, family history of diabetes, and complications

As shown in Table 6.4, there was no significant difference between the groups in the mean frequency of consumption of different types of food at baseline. High means > 4 days per week of inclusion of high fat food, sugar/ sweetened beverages and refined carbohydrates, were seen in all participant at baseline. However, there was great change in fat consumption pattern by all the groups at month 3 and 6month post intervention, where the mean for high fat food consumption dropped to 1 day per week or less (Table 6.4 and Table 6.5). A significant improvement ($p<0.01$) was seen in the NEP group 3 month and 6 months' post intervention in inclusion of vegetables (5.84±1.89 & 6.02±1.59, $p<0.01$), spacing carbohydrates (5.86±1.90&5.29±1.45, $p<0.01$) and limiting sodium (5.10±1.81 &5.54±1.37; $p<0.01$) in their meals.(Table 6.4 and Table 6.5).Additionally, an improvement was also seen in the NEP group in terms of including high fibre food for >5 days a week in the meal (5.85±0.99, $p<0.01$) 6 months' post intervention (Table 6.5). Moreover, participants in the NEP group also included low fat food in their diet for >4days a week (4.29±2.08, $p<0.01$) 6 months' post intervention and carbohydrates of low glycemic index for >3day per week (3.94±1.49, $p<0.01$ and 3.85±1.46, $p<0.01$) 3 and 6 months' post intervention respectively (Table 6.4 and Table 6.5).

As shown in Table 6.6 the participant in the all the groups had an average of 1000 MET minute physical activity levels at baseline. The physical activity level improved significantly ($p<0.01$) in the NEP group at month 1, 3 and 6 respectively after the intervention (+570.92; 174.51 MET minutes, +919.21; 192.96 MET minutes and +1105.36; 220.60) MET minute compared to the other groups (Table 6.6). Comparison of changes in physical activity levels between the groups showed significant difference between NEP and C, at month 3 and month 6 post interventions. However, no significant difference was found between NEP and NE as well as NE and C in physical activity level changes 1, 3 and 6 months' post intervention (Table 6.6).

Table 6. 4 : Frequency of food consumption for the participant at baseline andat month 3 intervention

Variables	Baseline				Month 3				Diffrences between group between group at month 3		
	NEP (=51) Mean±SD	NE (n=51) Mean±SD	C (n=51 Mean±SD	P value	NEP (n=51) Mean±SD	NE (n=50) Mean±SD	C (n=49) Mean±SD	P value	NEP-NE	NEP-C	NE-C
1	2.61±1.26	2.12±0.99	2.22±0.73	0.12	4.31±1.33	3.20±1.74	1.92±1.64	<0.01	1.09(0.32)**	2.36(0.32)**	1.26(0.32)**
2	2.96±1.23	2.55±1.46	2.78±1.38	0.34	3.58±2.31	2.68±2.17	2.27±2.44	0.02	0.83(0.47)	1.26(0.48)*	0.43(0.47)
3	3.02±0.68	2.80±0.66	2.80±0.63	0.17	5.84±1.89	3.88±2.45	3.63±2.62	<0.01	1.76(0.46)**	2.01(0.46)**	0.26(0.46)
4	2.49±0.90	2.52±1.13	2.51±1.13	0.99	3.94±1.49	2.60±1.51	1.77±1.61	<0.01	1.36(0.32)**	2.17(0.31)**	0.81(0.31)*
5	2.68±1.49	2.84±1.16	2.52±1.29	0.53	3.50±1.35	2.46±1.50	1.43±1.27	<0.01	1.01(0.28)**	2.02(0.28)**	1.02(0.28)**
6	4.80±0.80	4.22±1.05	4.52±1.11	0.06	0.69±1.16	1.02±1.13	1.22±1.49	0.11	-0.36(0.27)	-0.56(0.26)	-0.20(0.26)
7	0.71±1.22	1.00±1.32	0.92±1.29	0.38	0.71±1.22	1.02±1.33	0.94±1.31	0.35	-0.47(0.26)	-0.38(0.26)	0.09(0.25)
8	5.84±0.46	5.78±0.51	5.82±.059	0.30	0.71±1.64	0.70±1.43	1.29±1.72	0.12	-0.067(0.30)	-0.65(0.31)	-0.59(0.30)
9	2.80±0.89	2.86±0.89	2.70±1.04	0.68	5.86±1.90	3.88±2.45	3.63±2.62	<0.01	1.76(0.46)**	2.01(0.46)**	0.26(0.46)
10	2.31±1.49	2.33±1.61	2.76±1.42	0.24	3.82±2.59	1.64±2.07	0.93±1.75	<0.01	2.35(0.44)**	3.05(0.44)**	0.70(0.43)
11	2.98±1.01	3.01±0.88	2.98±0.84	0.95	5.10±1.81	3.76±2.55	2.00±2.02	<0.01	1.124(0.44)*	2.88(0.44)**	1.74(0.43)**
12	1.90±1.36	1.86±1.31	1.82±1.48	0.96	1.84±1.33	1.86±1.32	1.63±1.47	0.66	0.05(0.28)	0.28(0.28)	0.23(0.28)

Data presented as Mean±sd; statistically significant =p<0.05; ** significant at p<0.01; *significant at p<0.05; NEP-nutrition education peer to peer support, NE- nutrition education group and C – control group

Variables definition

1. On how many days per week in the last one month did you follow a healthful eating plan
2. On how many days per week in the last one month did you did you eat three to five or more servings of fruits each day
3. On how many days per week in the last month did you eat three to five or more servings of vegetables each day
4. On how many days per week in the last month did you include high fibre such as whole grain, legumes in your diet
5. On how many days per week in the last month did you include low caloric of low glycemic index food in your meal
6. On how many days per week in the last one month did you include high fat foods like fatty meat, skin on chicken, highly fried foods
7. On how many days per week in the last month did you include fish in your meal each day
8. On how many days per week in the last month did you include sugar and sweetened beverages
9. On how many days per week in the last month did you space your carbohydrates throughout the day
10. On how many days per week in the last month did you include low sodium diet in your meal
11. On how many days per week in the last month did you include low fat foods like skimmed milk, lean meat, lentils
12. On how many days per week in the last one moth did you prepare your food with unsaturated fats like canola oil, olive oil, sunflower oil

Table 6. 5: Frequency of food consumption for the participant month 6 post intervention

Variable	Month 6				Differences between group at month 6		
	NEP (n=48) Mean±SD	NE (n=49) Mean±SD	C (n=46) Mean±SD	P value	NEP-NE	NEP-C	NE-C
1	5.15±1.50	4.00±1.80	2.71±1.06	0.01	1.14(0.32)**	2.38(0.32)**	1.24(0.32)**
2	3.98±2.08	2.88±2.03	2.74±2.10	0.02	1.03(0.43)	1.21(0.44)*	0.18(0.43)
3	6.02±1.59	4.06±2.12	4.06±2.12	<0.01	1.83(0.41)**	1.92(0.42)**	0.9(0.41)
4	3.85±1.46	2.61±1.53	1.73±1.51	<0.01	1.24(0.31)**	2.1(0.32)**	0.87(0.31)*
5	5.85±0.99	4.14±1.47	2.67±1.23	<0.01	1.76(0.26)**	3.22(0.26)**	1.46(0.26)**
6	0.58±0.87	1.04±1.14	1.30±1.49	0.071	-0.46(0.24)	-0.72(0.25)	-0.26(0.24)
7	0.67±1.22	1.02±1.35	0.93±1.34	0.16	-0.42(0.27)	-0.34(0.27)	0.09(0.27)
8	0.58±1.30	0.69±1.44	1.30±1.76	0.19	-0.07(0.31)	-0.69(0.32)	-0.60(0.31)
9	5.29±1.45	3.78±1.43	2.28±1.28	<0.01	1.58(0.29)**	3.10(0.29)**	1.52(0.29)**
10	4.29±2.08	2.38±1.86	1.96±1.81	<0.01	1.95(0.40)**	2.38(0.40)**	0.43(0.40)
11	5.54±1.37	4.16±2.24	2.21±1.95	<0.01	1.35(0.39)	3.24(0.40)**	1.89(0.39)**
1	4.85±1.20	4.93±1.17	5.06±1.34	0.87	-0.10(.26)	-0.24(0.26)	0.14(0.26)

Data presented as Mean±sd; statistically significant =p<0.05; ** significant at p<0.01; *significant at p<0.05; NEP-nutrition education peer to peer support, NE- nutrition education group and C – control group

Variables definition

1. On how many days per week in the last one month did you follow a healthful eating plan
2. On how many days per week in the last one month did you did you eat three to five or more servings of fruits each day
3. On how many days per week in the last month did you eat three to five or more servings of vegetables each day
4. On how many days per week in the last month did you include high fibre such as whole grain, legumes in your diet
5. On how many days per week in the last month did you include low caloric of low glycemic index food in your meal
6. On how many days per week in the last one month did you include high fat foods like fatty meat, skin on chicken, highly fried foods
7. On how many days per week in the last month did you include fish in your meal each day
8. On how many days per week in the last month did you include sugar and sweetened beverages
9. On how many days per week in the last month did you space your carbohydrates throughout the day
10. On how many days per week in the last month did you include low sodium diet in your meal
11. On how many days per week in the last month did you include low fat foods like skimmed milk, lean meat, lentils
12. On how many days per week in the last one moth did you prepare your food with unsaturated fats like canola oil, olive oil, sunflower oil

Table 6. 6: Physical activity levels of the participants at Baseline, Month 1, Month 3 and Month 6 post intervention

	NEP	NE	C	P value	Difference in Change of physical activity between groups		
	Mean (SE)	Mean (SE)	Mean (SE)		NEP-NE	NEP-C	NE-C
					Mean (SE)	Mean (SE)	Mean (SE)
Baseline	1024.32 (139.38)	1049.70 (138.23)	1015.39 (137.82)	0.955	-25.38 (197.96)	8.94 (197.10)	34.32 (194.66)
Changes in PA at Month 1	+570.92 (174.51)	+116.21 (113.08)	+2.28 (172.56)	0.056	454.71 (247.87)	568.63 (246.79)	113.93 (243.73)
Changes in PA at Month 3	+919.21 (192.96)	+256.92 (193.45)	+15.71 (197.02)	0.004	662.29 (275.29)	903.50 (277.27) *	241.22 (275.48)
Changes in PA at Month 6	+1105.36(220.60)	+380.12(216.86)	+103.40 (223.92)	0.006	725.24(311.00)	1001.96 (316.12)*	276.72 (311.37)

Data presented as Mean (SE)
Physical activity levels presented as MET minutes per week
NEP: Nutrition education peer to peer support group; NE: Nutrition education group and C: control group
SE: Standard error of the mean
PA- physical activity level
MET; Metabolic equivalent
*-statistically significant at p<0.01Adjusted for age, gender, marital status, education level family history of diabetes and years lived with diabetes

6.5 Discussion

The current study determined the effect of a nutrition education programme with or without peer to peer support on metabolic syndrome and metabolic risk factors in T2DM patients. The 8-week nutrition education programme (Curriculum attached in Appendix XII) equipped participants with more detailed knowledge on diabetes-related nutrition and importance of physical activity than the standard education such patients usually receive in diabetes clinics in Kenya. The control group in the present study received the standard education. In addition to the standard education, one of the two intervention groups (NE) received the detailed nutrition education programme, and the other received the detailed nutrition education programme beefed up with a peer-to-peer support component (NEP group).

While there was worsening in mean values of most of the anthropometric and metabolic parameters such as weight, BMI, DBP, and LDL in the control group during the 6 months of the study, most of these parameters improved significantly in the NE and NEP group, with the NEP group achieving greater improvement than the NE group (Table 6.2). However, there were improvements in both HbA1c and fasting blood glucose in all the groups, and the means for these parameters were not statistically different at 6 months (Table 6.2). This may be attributed to the anti-diabetes medications taken by all the groups, which lowered the blood glucose.

Similar results were obtained for the prevalence of the MetS and its risk factors (Table 6.3), where there were improvements in HbA1c and FBG in all the groups; worsening in the anthropometric risk factors and BP in control group; and improvements in the latter for the NE and NEP groups. Elevated TC and LDL worsened in the control group but improved in the NE and NEP groups. Prevalence of elevated TG dropped significantly in the NEP group, but increased in the NE and Control groups. There was reduction in prevalence of the rest of the blood lipid profile components in all groups, with greater improvements in NEP and NE than C.

Improvements in blood lipid profiles even in the control group may be due to the effects of anti-diabetic medicines, such as metformin which has been shown to not only improve blood glucose but also blood lipids (Lin et al., 2018).

Overall, there was a worsening in the prevalence of the metabolic syndrome and its risk factors in the control group, and an improvement of the same in the NE and NEP groups, with greater improvements in the latter. The better improvements in MetS in the NEP than in NE and in the latter than in the C group may be attributed to different degrees of improvement in the food intake patterns and physical activity levels attained (Tables 6.4, 6.5 and 6.6).

Nutrition education is a main component in diabetes education and has been shown to improve dietary behavior and clinical outcomes in persons with diabetes (Askari et al., 2013; Liu et al., 2015; Muchiri et al., 2016). Previous studies have demonstrated that nutrition education or, lifestyle interventions aimed at correcting dietary behavior and enhancing physical activity in management of T2DM and MetS have a positive outcome in metabolic parameters (Askari et al., 2013; Muchiri et al., 2015). Inclusion of peer to peer support in the lifestyle intervention have been shown to have a better clinical outcome (Athena et al., 2011; Pan et al., 2016; Simmons et al., 2013, 2013). The results of the current study are in agreement with these previous studies.

A previous study showed strong correlation between BMI and WC with glycaemia, triglyceride, HDL and blood pressure (Rezende et al., 2006) with reduced level of BMI and WC being associated with low MetS. In the current study, the NEP group that had the strongest reductions in BMI also had the strongest reduction in the prevalence of TG, but the NE group had a greater drop in the prevalence of BP. The results for BP might be confounded by the effects of anti-BP medication.

As found in the current study, nutrition education and other health education intended to improve dietary habits and physical activity have been previously shown to improve dietary behavior, physical activity and clinical outcomes in persons with Type 2 diabetes Mellitus (Askari et al., 2013; Liu et al., 2015; Muchiri et al., 2016).

In interpreting the results of this study, some limitations need to be considered. The study period was limited to six months and this allowed assessment of short-term effects of the intervention. Longer periods of follow-up have been recommended in order to understand more of the sustainability of a peer-led intervention program and also in order to ensure long-term reduction of MetS risk factors. Additionally, the study was carried out in a public hospital set-up where patient population is of middle and low income hence the results can only be compared to a similar population. On the other hand, the high retention rate (93.7%) and the positive feedback obtained from the participants during the monthly follow-up was in was a strength of the study. The current study was also unique as it combined a comprehensive nutrition education programme with peer to peer support in the management of Type 2 Diabetes. The current study reported significant improvement of metabolic parameters and MetS prevalence on application of lifestyle intervention and might be a useful base for community based study targeting T2DM population.

6.6 Conclusion

The detailed nutrition education programme offered to T2DM patients in this study significantly improved the MetS and its risk factors in T2DM patients. Moreover, combining the nutrition education programme with peer-to-peer support resulted in significantly greater benefits in reduction of the MetS in T2DM. Therefore, such a programme can be recommended for inclusion in diabetes management programmes for improved health outcomes. Nevertheless, future studies should focus on improving the training contents and longer-term monitoring to achieve greater improvements. Therefore, such a programme can be recommended for inclusion in diabetes management programmes for improved health outcomes. Nevertheless, future studies should focus on improving the training contents and longer-term monitoring to achieve greater improvements.

Table: 6. 7: Summary of Nutrition Education Curriculum

Week	Topic	Content and activities	Participants
Introduction week	What is diabetes and how it is managed	Nature of disease (explanation of what happens when one has diabetes, including body's response to food in diabetic/non-diabetic states, insulin action, causes/risk factors, types) Symptoms and complications medication and their roles in treatment Aim for treatment and targets for good control Causes, symptoms and management of hypoglycemia and hyperglycemia Foot care and eye care.	All participants
Week One	Dietary guidelines on healthy eating	Principal of healthy eating: importance of regular and varied meals Guided discussion on improving dietary variety	Intervention groups
	Dietary guidelines continued; Overview of food groups and their role diabetes management	Cereals and starches as well as root and tuber groups and their role in diet Different type of starches and cereals, carbohydrate content and how it affects blood glucose Some healthy ways to include starches in meals Demonstration of portion/serving sizes of different cereals and starches Group work: practices on portioning and serving of starches Specific guidelines for cereals preparation	
Week Two	Dietary guidelines continued: Overview of food	Legumes group and nut and seed groups and their role in diet	Intervention groups

	groups and their role diabetes management	Carbohydrate content in legumes and how it affects blood glucose Different type of legumes, seed and nuts that can be used by Type 2 diabetes mellitus patient. Some healthy ways to include legumes, seed and nuts in meals Demonstration of portion/serving sizes of different cereals and starches Group work: practices on portioning and serving of legume and nuts Specific guidelines for cereals and legumes preparation	
Week Three	Dietary guidelines continued: Overview of food groups and their role diabetes management	Meat, dairy group and their role in diet Their role in diabetes management Trimming of fat in meat Reduction of cream in milk Different milk product and how to include different serving portion Importance of minimizing of processed meat in diabetes and chronic disease management	Intervention groups
Week Four	Dietary guidelines continued: Overview of food groups and their role diabetes management	Vegetables and fruits How to improve vegetables supply at home Importance of vegetables and fruit in diabetes management Carbohydrate content in fruits and vegetables and how it affects blood glucose Demonstration of different vegetables and fruits Group work: participant in groups to name different fruit and vegetables demonstrated and indicate how they will improve their supplies	Intervention groups
Week Five	Dietary guidelines	Fats and oil and their role in	Intervention

	continued: Overview of food groups and their role diabetes management	diet Importance of fat and oil Sources of fat Type of fats (saturated and unsaturated), Their sources and effect of each in the body. Some healthy way to include fat and oils in the diet Group activity: label reading of fat and oil products on display and identification of different content of different component of triglycerides, saturated fat and unsaturated fat levels.	groups
Week Six	Meal planning: portions and meal frequency	Facilitated group review of the effect of different food group on blood glucose Discussion on importance of food portion control and regular meals Guidelines for portion sizes Demonstration: portion sizes (household measures, Zimbabwe hand jive, plate model). Group activity: practice portioning various commonly used foods Reflection and group discussion about portion sizes and associated issues such as hunger. Planning meals on a limited budget, emphasis on variety and balance within available resources Importance of timing and combining meals	Intervention groups
Week Seven	Glycemic index and its importance in diabetes management	Role of glycemic index and glycemic load in blood glucose control. Glycemic index and glycemic load of different foods. Examples of glycemic index of various foods. Group activity: classifying food in terms of glycemic	Intervention groups

		index Label reading of different foods: reflection on current practices related to dietary guidelines and label reading plus group discussion	
Week Eight	Physical activity	Importance of physical activity in blood glucose control When to exercise Group activity: demonstration of the exercises by group leaders and All participant participate in exercise programme	Intervention groups
	Post Evaluation, Handouts: pamphlet and wall poster	Post evaluation and issue of handouts, pamphlets and wall posters	All groups

Table 6. 8: Dietary intake Variables

Serial No.	Variable	Score based on 7 days a week
1	On how many days per week in the last one month did you follow a healthful eating plan?[a]	0 1 2 3 4 5 6 7
2	On how many days per week in the last one month did you did you eat three to five or more servings of fruits each day?[ab]	0 1 2 3 4 5 6 7
3	On how many days per week in the last month did you eat three to five or more servings of vegetables each day? [ab]	0 1 2 3 4 5 6 7
4	On how many days per week in the last month did you include high fibre such as whole grain, legumes in your diet? [ab]	0 1 2 3 4 5 6 7
5	On how many days per week in the last month did you include low caloric of low glycemic index food in your meal?[a]	0 1 2 3 4 5 6 7
6	On how many days per week in the last one month did you include high fat foods like fatty meat, skin on chicken, highly fried foods? [a]	0 1 2 3 4 5 6 7
7	On how many days per week in the last month did you include fish or fish based product in your meal each day? [a]	0 1 2 3 4 5 6 7
8	On how many days per week in the last month did you include sugar and sweetened beverages?[a]	0 1 2 3 4 5 6 7
9	On how many day per week in the last month did you space your carbohydrates throughout the day?[a]	0 1 2 3 4 5 6 7
10	On how many days per week in the last month did you include low sodium diet in your meal?[b]	0 1 2 3 4 5 6 7
11	On how many days per week in the last month did you include low fat foods like?[dc]	0 1 2 3 4 5 6 7
12	On how many days per week in the last one moth did you prepare your food with unsaturated fats like canola oil, olive oil, sunflower oil?[a]	0 1 2 3 4 5 6 7

Healthful eating plan was defined as per WHO recommendation of health eating plan which was considered if a participant included fruit especieaclly whole fruits, a variety of vegetables from all of the subgroups—dark green, red and orange; fat-free or low-fat dairy, including milk, yogurt, cheese, and/or fortified soy beverages; a variety of protein foods, including seafood, lean meats and poultry, eggs, legumes (beans and peas), nuts, seeds, and soy products; whole grains (e.g. unprocessed maize, millet, oats, wheat and brown rice) in a meal in a day; exclude refined starch have less than 10% of total energy intake from free sugars have less than ≤30% of total energy intake from fats with <10% from saturated fat and 1% from *trans*-fats of all kinds, *and include* unsaturated fats in meal preparation as well as use of less than 5 g of iodized salt (equivalent to about one teaspoon) per day5 serving of fruit was considered as 400g of fruits

[a] construct borrowed from perceived diet Adherence questionnaire (PDAQ) . [b] borrowed from DASH[ab] borrowed from PDQA and medical nutrition therapy and [dc] from DASH and MTN

CHAPTER SEVEN

EFFECT OF NUTRITION EDUCATION ON ADHERENCE TO LIFESTYLE MODIFICATION (DIET AND PHYSICAL ACTIVITY) BY PATIENTS WITH TYPE 2 DIABETTES MELLITUS AT A LEVEL 5 HOSPITAL IN KENYA: "A RANDOMIZED CONTROLLED TRIAL"

Manuscript submitted for publication as Thuita A.W, Kiage B.N, Onyango A.O and Makokha A.O, Effect of a nutrition education programme on adherence to lifestyle modification (diet and physical activity) on participant with type 2 diabetes mellitus at a level 5 hospital in Kenya: "a randomized controlled trial"

7.1 Abstract

Type 2 diabetes mellitus (T2DM) is a chronic metabolic disorder, characterized by hyperglycemia. Lifestyle modification has been shown to be the cornerstone to its management. However, non-adherence to lifestyle modification remains a key challenge. Interventions employing nutrition education and peer to peer support could lead to improvement as well as compliance to lifestyle modification. Therefore, the current study explored the effect of nutrition education program on adherence to lifestyle modifications of T2DM patients. This study was a randomized control trial with two intervention groups (nutrition education peer to peer support; NEP and nutrition education; NE group) and a control group (C). All the groups received standard education before the start of intervention. The NEP group received nutrition education sessions with peer to peer support while NE group received only nutrition education. The nutrition education was done for eight weeks each 2 hr session. All the groups were followed for six months. Adherence to diet and physical activity data was collected at baseline, at 1 month post intervention, at 3 months post intervention and at 6 months post intervention. Analysis of data was done using analysis of co variance (ANCOVA) and regression. The prevalence to diet adherence improved significantly in the NEP (13.7% to 90.2%; 96.1% and 97.9%),) and NE (9.8% to 58.8%; 64.4% and 93.1%) compared to C at 1 month post intervention, at 3 months post intervention and at 6 months post intervention. There was also improvement in prevalence of good adherence to physical activity as well in NEP (47.1% to 90.2% and 91.7%) and NE (49.0% -to 84.0% and 87.8%) score compared to C at 3 months and at 6 months post intervention. Changes in mean diet adherence score and mean food frequency mirrored the changes in mean physical activity score, where the greatest improvements occurred in the NEP. In conclusions nutrition education programme alone or with peer to peer support component was beneficial in improving adherence to lifestyle modification (diet and physical activity) hence can be adapted in management of T2DM

Key words: Type 2 diabetes Mellitus, Nutrition education, Adherence, Diet, Physical activity

7.2 Introduction

Type 2 Diabetes is a major global public health concern with an estimated population of 425 million people aged 20-79 years having this chronic condition (IDF, 2017). Increased global prevalence of T2DM is reported each year; 285 million in 2009 , 366 million in 2011, 382 million in 2013 and 415 million by 2015 (IDF, 2009, 2011, 2015, 2017). The situation is not different in Kenya as there is a rise in the prevalence each year, and an increase in related complications, which lead to disability and death (IDF, 2015, 2017; WHO, 2016). Studies have also reported poor glycemic control in T2DM patients which is strongly related to the development of diabetic complications, such as retinopathy, neuropathy and cardiovascular events (IDF, 2015; Siu & Yuen, 2014). These complications are a major cause of disability, reduced quality of life and premature death (IDF, 2015). Lack of effective strategy in management of T2DM worsens the situation further (Alharbi & Alsubhi, 2016; Midhet et al., 2010). Such strategy includes among others lifestyle modification which if not followed can worsen the condition further (Kanauchi & Kanauchi, 2015).

Lifestyle modifications, including nutrition therapy, regular physical activity and weight loss are key to the management of T2DM and its complications (Abdi et al., 2015; Gerstel et al., 2013). Studies have shown that dietary management, physical activity or both promotes good glycemic control and reduces complications due to T2DM (Abdi et al., 2015; Askari, Rabiei, & Rastmanesh, 2013; Gerstel et al., 2013; Orchard et al., 2017). However, non- adherence to healthy lifestyle worsens the situation further (Maisharah et al., 2011). Adherence rate for healthy dietary choices and/or physical activity has been reported to be 20-70% both in the general population and in Type 2 diabetes mellitus patients (Alharbi & Alsubhi, 2016; Ganiyu et al., 2013; Musee et al., 2016; Saleh et al., 2014).

In the recent past, unhealthy diets and physical activity have become global public health issues due to their strong association with the development of T2DM as well as related complications (IDF, 2017; WHO, 2016). Besides non-adherence having undesirable impact on clinical outcomes, it might also cause an increased financial burden for societies including excess urgent care visits, hospitalizations and higher

treatment costs related to T2DM as well as complications (Alharbi & Alsubhi, 2016). This therefore underscores the need to intervene in order to improve on adherence to lifestyle modification for patients with Type 2 diabetes mellitus. Hence, the primary aim of this study was to conduct a nutrition education programme with peer to peer support for 8 weeks and evaluate its effectiveness on patient adherence to lifestyle modification namely: diet and physical activity

7.3 Methods

7.3.1 Study site and participants

This was a randomized control trial conducted in T2DM patients attending care at Thika Level 5 Hospital (TL5H) diabetes comprehensive care Centre (DCC). The patients included in the study were T2DM patients aged 20-79 years with no complications and willing to attend weekly meetings after commencement of the study and six months follow up. Type 2 Diabetes mellitus (T2DM) patients with complications, like renal failure, congestive heart failure (CCF), and stroke were excluded from the study during recruitment. The study participants were recruited during their clinic appointment days as they waited for treatment in the DCC. The principal investigator gave a brief talk about T2DM every morning for 15 minute at the DCC and explained to the patients about the upcoming study. Participation in the study was voluntary. Type 2 diabetes mellitus (T2DM) patients who consented to participate in the study, met the inclusion criteria and signed an informed consent were recruited. The recruitment took 2 months (August 2016-October 2016). A total of 215 patients showed interest to be included in the study. Out of these, an estimated sample size of 153 participants was required. Out of the 215, who showed interest 62 were excluded (30 did not meet the exclusion criteria, 15 declined to participate, 12 could not be available).

After recruitment, the study participants were randomized into three groups (2 intervention groups- nutrition education peer to peer support group; NEP and Nutrition education group; NE and 1 control group; C). Randomization of the participants to the entire group was done by the principal investigator using random numbers generated by computer. Sealed sequentially numbered opaque envelopes per each stratum (1-

3) mixed using the lottery method were used. The participants were requested to pick an envelope each and join their groups (1-3). A volunteer from each group was then requested to move forward and pick another envelop each containing their treatment allocation (NE, NEP and C). Upon confirmation of the treatment allocation, the participants were allocated to their treatment group, and the group members recorded. After randomization, baseline data was collected from all the participants. The 1st intervention group (NEP) received nutrition education in combination with physical activity and peer to peer support and 2nd intervention group (NE) received nutrition education in combination to physical activity (NEP) while control group (C) received standard care. For the two intervention groups, training was done for eight weeks with 2 hours session each and follow up for all groups done for six months.

7.3.2 Sample size

A sample size of 46 participants per study arm was calculated using the formula by Armitage *et al.,* (Armitage, 2008) and Lwanga & Lemeshow (1991). Assuming 10% attrition the sample was increased to a total of 51 participants per group.

7.3.3 Intervention

The current study used the social cognitive theory to influence behavior change (Bandura, 2012). The nutrition education curriculum consisted of eight sessions. Before start of the interventions all participants were taken through one session was given to all groups on general management of T2DM. The nutrition curriculum was given 2-hour weekly meetings, which were held at the DCC during the intervention period. Each group was met on separate days. The NEP received nutrition education sessions with peer to peer support and NE received only nutrition education lessons, while the C group received standard care (blood glucose and blood pressure monitoring, treatment for those with problems as well as education on diabetes care by a clinician).

The nutrition education sessions consisted of lessons addressing nutrition in relation to diabetes, food portion control for weight reduction, use of healthier food choices, an individualized meal planning; glycemic index and glycemic load of different foods

and their importance in blood glucose control; food pyramid and its use together with food exchange list. The curriculum was presented in eight lessons each 2 hours.

The nutrition content was presented using lectures, demonstrations, discussions, and other participatory methods. The nutrition education curriculum was first tested in a subgroup (10% of sample) of patients not involved in the study before the actual implementation. All the groups had their blood glucose and blood pressure monitored before the lesson started and those in need of any treatment appropriately attended to.

The first five lessons focused on dietary guidelines on healthy foods in management of type 2 diabetes mellitus. The principle of healthy eating and the importance of regular and varied meals using the food groups were emphasized. Participants in these lessons learnt about the basics food groups and some healthy ways to include meals (Table 6.7. in Chapter 6). In brief the topics covered included starch and cereals;, legumes, nuts and seeds; meat and dairy products; fruits and vegetables; fats and oils; servings and number of recommended serving per food group per day; the difference between simple and complex carbohydrates; fibre content of different foods (fruits, vegetables, legumes, cereals and starches; the difference between saturated and unsaturated fats and their relation to diabetes management; hidden calories contained in beverages; and the micronutrient and fiber values of fruits and vegetables.

During these lessons, posters with the food groups as well as real food samples were used to emphasize on their importance.

In lesson six, the importance of meal plans and portion control was given. Portion sizes using different methods like: household measures, plate model, Zimbabwe hand jive among other were demonstrated and participants were given an opportunity to do the portion sizes. The participants were also taken through a lesson of planning meals using a limited budget within the available resources with emphasis on variety and balance. Importance of timing and combining meals was also emphasized. Demonstrations on how menus can be adapted for energy as well as family needs were done. Prepared foods were used to give demonstrations on meal planning. The participants did a sample menu together with the researcher, by incorporating suggested foods by the group members that were locally available, financially

affordable and culturally acceptable. They were also divided into groups and allowed to practice menu planning with the guidance of the researcher and research assistants.

Lesson seven discussed the importance of glycemic index and glycemic load of different types of food on blood glucose control. Participants were also taken through a session on carbohydrate counting using locally available foods. A practical on carbohydrate counting was done and participants were requested to classify foods given as per their glycemic index (GI) indicating which foods had high or low GI. Practical's demonstrating of glycemic load of foods was also given. The participants were allowed to take part in classification of food samples according to glycemic load. Additionally, the participants were taken through label reading of different foods and a reflection on current practices related to dietary guidelines and label reading in relation to diabetes. Label reading practicals' were also given using available foods in the market was done by the participants and group discussions were encouraged.

The last lesson done on week eight was about physical activity and its importance on blood sugar control. Participants were informed on different types of physical activities, when to perform them as well as their importance. Practical sessions were given by a trained physiotherapist who has been involved in diabetes care in TL5H. After lesson eight participants were given posters and reading materials to use at home. After every lesson, participants were given 5 minutes to share their experiences with other members and a volunteer could be requested to address the other participants on his/her experience on each lesson day.

7.3.4 Follow up

Weekly meetings during intervention period were held for the intervention groups. Monthly follow up meetings were done for all the groups and data on adherence to diet and physical activity was collected at month 1, month three and month 6 for all the groups. In order to minimize drop-out, the PI made a phone call to all participants 3 days prior to each weekly meeting and reminded them one the day before the meeting. Similarly, they were called one week prior to each monthly meeting and reminded them one day before the meeting. Other strategies applied included; active participation, allowing participants to choose appropriate day and time for the

meetings and providing snacks during the meetings. The participants requiring treatment and other hospital services were supported by the clinicians and any problem encountered during their clinics visit was addressed.

7.3.5 Ethical clearance

The study was approved by the Kenyatta National Hospital-University of Nairobi Ethics and Research Committee (Permit No. KNH-ERC/A/232) and the National Commission for Science, Technology and Innovation (NACOSTI) (Permit No. NACOSTI /P /16/83452 /10118). The study has been registered by Pan African Trial registry (PACTR); Registry No. PACTR201910518676391P as per WHO requirement for clinical trials.

7.3.6 Data collection

Adherence to diet and physical activities were considered for the study. Baseline data that included demographic profile, types of foods eaten, and time of consumption and physical activity levels were collected before the start of the intervention. Physical activity levels data were collected using a modified WHO designed physical activity questionnaire (WHO, 2010.) It included questions on the type of activity done with its time and number of days per week. The metabolic equivalent for each physical activity was tabulated and recorded. Total physical activity level was calculated by adding up the metabolic equivalent (MET) for each activity. A participant was regarded as adherent to exercise if she or he reported exercising for duration of 150 minutes in all activities (>600 metabolic equivalent; MET minutes) per week. Non-adherence to exercise was considered if one reported light activity (<150 minute of exercise per week; <600 MET minutes per week) this was done at baseline, month 1, month 3 and month 6.

Adherence to dietary recommendation was measured based on compliance to recommendations of a healthy diet plan, diet rich in fruits and vegetables, complex carbohydrates high in fibre, low glycemic index food that included whole grains, reduced intake of salt and sugars, spacing carbohydrate intake, reduced intake of saturated fat and overall fat as well as uptake of mono-unsaturated and poly-

unsaturated fat. It was determined using 12 questions geared to cover healthy dietary habits adapted from the perceived dietary adherence questionnaire (PDAQ) (Musee et al., 2016), dietary approach to stop hypertension (DASH) (Apovian et al., 2010) and medical nutrition therapy (MNT) (Evert, 2014; Morris & Wylie-Rosett, 2010) (Chapter 6, Table 6.8). The responses to the question were based on a 7-likert scale to answer the question as shown on Chapter 6, Table 6.8.. Higher responses reflected good adherence except for question 6 and 8 which reflected unhealthy choices whereby in this case, higher scores reflected lower adherence and therefore during computing the total adherence scores the scores for these items were reversed. The highest adherence score was 84 point translating to 100%. Good adherence to dietary recommendation was for a score of >3 times a week for all the construct except for construct 6 and 8 where good adherence was considered for participants who used high fat food and sugar/sweetened beverages <3 times a week. In order to get the adherence percentage, the total adherence score obtained after summing up all the 12 constructs was multiplied by 100 and divided 84 to give the percentage score. Based on ADA recommendation on Medical Nutrition Therapy (Evert, 2014; Morris & Wylie-Rosett, 2010) a score of 36 points out of 84 (42.86%) was considered okay for good adherence. Non-adherence to dietary recommendations was defined as self-reported adherence of less than 3 days a week of the entire construct except construct 6 and 8 where it was considered as > 3 days a week (Chapter 6, Table 6.8,).

7.3.7 Data analysis

Baseline data was presented as means ±S D or proportions. The baseline difference between groups was determined using chi square for categorical variables and analysis of variance (ANOVA) for continuous data. Differences between groups measured (physical activity level and dietary adherence percentage) for baseline data, at month 1 post intervention, at month 3 post intervention and, at month 6 post intervention were analyzed using analysis of co-variance (ANCOVA) followed by Bonferroni post hoc test while controlling for age, marital status, gender, family history of diabetes and years lived with diabetes. Post intervention outcome (physical activity levels and dietary adherence percentage) changes with baseline at month 1 post intervention,at month 3 post intervention and at month 6 post intervention were also compared using

ANCOVA while controlling for baseline characteristics (age, marital status, gender, family history of diabetes and years lived with diabetes). The frequencies of participant adherence patterns using the 12 questions at baseline and 1month post intervention, baseline and 3 months' post intervention and, baseline and 6 months' post intervention were compared using chi-square test. Means of each construct were tabulated at baseline, at 1 month post intervention, at 3 months post intervention and at 6 months post intervention and comparison done using ANCOVA while controlling for age and gender. Patients were also classified according to their adherence level for diet and physical activity and comparison done using multinomial regression. Statistical significance for all tests was set at $p<0.05$.

7.4 Results

7.4.1 Study participants at baseline

A total of 153 participants (40.5% males and 59.5% female) were included in the study. Out of the 153, 1 was lost to follow-up 1-month post intervention, 5 were lost to follow after 3-month post intervention while a total of 10 were lost to follow at 6-month post intervention. As shown in Table 7.1, all the characteristics of the participants (demographic and food patterns) were similar among the groups at baseline. The participants in the study had a mean age of 56 years with 47.1% having comorbidity other that T2DM (Table 7.1). Seventy-eight percent (78%) of the participants had a HbA1c of >7% while 88.2% and, 86.3% had metabolic syndrome (MetS) as per harmonized criteria (Alberti et al., 2009) and WHO(1998) criteria, respectively at baseline More than half (53.6%) of the participants had been doing moderate physical activity before the study.

Other baseline characteristics of the participants are shown on Table 7.1. According to Table 7.1, majority (94.5%) of the participants ate vegetables, 94.1% ate African corn mash prepared from maize flour (African corn mash; Ugali), while 74.5% ate legumes. Rice was consumed by 71.9% of the participants, while only 60.8% included fruit (Table 7.1). Over half (59.5) of the participants bought food for themselves, 24% had their food bought by their spouses, while 13% have their food bought by children

(Table 7.1). Less than half of the participants (30 9 %) ate their lunch away from home while 4.6% and 0.7% ate their breakfast and lunch, respectively, away from home.

Table 7. 1: Baseline characteristics of the patients stratified per intervention group.

Parameters	Total Mean±SD or n (%)	NEP Mean±SD or n (%)	NE Mean±SD or n (%)	C Mean±SD or n (%)	Pvalue
Age	56.07±11.67※	57.03±10.88※	55.37±12.34※	55.80±11.97※	0.76
Complications	72(47.1)	22(30.6)	26(36.1)	24(33.3)	0.73
Type of food eaten					
Maize flour based diet (Ugali)	144(94.1)	48(33.3)	50(32.7)	46(30.1)	0.24
Porridge	67(43.8)	29(19.0)	20(31.0)	18(26.9)	0.07
Rice	110(71.9)	39(25.5)	35(22.9)	36(23.5)	0.66
Legume based diet(beans, green grams, dolicos)	114(74.5)	38(24.8)	37(24.2)	24(25.5)	0.90
Githeri (maize and beans)	73(47.7)	23(31.5)	28(38.4)	22(30.1)	0.44
Wheat based diet					
Chapati	23(21.6)	13(8.5)	9(5.9)	11(7.2)	0.63
Bread	80(50.2)	30(37.5)	26(32.5)	24(30.0)	0.48
Meat	37(24.2)	13(8.5)	12(7.8)	12(7.8)	0.98
Vegetables	144(94.5)	49(34.0)	47(32.6)	48(33.3)	0.70
Fruits	93(60.8)	37(39.8)	27(29.0)	29(31.2)	0.10
Tea (water and milk)	137(89.5)	45(29.4)	45(29.4)	47(30.7)	0.76
Physical activity Light	71(46.4)	24(15.7)	25(16.3	22(14.6)	0.55
Moderate	73(47.7)	23(15.0)	22(14.3)	28(18.3)	
Vigorous	9(5.9)	4(2.6)	4(2.6)	1(0.7)	
Meals eaten away from home					
Breakfast	7(4.6)	2(1.3)	2(1.3)	3(2.0)	0.89
Lunch	47(30.7)	16(10.5)	15(9.8)	16(10.5)	
4.00pm	1(0.7)	0(0.0)	0(0.0)	1(0.7)	
Alcohol consumption	6(3.9)	2(1.3)	2(1.3)	2(1.3)	1.00
Missing meal	13(18.5)	6(3.9)	3(2.0)	4(2.6)	0.55
Trigger that make one eat other than hunger					
Availability	14(9.2)	6(3.9)	3(2.0)	6(3.9)	0.51
In a party	1(0.7)	0(0.0)	0(0.0)	1(0.7)	

Data presented as proportion (n) and percentage and only data for age represented as Mean±SD
statistical signigicant- $p<0.05$

As shown in Table 7.2, the major source of starch for the participants was maize flour consumed in form of African corn mash (ugali), rice, and wheat consumed inform of chapati or bread. Almost half of the participants (42.5% and 45.8%) consumed African corn mash (ugali) during lunch and supper, respectively while 68.0% and 72.5% consumed vegetables at lunch time and supper (Table 7.2). Additionally, 34.6% consumed rice during lunch while 29.4% consumed rice during supper respectively (Table 7.2). Tea (86.9%) and bread (51.6%) were mostly consumed in the morning by the participants (Table 7.2). Legumes, the major source of protein, were consumed by 39.9% and 39.2% of the participant at lunch and supper (Table 7.2).

As shown in Table 7.3 there were no significant differences among the groups at baseline in adherence level to diet and physical activity. A low adherence level to diet modification of below 15 % as well as an adherence level to physical activity of below 50% was reported at baseline in all the groups. However, the NEP intervention group significantly increased level to dietary adherence at one month (Odd Ratio; OR=65.45, Confidence Interval; CI=17.65-242.64, P<0.001); at three months (OR=58.08, CI=11.95-282.24, p<0.001) and at six month OR=20.55, CI=2.51-168.53, p=0.005) after the intervention compared to C (Table 7.3). Additionally, comparison of NE and C, at one-month post intervention (OR=8.93, CI=3.29-24.22, p<0.001); at three months post intervention (OR=4.32, CI=1.78-10.55, P<0.001) and at six months post intervention (OR=7.54, CI=1.93-29.23, p=0.003) also showed significant increase in prevalence to good adherence score (Table 7.3). Additionally, comparison of NEP and C three month (OR=8.91, CI=2.75-28.79, p<0.001) and six months (OR=8.73, CI=2.43-31.42, p<0.001) post intervention showed a significant increase in prevalence of participants having good adherence to physical activity (Table 7.3). Similarly, comparison of NE and C three month (OR=3.78, CI=1.39-10. 30, p=0.009) and six months' (OR=4.38, CI=1.46-13.17, p=0.009) post intervention showed a significant increase in prevalence of participant having good adherence to physical activity. Moreover in comparison to NEP and NE to C, NEP showed a higher odd in participant having good adherence and physical adherence that NE in the three and six months' post intervention (Table 7.3).

Table 7. 2: Food Consumption Patterns of the Participants

Type of food	Break fast n (%)	10.00am n (%)	lunch n (%)	4.00am n (%)	Supper n (%)
Maize flour-based diet (Ugali)	20(13.1)	7(4.6)	65(42.5)	2(1.3)	70(45.8)
Porridge (Millet and maize)	10(6.5)	29(19.0)	1(0.7)	16(10.5)	0(0.0)
Rice	6(3.9)	6(3.9)	53(34.6)	1(0.7)	45(29.4)
Potatoes	0	0	60	0	70
Sweet potatoes	30	10	1(0.7)	1(0.7)	2(
Legume based diet (beans, green grams or dolicos)	12(7.8)	0(0.0)	61(39.9)	1(0.7)	60(39.2)
Githeri (maize and beans)	5(3.3)	0(0.0)	32(20.9)	0(0.0)	29(19.0)
Wheat flour (Chapati)	6(3.9)	2(1.3)	8(5.2)	2(1.3)	6(3.9)
Wheat flour (Bread)	79(51.6)	10(6.5)	1(0.7)	10(6.5)	3(2.0)
Meat	0(0.0)	0(0.0)	21(13.7)	0(0.0)	17(11.1)
Vegetables	25(16.3)	3(2.0)	104(68.0)	2(1.3)	111(72.5)
Fruits	3(2.0)	19(12.4)	14(9.2)	22(14.4)	10(19.0)
Tea (water and milk plus tea leaves)	133(86.9)	25(16.3)	5(3.3)	30(19.6)	3(2.0)
Bananas (ripe)	12(7.8)	9(5.9)	10(6.5)	9(5.9)	8(5.2)
Milk	6(3.9)	2(1.3)	4(2.6)	6(3.9)	3(2.0)

Data presented as proportion (n) and percentage (%)

Table 7. 3: Adherence to lifestyle modification at baseline, at month 1. At month 3 and at month 6 post intervention

Parameter		NEP n (%)	NE n (%)	C n (%)	NEP		NE	
					Odd ratio [a] (95% CI)	P value	Odd ratio [b] (95% CI	P value
		Before the intervention						
Diet adherence	**Poor**	44(86.3)	46(90.2)	48(94.1)	Reference			
	Good	7(13.7)	5(9.8)	3(5.9)	0.45(0.11-1.89)	0.276	0.56(0.12-2.50)	0.444
Physical activity adherence	**Poor**	24(47.1)	25(49.0)	22(42.1)	Reference			
	Good	27(52.9)	26(51.0)	29(56.9)	0.93(0.42-2.08)	0.855	0.77(0. 35-1.70)	0.512
		One month after the intervention						
Diet adherence	**Poor**	5(9.8)	20(42.0)	43(63.2)	Reference			
	Good	46(90.2)	30(58.8)	8(9.4)	65.45(17.65-242.64)	<0.001**	8.93(3.29-24.22)	<0.001**
Physical activity adherence	**Poor**	7(13.7)	10(19.6)	14(27.5)	Reference			
	Good	44(86.3)	40(80.0)	37(72.5)	2.76(0.96-7.93)	0.059	1.62(0.63-4.15)	0.320
		Three month after the intervention						
Diet adherence	**Poor**	2(3.9)	18(36.0)	33(68.8)	Reference			
	Good	49(96.1)	32(64.0)	15(31.2)	58.08(11.95-282.24)	<0.001**	4.32(1.78-10.55)	0.001**
Physical activity adherence	**Poor**	5(9.8)	8(16.0)	19(39.6)	Reference			
	Good	46(90.2)	42(84.0)	29(60.4)	8.91(2.75-28.79)	<0.001**	3.78(1.39-10. 30)	0.009**
		Six month after the intervention						
Diet adherence	**Poor**	1(2.1)	3(6.1)	15(32.6)	Reference			
	Good	47(97.9)	46(93.9)	31(67.4)	20.55(2.51-168.53)	0.005**	7.54(1.93-29.23)	0.003**
Physical activity adherence	**Poor**	4(8.3)	6(12.2)	16(34.8)	Reference			
	Good	44(91.7)	43(87.8)	30(65.2)	8.73(2.43-31.42)	0.001**	4.38(1.46-13.17)	0.009

Data are presented as proportion; n (percentages; %), *statistical significance at p value<0.05; **statistical significance at p value<0.01
Good dietary adherence ≥42.86%; poor dietary adherence <42.86%; Good physical adherence score ≥600MET while poor physical adherence score < 600MET. Odd ratio[a] –comparison adherence prevalence NEP and C, Odds ratio[b]-comparison comparison of adherence prevalence of NE and C, CI; confidence interval All data adjusted for age, gender, marital status, years; lived with diabetes, family history of diabetes, and complication

As shown in Table 7.4 there was no statistical difference between the mean dietary adherence score at baseline. A statistical significant difference was seen at month 1, 3, and 6 between the mean dietary adherence score of the group with NEP registering significant highest mean in all the months 54.66 (1.22) %, 60.68 (1.54) % and 69.31 (1.05) %) (Table7.4). Furthermore, the difference in diet adherence was significant ($p<0.01$) between NEP and NE (11.96, %, 13.81% and 14.22%), NEP and C (20.79%, 23.45% and 24.33%) as well as NE and C (8.88%, 9.64% and 10.11) one month, three months and six months' post intervention respectively (Table 7.4). Additionally, as shown in Table 7.4 the entire group of participants all the groups had an average of 1000 MET minute physical activity levels at baseline. The physical activity level improved significantly in at month 1, 3 and 6 respectively after the intervention 1595.24 (94.82) MET minutes, 1939.40 (131.01) MET minutes and 2119.49 (151.87) MET minute) compared to the other groups (Table 7.4). The difference in physical activity level was significant ($P<0.01$) between NEP and NE and NEP and C month 1 post intervention (429.32 and 577.57), month 3 post intervention (624.65 and 912.04) and month 6 post intervention (666.85 and 984.61) but no significant difference in physical activity was observed at month 1, 3 and 6 between NE and C (Table 7.4).

As shown in Table 7.5, the NEP group registered a significant improvement in the dietary adherence score between month 6 and baseline [+32.37 (1.04) %)], month 3 and baseline [+23.78 (1.22) %] month 1 and baseline [+17.77 (0.98) %)] (Table 7.5).

Table 7. 4: Mean Dietary and Physical Adherence Score of the participants at Baseline, Month 1, Month3 and Month 6

Months	NEP Mean(SE)	NE Mean(SE)	C Mean(SE)	P value	NEP-NE Mean(SE)	NEP-C Mean(SE)	NE-C Mean(SE)
Dietary Adherence Score (percentage; %)							
Baseline	36.89(0.67)	35.16(0.66)	35.56(0.66)	0.554	1.72(0.95)	1.33(0.94)	-0.40(0.93)
Month1	54.66(1.22)	42..71(1.21)	33.88(1.21)	<0.001	11.96(1.74)*	20.79(1.73)*	8.83(1.71)*
Month3	60.68(1.54)	46.87(1.54)	37.24(1.55)	<0.001	13.81(2.19)*	23.45(2.20)*	9.64 (2.18)*
Month6	69.31(1.05)	55.09(1.03)	44.98(1.07)	<0.001	14.22(1.48)*	24.33(1.50)*	10.11(1.48)*
Physical activity Adherence Score (MET) minutes per week)							
Baseline	1024.32(139.38)	1049.70(138.231)	1015.39(137.82)	0.955	-25.38(197.96)	8.94(197.10)	34.32(194.66)
Month1	1595.24(94.82)	1165.92(94.04)	1017.67(93.76	<0.001	429.32(134.68)*	577.57(134.09)*	148.24(132.43)
Month3	1939.40(131.01	1314.75(131.34)	1027.36(133.77)	<0.001	624.65(189.91)*	912.04(188.25) *	287.38(187.04)
Month6	2119.49(151.87)	1452.65(149.30)	1134.89(154.16)	<0.001	666.85(214.10)*	984.61(217.63)*	317.76(214.36)

Data presented as Mean (SE); statistical significant set at $p<0.05$
Dietary adherence data presented as percentage (%), while physical adherence data presented as MET minutes per week
NEP: Nutrition education peer to peer support group; NE: Nutrition education group and C: control group
SE: Standard error of the mean; SED: Standard error of difference
MET; Metabolic equivalent

Table 7. 5: Changes in mean dietary and physical activity adherence score

Changes in adherence score	Dietary adherence (%)			
	NEP (n=48) mean (SE)	NE(n=49) mean (SE)	CN=(46) mean (SE)	p value
Month6-baseline	32.37(1.04)	19.92(1.05)	9.99(1.07)	<0.001
Month3-baseline	23.78(1.22)	11.78(1.23)	2.59(1.25)	<0.001
Month1-baseline	17.77(0.97)	7.48(0.98)	-1.68(0.96)	<0.001

Data presented as Mean (SED); statistical significant set at p<0.05
Dietary adherence data presented as percentage (%), while physical adherence data presented as MET minutes per week
NEP: Nutrition education peer to peer support group; NE: Nutrition education group and C: control group; SED: Standard error of difference the mean
MET; Metabolic equivalent

As shown in Table 7.6, there was no significant difference in the pattern of food intake of the participants at baseline**.** However, there were statistically **s**ignificant differences seen in frequency of eating healthy diets at month 1,3 and 6 post intervention with NEP group recording the highest proportion of participants who ate healthy diets 5-7 time per week at month 1 (54.9, p<0.001),3 (54.9%, p<0.001), and (56.7, p<0.001) (Table 7.6). Additionally, significant improvements were seen in participants eating fruits (35.3%, 37.3% and 39.6%; p<0.001), vegetables (76.5%, 74.5% and 79.5%; p<0.001), reduced intake of sodium (39.2%, 39.2% and 39.6% respectively; p<0.001), inclusion of low fat diet (39.2%, 39.2%, 39.6%; p<0.001), and spacing carbohydrates (74.5%, 75.0% and 79.2%; p<0.001) 5-7 time per week at month 1, 3 and 6 respectively in the NEP group compared to other groups (Table 7.6). Moreover, there was a significant improvement in the consumption of unsaturated fat and low calories diet 3-4 times a week (54.9% and 60.9% respectively, p<0.01) in month 3 and 5-7 day a week (70.8 and 58.8% respectively; p<0.01) in month 6 was seen (Table 7.6). Furthermore, improvements in participants eating no high fat diet was seen in month 1(58.8%; p<0.01), 3(60.8%; p<0.01) and 6 (62.5%; p<0.01) respectively for NEP group (Table 7.6). Moreover, participant eating high fibre diet 3-4 month a week increased significantly in the NEP group at month 3(62.7; p<0.01) and at month 6(64.6%, p<0.01) respectively (Table 7.6). Notably, there

was a statistically significant improvement in the choice of good dietary practices in NE for all the foods and practice s included in NE compared to the Control (Table 7.6).

Table 7. 6: Dietary practice patterns of the participants at baseline, month 1, month 3 and month 6

Parameter	Baseline				Month 1				Month 3				Month6			
	NEP (n=51)	NE (n=51)	C (n=51)	χ^2(p value)	NEP (n=51)	NP (n=50)	C (n=51)	χ^2(p value)	NEP (n=51)	NP (n=50)	C (n=48)	χ^2(p value)	NEP (n=48)	NP (n=49)	C (n=46)	χ^2(p value)
1. Days per week a healthful eating plan was followed																
0	0(0.0)	0(0.0)	0(0.0)	5.283 (0.26)	2(3.9)	8(16)	18(35.2)	45.33 (<0.001)	2(3.9)	9(18.0	19(65.5)	48.369 (<0.001)**	0(0)	4(80)	2(20)	67.28 (<0.001)
1-2	20(39.2)	23(45.1)	26(51)		1(2.0)	4(8)	11(19.6)		1(2.0)	4(8.0)	964.3)		2(7.1)	17(34.0)	22(78.6)	
3-4	24(47.1)	24(47.1)	24(47.1)		20(39.2)	24(48.0)	21(41.2)		20(39.2)	24(48.0)	20(31.2)		12(24.0)	17(34.0)	21(42.0)	
5-7	7(13.7)	4(7.8)	1(2.0+)		28(54.9)	14(28.0	2(3.9)		28(54.9)	14(28.0	1(2.3)		34(56.7)	24(40.0)	2(3.3)	
2. Days per week three to five or more servings of fruits were consumed																
0	0(0.0)	0(0.0)	0(0.0)	8.059 (0.09)	5(9.8)	4(8)	13(25.5)	21.14 (0.002)	5(22.7)	4(8.0)	13(27.7)	22.126 (0.001)	0(0)	0(0)	0(0)	18.235 (0.001)
1-2	19(37.3)	30(58.8)	27(52.9)		14(27.5)	26(52.0)	24(47.1)		14(27.5)	26(52.0)	23(48.9)		16(33.3)	19(38.8)	34(73.9)	
3-4	24(47.1)	13(25.5)	13(26.0)		14(27.5)	12(24.0)	3(6.0)		13(25.5)	11(22.0)	3(6.3)		13(27.1)	11(22.4)	3(6.5)	
5-7	8(15.7)	8(15.7)	11(40.7)		18(35.3)	9(18.0)	11(21.6)		19(37.3)	9(18.0)	9(19.1)		19(39.6)	9(18.4)	9(19.6)	
3. Days per week three to five or more servings of vegetables were consumed																
0	0(0.0)	0(0.0)	0(0.0)	0.546 (0.76)	2(3.9)	5(10.0)	8(15.7)	26.440 (<0.001)	2(3.9)	6(12.0)	9(18.4)	28.085 (0.003)	0(0)	0(0)	0(0)	36.169 (<0.001)
1-2	14(27.5)	17(33.3)	17(33.3)		1(2.0)	9(18.0)	13(25.5)		19(27.9)	9(17.6)	13(26.5)		2(4.2)	15(30.6)	21(45.7)	
3-4	37(68.6)	34(66.7)	34(66.7)		9(17.6)	17(34.0)	11(21.6)		9(17.6)	17(34.0)	10(/20.4)		8(16.7)	17(34.7)	9(19.6)	
5-7	0(0.0)	0(0.0)	0(0.0)		39(76.5)	19(38.0)	19(37.3)		38(74.5)	18(36.0)	17(34.7)		38(79.2)	17(34.7)	16(34.8)	
4. Days per week high fibre such as whole grain, legumes was included in the diet																
0	0(0.0)	0(0.0)	0(0.0)	3.231 (0.520)	0(0)	3(6.0)	10(19.6)	53.95 (<0.001)	0(0)	3(6.0)	10(20.4)	54.949 <0.001	0(0)	3(6.1)	8(17.4)	62.69 <0.001
1-2	19(37.3)	23(45.1)	26(51.0)		5(9.8)	22(44.0)	30(58.8)		5(9.8)	22(44.0)	29(59.2)		5(10.4)	21(42.9)	28(60.9)	
3-4	28(54.9)	23(45.1)	19(37.3)		32(62.7)	22(44.0)	8(115.7)		32(62.7)	21(42.0)	8(16.3)		31(64.6)	21(42.9)	8(17.4)	
5-7	4(7.8)	5(9.8)	6(11.8)		14(27.5)	4(8.0)	3(5.8)		14(19.0)	4(10.0)	2(4.1)		12(25.0)	4(8.2)	2(4.3)	
5. Days per week low caloric of low glycemic index food was included in meal																
0	0(0.0)	0(0.0)	0(0.0)		3(5.9)	9(18.0)	17(33.3)	46.403 (<0.001)	9(17.6)	9(18.0)	18(60.0)	44.428 (<0.001)	0(0)	0(0)	0(0)	85.98 (<0.001)
1-2	19(37.3)	20(39.2)	27(52.9)		4(7.8)	13(26.0)	21(41.2)		5(9.8)	13(26.0)	19(51.4)		0(0)	9(18.4)	25(54.3)	
3-4	25(49.0)	27(52.9)	19(37.3)		31(60.9)	26(52.0)	13(25.5)		30(58.8)	25(50.0)	12(17.9)		2(4.2)	19(38.8)	19(41.3)	
5-7	7(13.7)	4(7.8)	5(9.8)		13(25.5)	3(6.0)	0(0)		13(25.5)	4(8.0)	0(0.0)		46(98.8)	21(42.5)	2(4.3)	
6. Days per week high fat foods like fatty meat, skin on chicken, highly fried foods were consumed																
0	0(0.0)	0(0.0)	0(0.0)	7.756 (0.10)	30(58.8)	17(34.0)	17(33.3)	16.074 (0.01)	31(60.8)	18(36.0))	21(42.9)	12.723 (<0.05)	30(62.5)	17(34.7)	17(37.0)	16.074 (0.01)
1-2	2(3.9)	0(0.0)	0(0.0)		16(31.4)	28(56.0)	19(37.3)		16(31.4)	28(56.0)	18(36.7)		16(33.3)	28(57.1)	19(41.3)	
3-4	41(80.4)	48(94.1)	42(82.4)		2(3.9)	3(6.0)	9(17.6)		3(5.9)	2(4.0)	9(18.4)		2(4.2)	3(6.1)	9(19.6)	
5-7	8(15.7)	3(5.9)	9(17.6)		0(0)	1(2.0)	1(2.0)		1(2.0)	2(4.0)	1(2.0)		0(0)	1(2.0)	1(2.2)	

7.	**Days per week fish was in the meals**															
0	**35(68.6)**	**27(52.9)**	**25(49.0)**	**7.627 (0.27)**	**35(68.6)**	**27(54.0)**	**25(49.0)**	**7.607 (0.27)**	**35(68.6)**	**26(52.0)**	**24(49.0)**	**7.487 (0.28)**	**34(70.8)**	**26(53.1)**	**23(50.0)**	**7.967 (0.24)**
1-2	**10(196)**	**16(31.3)**	**21(41.2)**		**10(19.6)**	**16(32.0)**	**21(41.2)**		**10(19.6)**	**16(32.0)**	**20(40.8)**		**8(16.7)**	**15(30.6)**	**18(39.1)**	
3-4	**6(11.8)**	**7(13.7)**	**4(7.8)**		**6(11.8)**	**7(14.0)**	**4(7.8)**		**6(11.8)**	**7(14.0)**	**4(8.1)**		**6(12.5)**	**7(14.3)**	**4(8.7)**	
5-7	**0(0.0)**	**0(0.0)**	**0(0.0)**		**0(0)**	**1(2.0)**	**1(2.0)**		**0(0.0)**	**1(2.0)**	**1(2.0)**		**0(0)**	**1(50)**	**1(2.2)**	
8.	**Days per week sugar and sweetened beverages was in the meals**															
0	**0(0.0)**	**0(0.0)**	**0(0.0)**	**0.927 (0.63)**	**35(72.5)**	**33(66.0)**	**24(47.1)**	**12.405 (0.05)**	**37(72.5)**	**33(34.4)**	**26(27.1)**	**12.006 (0.06)**	**35(72.9)**	**33(35.1)**	**26(27.7)**	**11.50 (0.07)**
1-2	**0(0.0)**	**0(0.0)**	**0(0.0)**		**10(19.6)**	**12(24.0)**	**10(19.6)**		**11(21.6)**	**13(37.1)**	**11(31.4)**		**10(31.2)**	**12(37.5)**	**10(31.2)**	
3-4	**10(19.6)**	**13(25.5)**	**14(27.5)**		**1(2.0)**	**2(4.0)**	**9(17.6)**		**1(8.3)**	**2(6.9)**	**9(75.0)**		**1(8.3)**	**2(16.7)**	**9(75)**	
5-7	**41(80.4)**	**38(74.5)**	**37(72.5)**		**2(3.9)**	**2(4.0)**	**3(5.9)**		**2(28.6)**	**2(28.6)**	**3(42.9)**		**2(28.6)**	**2(28.6)**	**3(42.9)**	
9.	**Days per week carbohydrates were spaced throughout the day**															
0	**0(0.0)**	**0(0.0)**	**0(0.0)**	**1.772 (0.7)**	**0(0)**	**0(0)**	**0(0)**	**80.034 (<0.001)**	**0(0)**	**0(0)**	**1(100)**	**53.28 (<001)**	**0(0)**	**0(0)**	**3(6.5)**	**90.50 (<0.001)**
1-2	**12(23.5)**	**16(31.4)**	**18(35.3)**		**3(5.9)**	**10(20.0)**	**34(72.3)**		**3(5.7)**	**22(41.5)**	**28(52.8)**		**3(6.3)**	**10(20.4)**	**34(73.9)**	
3-4	**37(72.5)**	**33(64.7)**	**31(60.8)**		**7(13.7)**	**25(50.0)**	**10(23.8)**		**18(32.1)**	**22(39.3)**	**16(28.6)**		**7(14.6)**	**25(51.0)**	**10(21.7)**	
5-7	**2(3.9)**	**2(3.9)**	**2(3.9)**		**38(74.5)**	**14(30.0)**	**2(3.70**		**30(75.0)**	**6(15.0**	**4(10.0)**		**38(79.2)**	**14(28.6)**	**2(3.4)**	
10.	**Days per week low sodium meal was consumed**															
0	**22(43.1)**	**20(39.2)**	**23(45.1)**		**10(19.6)**	**25(50.0)**	**36(70.6)**	**37.274 (<0.01)**	**9(17.6)**	**25(50.0)**	**35(71.4)**	**38.423(<0.01)**	**2(4.2)**	**12(24.5)**	**18(39.1)**	**28.96(<0.00 1)**
1-2	**10(19.6)**	**10(19.6)**	**9(17.6)**		**5(9.8)**	**9(18.0)**	**6(11.8)**		**0(0.0)**	**0(0.0)**	**1(2.0)**		**5(10.4)**	**8(16.3)**	**5(10.9)**	
3-4	**16(31.4)**	**19(373)**	**18(35.3)**		**16(31.4)**	**11(22.0)**	**6(11.8)**		**22(43.1)**	**19(20.4)**	**10(19.6)**		**22(45.8)**	**23(46.9)**	**21(457)**	
5-7	**3(5.9)**	**2(4.0)**	**1(2.0)**		**20(39.2)**	**6(12.0)**	**3(5.9)**		**20(39.2)**	**6(12.0)**	**3(12.2)**		**19(39.6)**	**6(12.2)**	**3(6.5)**	
11.	**Days per week low fat foods like skimmed milk, lean meat, lentils were consumed**															
0	**0(0.0)**	**0(0.0)**	**0(0.0)**	**2.932 (0.57)**	**1(2.0)**	**11(22.0)**	**17(33.3)**	**52.5 8 (<0.001)**	**1(2.0)**	**11(22.0)**	**18(66.0)**	**47.022 <0.001**	**0(0)**	**6(12.2)**	**14(30.4)**	**69.39 (<0.001)**
1-2	**22(43.1)**	**32(34.0)**	**33(35.1)**		**4(7.8)**	**2(4.0)**	**16(31.4)**		**5(9.8)**	**2(4.0)**	**13(36.7)**		**1(2.1)**	**2(4.1)**	**17(37.0)**	
3-4	**29((569)**	**32(34.0)**	**33(35.1)**		**10(19.6)**	**18(36.0)**	**12(23.5)**		**10(19.6)**	**17(34.0)**	**12(24.5)**		**8(167)**	**20(40.8)**	**12(26.1)**	
5-6	**0(0.0)**	**0(0.0)**	**1(100)**		**36(70.6)**	**19(38.0)**	**6(11.8)**		**35(68.6)**	**20(420)**	**6(12.2)**		**39(81.2)**	**21(42.3)**	**6(13.0)**	
12.	**Days per week food was prepared with unsaturated fats like canola oil, olive oil, sunflower oil**															
0	**8(15.7)**	**5(9.8)**	**6(11.8)**		**8(15.7)**	**5(10)**	**8(15.7)**	**3.308 (0.77)**	**0(0)**	**0(0)**	**3(6.1)**	**43.700(<0.001)**	**0(0)**	**1(16.7)**	**5(10.9)**	**12.747 (<0.05)**
1-2	**29(56.9)**	**33(64.7)**	**30(58.8)**		**29(56.8)**	**33(66.0)**	**33(64.7)**		**10(19.6)**	**23(46.0)**	**37(75.5)**		**2(4.2)**	**0(0)**	**0(0)**	
3-4	**12(23.5)**	**12(23.5)**	**13(25.5)**		**12(23.5)**	**12(24)**	**7(13.7)**		**28(54.9)**	**22(44.0)**	**7(14.3)**		**12(25.0)**	**12(24.5)**	**7(15.2)**	
5-7	**2(3.9)**	**1(2.0)**	**2(3.9)**		**2(3.9)**	**1(2.0)**	**2(3.9)**		**13(25.5)**	**5(10.0)**	**2(4.0)**		**34(70.8)**	**36(73.4)**	**32(69.6)**	

Data presented as numbers (n) and percentage (%), Statistical significant set at $p<0.05$ using chi-square (χ^2)
Days per week refer to previous one month

7.5 Discussion

The current studied explored the effect of a nutrition education with a peer to peer component on adherence to lifestyle modifications on diet and exercise. Good adherence to lifestyle modification has been shown to be a corner stone to T2DM management. Enhanced dietary advice and physical activity level is one of the strategies that is advocated in management of T2DM (MoPHS, 2010).

The study revealed that patient adherence to diet was low before the start of the interventions in all the groups. At baseline, participants had a mean dietary adherence score of below 40% with only 9.8% having a good dietary adherence score (Table 7.3). These results are in agreement with other studies that report a low adherence rate to dietary modification in T2DM patients regardless of the criteria used to determine the level of adherence (Adisa & Fakeye, 2014; Alharbi & Alsubhi, 2016; Ayele et al., 2018; Ganiyu et al., 2013; B. Sharma & Agrawal, 2017). Moreover, a study by Parajuli et al (2014) reported 87.5% and 42.1% non-adherent rate to dietary advice and physical activity respectively in T2DM population and are in support of the current study.

Physical activity in T2DM patients is associated with reduced incidence of metabolic outcomes as well as improved insulin sensitivity and reduced insulin resistance (Hwang & Kim, 2015, 2017; Jahangiry et al., 2017). To achieve these benefit, WHO recommends 600 MET minutes per week for Type 2 diabetes mellitus patients (WHO, 2010b). In the current study, participants recorded an average activity level of 1000 MET minutes with 47.4% recording a METS score of <600MET minutes per week before the start of the study. However, this improved significantly by six months' post intervention in the NEP group (>2000 MET minutes per week; 91.7% recording >600 MET minutes per week) compared to the others. Further, an improvement (>600 MET minute per week) was seen in the NE group 6 months' post intervention. Indeed, this indicates that physical activity improved with peer to peer support enhancing the benefit further. In fact, studies employing physical activity intervention in T2DM patient have reported significant outcome and are in support of the current study (Jahangiry et al., 2017; Sciacqua et al., 2003).

Emphasis on adherence to lifestyle modification is very important. Studies have shown that patients who adhere to dietary or physical activity changes or both have improved metabolic outcomes (Asaad et al., 2016; Mardani et al., 2018). Improved adherence to lifestyle modification can be enhanced by use of programmes aimed at increasing the proportion of patients choosing healthy behavior outcomes. Such programmes include nutrition education, group counseling on health food choices as well as emphasis on physical activity among others (Asaad et al., 2016; Casas et al., 2018; Gupta et al., 2019; Santo et al., 2018). However, lack of peer and community support has been shown to be among the factors associated with non-adherence to lifestyle modifications in addition to low knowledge level and lack of financial support. Studies have shown that improving the knowledge levels on health diet and physical activity as well as inclusion of peer support in T2DM management could lead to improved adherence to lifestyle management (Thankappan et al., 2018). The current study reported a statistically significant improvement in adherence to dietary modifications and physical activity levels in all the groups with a significant improvement in the NEP group. Indeed, this supports the importance of using nutrition education to improve dietary choices on T2DM patient (Asaad et al., 2016). Furthermore, the inclusion of the physical activity component in the program seems to improve adherence level that might lead to improved benefits.

Peer to peer support strategy in management of chronic conditions like T2DM has been shown to provide beneficial outcomes especially at improving adherence to dietary and physical activity modifications as well as good metabolic out comes (Johansson et al., 2016; Liu et al., 2015; Yin et al., 2015b). In this study, the inclusion of peer support led to improved adherence to dietary as well as physical activity modifications. Additionally, there was increased prevalence of participants having >3 days of consumption of the recommended servings of fruits and vegetables, use of unsaturated fat, including fibre- rich foods and foods of low glycemic index, controlling carbohydrates intake, and reducing fat intake in the NE and NEP groups, with significantly higher changes being seen in the NEP group. Therefore, this indicates that nutrition education had a significant role improving the adherence levels that were enhanced by the addition of peer support groups.

7.6 Conclusion

In conclusion, it was found that the nutrition education programme caused improved adherence to lifestyle modifications i.e. dietary and physical activity levels and that the inclusion of peer to peer support improves outcomes further. Additionally, healthy dietary choices were seen post intervention with NEP group showing better outcomes. Hence, the inclusion of nutrition education with peer to peer support component in T2DM management can be a good strategy in improving adherence to lifestyle modifications which in long run could improve the metabolic outcomes in these patients

CHAPTER EIGHT

EFFECT OF NUTRITION EDUCATION ON HEALTH CARE COSTS INCURRED BY TYPE 2 DIABETES MELLITUS PATIENTS: "A RANDOMIZED CONTROL TRIAL"

Manuscript to be submitted for publication as: Thuita A. w, Kiage B.N, Onyango A.O and Makokha A.O. Effect of lifestyle intervention through nutrition education programme on health care cost incurred by Type 2 Diabetes; "a randomized control trial"

8.1 Abstract

Type 2 diabetes mellitus (T2DM) imposes a large economic burden due to costs associated with its management as well as management of related complications. To combat this burden, strategies aimed at preventing T2DMas well as managing complications need to be pursued. Hence this study employed a nutrition education and studied its effects on health care costs incurred by T2DM patients. The study was a randomized control trial with 2 intervention groups and a control group. The first intervention group; Nutrition education peer to peer support (NEP) received nutrition education with peer to peer support, while the second intervention group received nutrition education and control group received standard care. Data on cost incurred by the patients was collected before the study and monthly after the intervention. Changes in all costs six months' post intervention were determined. Monthly mean costs between the groups as well differences between the changes in cost were determined using analysis of covariance (ANCOVA). The average total cost at baseline was not statistically significant averaged at Ksh.4821 for all the groups; (Ksh.5115.9 for NEP, Ksh.4653 for NE and Ksh.4692 for C. There was no significant change between groups in total costs incurred by the participants six months after the intervention; Ksh.99.06 in NEP, Ksh.-3.77for NE Ksh.22.70 for C. Additionally there was no significant difference between groups in direct cost (Ksh.382.28, ksh.-6.05 and Ksh. 103.54 in NEP, NE and C group respectively) and indirect cost (Ksh.-12.41, Ksh.-14.72 and Ksh.-83.11 in NEP, NE and C group respectively) incurred by the participants as well as cost of managing complication (Ksh.119.3, Ksh.-206.4 and Ksh.-268.4 in NEP, NE and C group respectively). The total average cost of ksh.4821 reported in our study was far below cost reported elsewhere. This cost was not affected by the intervention. Studies determining all factor associated with cost of care for T2DM need to be further explored.

Key words: Type 2 Diabetes Mellitus, Heath care cost, Nutrition education and peer to peer support

8.2 Introduction

Type 2 Diabetes mellitus (T2DM) is a global health concern that imposes a large economic burden on individuals, national healthcare systems and economies (IDF, 2013, 2014, 2015; Li et al., 2013; Petersen, 2013; Seuring etal., 2015). Diabetes and its complications that include cardiovascular disorders, kidney failure, neuropathy, retinopathy and amputations (IDF, 2016; Litwak et al., 2013) are on the increase, and are associated with increased mortality (IDF, 2015, 2016). In the presence of these comorbidities' and chronic complications, health care costs of the management of T2DM is enormous (Laliberté et al., 2009; Li et al., 2013; Petersen, 2013).

Health care expenditure on T2DM management accounted for about USD673 billion in 2015 and USD727 billion of total health care expenditure in the world and, about 80% of countries are predicted to spend between 5% and 20% of their total healthcare finance on diabetes (IDF, 2015, 2017). Beside excess health expenditure, T2DM patients also imposes a large economic burdens in the form of loss of productivity and foregone economic growth, as a result of reduced earnings due to lost work days, restricted activity days, low productivity at work, increased morbidity and mortality due to complications and permanent disability (IDF, 2015, 2017).

Such losses are perhaps relatively larger in developing countries like Kenya due lack of good care, increased morbidity and premature deaths (IDF, 2015, 2017). Studies have reported increased health care expenditure on people who have lived longer since diagnosis of T2DM, on females with T2DM, and those with comorbidities and complication due to T2D (IDF, 2015, 2017; Li et al., 2013).

Poor management of Type 2 Diabetes mellitus leads to increased prevalence's of complication as well as metabolic syndrome (MetS), thus increasing the cost of care. This economic cost intensifies due to reduced quality of life of the people with T2DM,

their families, friends, community as they contribute to care for the condition as well as the stress that arises during its management (IDF, 2017). The economic cost further increases if the people with T2DM have unhealthy food choices, they are physically inactive as well as if there non-adherent to lifestyle and medication use. Physical inactivity has been rated as the fourth leading cause of global mortality with 5.2 million of 52 million deaths, 7% being T2DM patients (WHO, 2010).

Lifestyle modification including healthy food choices and physical activity has been shown to be important in T2DM management. A study by Abdi et al (2015) reported an improvement in glycemic control after implementation of a behavior lifestyle intervention in T2DM patients. Others studies conducted on T2DM patient mellitus using either an exercise program or nutrition programme or both have shown a great improvement in patient outcomes which include, glycemic control body weight, waist circumference, blood pressure as well as lipid profiles (Abdi et al., 2015; Gerstel et al., 2013). Studies have shown that improvement in such out comes in T2DM patient leads to reduced complication as well as reduced cost of care. Such programme aimed at preventing progression of T2DM will substantially reduce the risk of people developing complications and overall cost of care (IDF, 2016). Therefore, the current study was conducted to determine the effect of nutrition education programme on cost of care incurred by T2DM patients.

8.3 Methods

8.3.1 Study design and participants

This was a randomized control trial conducted in T2DM attending care at Thika Level 5 Hospital. The patients included in the study were T2DM patient aged 20-79 years with no complications like renal failure. The study included two intervention groups and one control. The intervention groups either received nutrition education with a physical activity component; or nutrition education in combination with physical activity and peer to peer support. The training was done for two months and then

follow up for six months. Details of the training are explained in detail Chapter 5; Section 5.3.7 and Chapter 6; Section 6.3.6.

8.3.2 Data Collection

Baseline data on cost incurred by patients on monthly basis as well complications experienced by the participants were collected before commencement of the study. Data on health costs was collected using a structured questionnaire that was administered to the participants monthly after the intervention. The data collected included direct medical cost, indirect medical cost and indirect cost. For direct medical cost, cost incurred by participants for managing either diabetes or its complication; including costs of medication, treatment, laboratory investigation and hospitalization were recorded and summed up. Also costs incurred for nursing care in case a patient needed medical care was also included in direct medical cost. Indirect medical cost included cost of transportation to the hospital, productivity loss and earning lost for employed people on day they missed work because of their illnesses which was determined using Kenya minimum wage bill 2016 for agricultural industry (KNBS 2017) as majority of the participants were involved in farming and business a indicated in Chapter 3. A questionnaire exploring complications that the patient experienced during the study was administered and any cost on treatment, medication, laboratory investigation, hospitalization if any was used to compute cost incurred due to complication. This cost was the added up to cost of care for diabetes to give total direct cost. The cost incurred as transport to hospital due to complication as well as productivity loss when sick was considered as an indirect cost. Total cost of care included a summation of all direct cost and indirect cost. This data was collected monthly for six months and an average cost for each type of cost incurred by the participants computed. All cost value was computed using Thika Level 5 Hospital rates used in charging patients for service given at the hospital. For example if the cost of Glucophage drug in the hospital is Ksh.5 per tablet, this was used to compute monthly cost incurred by the participants who used Glucophage for treatment.

8.3.3 Data Analysis

The data collected was analysed using statistical package for social science (SPSS, Version 20) software. The data on complication as well as medication used by the participants was present as frequencies in percentages. The data on complication was collected in order to assist the researcher be able to compute cost incurred by the participant to manage the complications. Continuous data on cost; direct cost, cost of complications, indirect cost was analysed using analysis of co variance (ANCOVA) while, controlling for baseline data (Age, marital status, complications, family history of diabetes, year lived with diabetes). The data was presented as mean (SE) and statistical significance set at $P<0.05$.

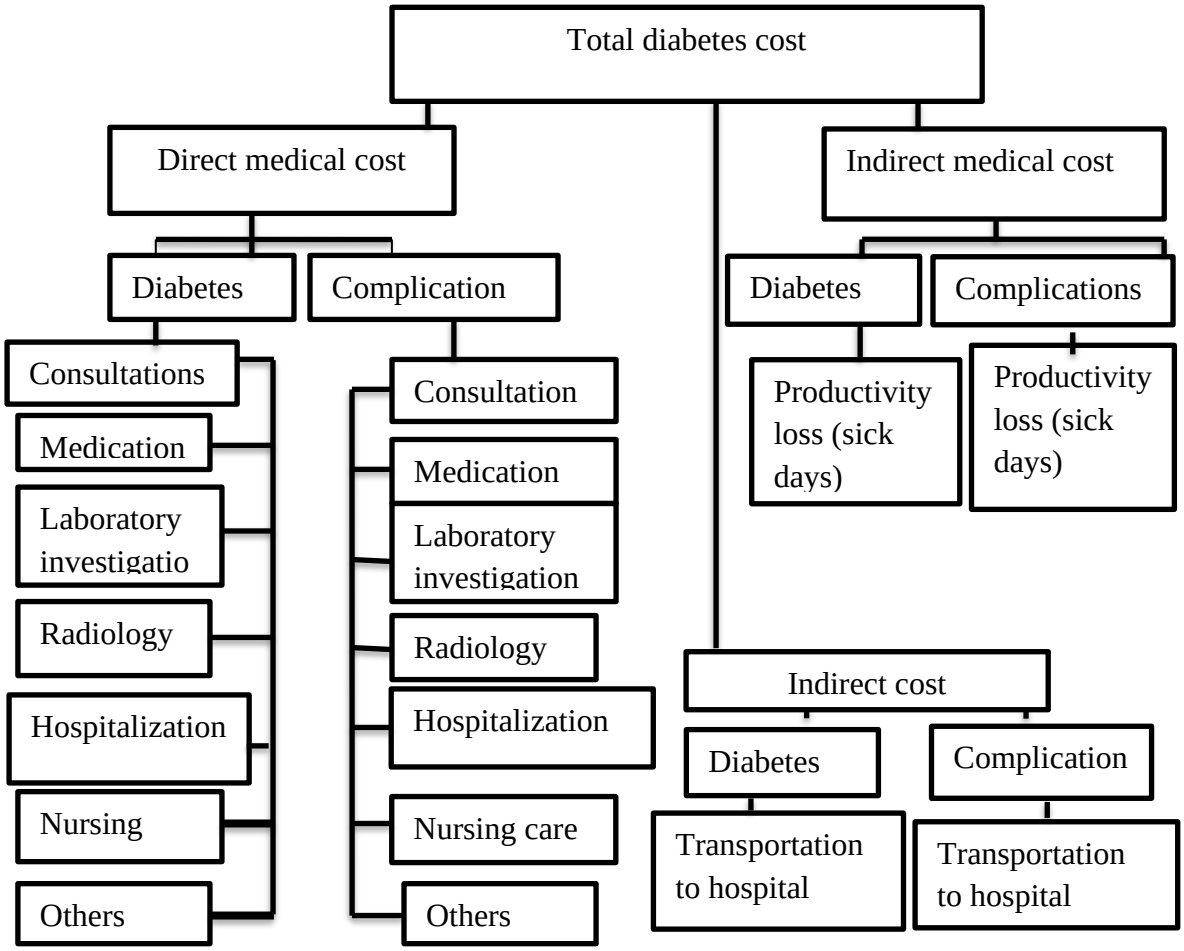

Figure 8. 1: Classification of health cost incurred by Type 2 diabetes mellitus (T2DM) patients

8.4 Results

8.4.1 Baseline characteristics

A total of 153 participants (51 participants per group) were included in the study at baseline but only 93.5% (143 participants; 48 in NEP, 49 in NE and 46 in controls) were available for post intervention review. As shown in Table 8.1 there was no significant difference in complications (hypertension, neuropathy, and nephropathy and retinopathy) related to T2DM among participant in each group at baseline as well in the follow up period. However, hypertension was the leading cause of co-morbidity, followed by retinopathy throughout the study in all the groups (Table 8.1). Only a few participants had nephropathy as a complication in all the groups in the entire study period. However, Control (C) group registered the highest number of nephropathy (10.2%) in Month 2 of follow up while NEP registering the highest number of nephropathy cases (6.0%). in Month 4 of follow up (Table 8.1)

8.4.2 Medication Used by Type 2 Diabetes Mellitus (T2DM) Patients

As shown in Table 8.2 the major treatment for T2DM used by the participants in the entire study period was oral hypoglycemic drugs. The major oral hypoglycemic drug was glucose lowering drug metformin (96.1% at baseline; 88.7% at month 3 and 96.5% at month 6 of post intervention) in form of glucomet (500 mg two time a day and 850 mg), Glucophage (500 mg and 850 mg) and metformin (1 g) itself. Sulfonylurea in form of Nogluc was only used by 33.3% at baseline, 32.2% at month 3 of follow up and 31.7% at month 6 of follow up. Insulin in form of mixtrad 30 (soluble 30, isophane 70) was used by 49.7%, 42.7% and 31.7% at baseline, month 3 and month 6 respectively.

Additionally, as shown in Table 8.2 most of the participant who had hypertension were on angiotensin II receptor blockers (30.1% at baseline, 28.9% at month 3 and 25.2 at month 6) followed by calcium channel blockers (23.5% at baseline, 14.8% at month 3 and 18.9% at month 6). Lostarn 50 mg was the most used angiotensin II receptor

blockers in all the groups and amlodipine was the most used calcium channel blockers (Table 8.2). Distribution of specific drug type for T2DM and hypertension as used at baseline, month 3 of follow up and at month 6 of follow in each group is as show in (Table 8. 2).

Table 8. 1: Prevalence of complication in patients with Type 2 Diabetes Mellitus (T2DM)

Month	Hypertension			Neuropathy			Nephropathy			Eye problem			Peripheral heart disease		
	NEP	NE	C	NEP	NE	C	NEP	NE	C	N:EP	NE	C	NEP	NE	C
Baseline	34 (66.7)	38(74.5)	28(54.9)	1(2.0)	0(0)	3(5.9)	0(0)	2(3.9)	0(3.9)	13(25.5)	12(23.5)	11(21.6)	6 (11.8)	7(13.7)	5(9.8)
Month 1	28(54.9)	25(50.0)	30(58.8)	6(11.8)	5(10.0)	2(3.9)	1(2.0)	0(0.0)	3(5.9)	14(27.5)	11(22.0)	11(21.6)	7(13.7)	6(12.0)	5(9.8)
Month 2	27(52.9)	25 (50.0)	28(57.1)	6(11.8)	4(8.0)	2(4.1)	1(2.0)	0(0.0)	5(10.2)	14(27.5)	11(22.0)	11(22.4)	7(13.7)	6(12.0)	5(10.2)
Month 3	28(54.9)	25(50.0)	25(52.1)	6(11.8)	4(8.0)	2(4.2)	1(2.0)	2(4.0)	4(8.3)	18(35.3)	12(24.0)	12(25.0)	7(13.7)	6(12.0)	5(10.4)
Month 4	28(56..0)	24(48.0)	27(56.2)	6(12.6)	5(10.0)	4(18.3)	3(6.0)	0(0.0)	2(4.2)	12(24.0)	14(28.0)	17(35.4)	9(18.0)	5(10.0)	7(14.6)
Month 5	28(57.1)	22(44.0)	31(66.0)	6(12.2)	4(8.0)	2(4.3)	0(0.0)	0(0.0)	2(4.3)	14(28.6)	11(20.0)	10(21.3)	7(14.3)	6(12.1)	5(10.6)
Month 6	25(52.1)	22(44.9)	27(58.7)	4(8.2)	2(4.3)	12(8.4)	0(0)	0(0)	2(4.3)	12(25.0)	10(20.4)	10(21.7)	6(12.5)	6(12.2)	5(10.9)

Data represent as proportion(n) and percentage (%); Baseline (n=51 in all the groups,); month1(n= 51 in NEP group, n=50 in NE group, n=51 in C group); month2 (n=51 in NEP group, n=50 in NE group and N=49 in C group); month3(n=51 in NEP group, n= 50 in NE group and n=48 in C group); month4 (n= 50 in NEP group, n=50 in NE group, n=48 in C group); month5 (n=49 in NEP group, n=50 in NE group, n= 48 in C group); month6 (n=48 in NEP group, N=49 in NE group and n=46 in C group).

Table 8. 2: Type of medication used by the participant for T2DM and hypertension classified per group

Drug type	Specific drug	Baseline				Month 3				Month 6			
		Total (n=153)	NEP (n=51)	NE (n=51	C (n=51)	Total n=(149)	NEP (n=50)	NE (n=50)	C (n=48)	Total (n=143)	NEP (n=48)	NE n=49)	C (n=46)
Glucose lowering drug (Metformin)	Metformin (1g)	147(96.1%)	11(21.6)	10(19.6)	12(23.5)	141(88.7)	13(25.5)	10(20.0)	13(26.5)	141(96.5)	12(41.7)	10(20.4)	12(26.1)
	Glucophage (850mg)		0(0.0)	1(2.0)	2(3.9)		0(0.0)	1(2.0)	1(2.0)		3(6.2)	6(12.2)	7(15.2)
	Glucophage (1000mg)		4(7.8)	6(11.8)	4(7.8)		39(5.9)	5(10.0)	6(12.2)		0(0.0)	1(2.0)	2(4.3)
	Glucomet (850mg)		293.9)	0(0.0)	2(3.9)		3(5.9)	1(2.0)	2(4.1)		2(4.0)	0(0.0)	2(4.3)
	Glucomet (500mg) BD		33(64.7)	32(62.7)	27(52.9)		29(56.9)	31(62.0)	25(51.0)		29(60.5)	30(60.2)	24(54.2)
	Glucomet (500mg) TD		090.0)	1(2.0)	0(0.0)		0(0.0)	1(2.0)	0(0.0)				
Sulfonylurea	Nogluc 5mg	51(33.3)	9(17.6)	10(19.6)	9(17.6)	48(32.2)	6(11.8)	8(18.0)	7(14.3)	45(31.7)	4(8.3)	9(18.4)	4(8.7)
	Nogluc 10mg		7(13.7)	6(11.8)	9(17.6)		10(19.6)	7(14.0)	7(14.3)		9(18.8)	5(10.2)	7(15.7)
	Nogluc 20mg		0 (0.0)	1(2.0)	0(0.0)		0(0.0)	2(4.3)	0(0.0)		2(4.2)	2(4.1)	3(6.5)
Insulin (Mixtard 30 (soluble 30, isophane 70)		79(49.7%)	24(41.7)	23(45.4)	29(56.9)	64(42.7)	21(41.2)	19(38.0)	24(42.7)	59 (31.7)	20(41.7)	18(36.7)	21(45.7)
Angiotensin II lockers		46(30.1	14(27.5)	26(51.0)	19(37.3)	43(28.9)	12(23.5)	12(24.0)	19(39.6)	36(25.2)	8(16.7)	10(20.4)	18(39.1)
	Loscar 50mg		4(7.8)	2(3.9)	4(7.8)		0(0.0)	0(0.0)	0(0.0)		0(0.0)	0(0.0)	0(0.0)
	Atcard 75mg		3(5.9)	3(5.9)	0(0)		1(2.0)	1(2.0)	1(2.10		1(2.1)	0(0.0)	3(6.5)
	Lostarn 50mg		7(13.7)	21(41.2)	17(33.3)		11(21.6)	11(22.0)	18(37.5)		7(14.6)	10(20.4)	15(32.6)
Calcium channel blockers		45(29.4)	21(41.2)	15(29.4)	9(17.6)	22(14.8)	13(25.5)	5(10.0)	4(8.3)	27(18.9)	14(29.2)	8(16.3)	5(10.9)
	Amlodipine Norvasc 2mg		10(19.6)	8(15.7)	4(7.8)		6(11.8)	4(8.0)	3(6.2)		6(12.5)	5(10.2)	4(8.7)
	Nifedipine 20mg		5(9.8)	5(9.8)	1(2.0		3(5.9)	1(2.0)	1(2.0)		4(8.3)	2(4.1)	1(2.2)
	Nifelat 20mg		3(5.9)	1(2.0)	3(5.9)		2(3.9)	1(2.0)	0(0.0)		2(4.2)	2(4.0)	0(0.0)
	Plendil 10mg		3(5.9)	1(2.0)	1(2.0)		2(3.9)	0(0.0)	0(0.0)		2(4.2)	0(0)	0(0)
Beta blockers		37(24.2)	14(27.5)	15(29.4)	8(15.7)	16(10.7)	5(9.8)	6 (12.0)	5(10.4)	16(11.2)	5(10.4)	6(12.2)	5(10.9)
	Atenol (cardinoll) 50mg		9(17.6)	8(15.7)	8(15.7)		3(5.9)	4(8.0)	5(10.4)		3(6.2)	4(8.2)	5(10.9)
	Atenol (Cardinol) 100mg		5(9.8)	7(13.7)	0(0.0)		2(3.9)	2(4.0)	0(0.0)		2(4.2)	2(4.1)	0(0)
Angiotensin converting enzyme (ACE) inhibitors (Enalapril 10mg)		12(7.8)	6(11.8)	3(5.9)	5(9.8)	10(6.7)	5(9.8)	1(2.0)	4(8.3)	14(9.8)	6(12.5)	3(6.1)	5(10.9)
Diuretics		17(11.1)	9(17.6)	6(11.8)	9(17.6)	11(7.4)	7(13.7)	0(0.0)	2(4.2)	11(7.7)	7(14.6)	1(2.0)	3(6.5)
	HTZ (Hydrochlorothiazide)		6(11.8)	5(9.8)	6(11.8)		3(5.9)	0(0.0)	1(2.1)		3(6.2)	1(2.0)	1(2.0)
	HTZ+Lostarn		3(5.9)	1(2.0)	3(5.9)		4(7.8)	0(0.0)	1(2.1)		4(8.3)	0(0.0)	2(4.3)

Data present as proportion (n) and percentage.

8.4.3 Total Cost of Care incurred by the patients with Type 2 Diabetes Mellitus (T2DM)

As shown in Table 8.3, there was no significant difference in mean change in total health cost incurred by the participant six months' post intervention Ksh.99.06 in NEP, Ksh. -3.77 for NE Ksh.22.70for C. The average total cost at baseline was not significantly different between the groups and it ranged from Ksh 4600 to Ksh.5000 (Ksh.5115.9 for NEP, Ksh.4653.7 for NE and Ksh.4692.5 for C) for all the groups at baseline. NEP registered the highest cost (Ksh.5463.5) at month 5, while NE registered highest cost (Ksh.5702.6) at month 2 and C registered the highest cost (Ksh.5188.7) at month 4. However, the total cost incurred by the participant in all month was not significantly different between groups. Distribution of total cost incurred by the participant per month in management of T2DM in each group is as shown in Table 8.3.

As shown in Table 8.4, there was no significant difference in mean change in total direct health cost incurred by the participants six months' post intervention (Ksh.382.2in NEP group, Ksh.-6.05 in NE group and Ksh.-103.5 for C group respectively). The average total direct cost at baseline was not significantly different between the groups and it ranged from Ksh.2900- ksh.3600 (Ksh.3605.0 for NEP, Ksh.2950.1 for NE and Ksh.3206.2 for C). NEP registered the highest direct cost (Ksh.3852.5) at month 6, while NE registered highest cost (Ksh.3763.8) at month 2 and C registered the highest cost (Ksh.3389.9) at month 4

Table 8. 3: Monthly distribution of Total cost incurred by T2DM patient

Month	NEP		NE		C		Total cost		Value (df)	P value
Baseline	5115.9(403.4)	4318.6-5913.6	4653.7(400.1)	3893.0-5444.4	4692.5(398.4)	3904.1-5480.9	4820.7(229.6))	4366.8-5274.5	0.40 (2,145)	0.62
Month1	5333.9(361.5)	4624.4-6053.5	4665.4(362.0)	3949.9-5380.9	4204.2(357.9)	3496.9-4911.5	4736.2(206.6)	4327.8-5144.6	2.48 (2,144)	0.09
Month 2	5172.89(443.8)	4295.6-6050.2	5702.6(444.9)	4822.0	4764.6(448.5)	3878.0-5651.2	5213.4(255.5)	47.8.3-5718.4	1.11 (2,142)	0.33
Month3	5326.8 (368.6)	4598.1-6055.2	4837.7(369.6)	4107.0-5568.3	4825.9(376.4)	4081.8-5570.0	4996.7(313.0)	4575.7-5417.9	0.59 (2,141)	0.59
Month4	5322.9(395.7)	4540.6-6105.2	4968.8(394.1)	4189.6-5747.9	5188.7(401.2)	4395.7-5981.8	5160.1(228.1)	4709.2-5611.1	0.20 (2,140)	0.82
Month5	5463.5(411.4)	4649.9-6277.1	4940.9(404.53)	4140.9-5740.9	5102.2(426.3)	4259.2-5945.2	5168.9(237.6)	4698.9-5638.8	2.14(2,138)	0.65
Month6	5311.9(406.5)	4507.5-6115.8	4997.9(399.6)	4207.6-5788.3	5047.7(412.6)	4231.6-5863.8	5119.2(233.0)	4658.4-5580.0	0.0171(2,135)	0.84
Changes in cost	99.06(318.1)	-530.1-728.2	-3.77(316.11)	-628.99-621.5	22.70(322.95)	-616.1-661.4	39.33(182.9)	-322.5-401.2	0.028(2,135)	0.97

Data represented in mean (Standard error; SE). Baseline (n=51 in all the groups,); month1(n= 51 in NEP group, n=50 in NE group, n=51 in C group); month2 (n=51 in NEP group, n=50 in NE group and N=49 in C group); month3(n=51 in NEP group, n= 50 in NE group and n=48 in C group); month4 (n= 50 in NEP group, n=50 in NE group, n=48 in C group); month5 (n=49 in NEP group, n=50 in NE group, n= 48 in C group); month6 (n=48 in NEP group, N=49 in NE group and n=46 in C group).

All cost in the group and total population are in Kenya shilling (Ksh)

df: degree of freedom; Statistical significance at $p<0.05$. Data analyzed using analysis of Co- variance (ANCOVA)

All data adjusted for baseline characteristics (age, gender, and marital status, family history of diabetes and years lived with diabetes)

Table 8. 4: Monthly distribution of direct cost (DC) incurred by the participant

Month	NEP	95% CI	NE	95% CI	C	95% CI	Total	95% CI	(df) Fvalue	P value
Baseline	3605.0 (346.1)	2950.1 –4319.15	3206.2 (343.3)	2527.7 – 3884.7	3204.6 (342.3)	2564.2– 3917.1	3360.6 (197.0)	2971.2–3750.1	0.47(2,145)	0.63
Month1	3634.6 (336.5)	2669.5 – 4299.6	3070.2 (336.9)	2408.3 – 3740.2	2852.5 (333.1)	2194.2 -3510.8	3187.1 (192.0)	2807.0 -3510.8	1.42 (2,144)	0.25
Month 2	3675.0 (334.0)	3015.8 – 4334.2	3763.8(334.3)	3102.9 -4424.7	3233.2(337.1)	2567.0 – 3389.4	3557.3 (192.0)	3177.8–3936.9	0.722 (,142)	0.49
Month3	3644.1 (330.9)	2989.9-4298.3	3106.3(331.8)	2450.4 -3792.2	2957.9 (337.9)	2289.9 – 3625.9	3236.1 (191.2)	2858. – 3614.1	1.16 (2,141)	0.32
Month4	3497.9 (337.1)	2831.4 – 4164.4	3189.9 (335.8)	2525.2 – 3852.9	3389.9 (341.8)	2714.2– 4065.6	3395.9 (194.3)	2974.5–3743.1	0.2(2,140)	0.81
Month5	3722.7 (341.9)	3046.6 – 4398.9	3111.1 (336.4)	2445.7 – 3776.2	3054.2 (346.7)	2368.6 – 3739.8	3296.0 (196.1)	2908.3–3683.7	1.16 (2,138)	0.32
Month6	3852.5 (336.3)	3187.5 -4517.5	3163.0 (337.3)	2495.0- 3830.0	3339.9 (344.7)	2658.2– 4021.0	3451.8 (194.5)	3067.1–3836.5	1.11 (2,135)	0.33
Changes in DC	382.3(194.3)	-1.99-766.6	-6.05(194.93)	-391.6-379.5	-103.5(199.1)	-497.4-290.3	90.89(112.39)	-131.4-313.2	1.70(2,135)	0.19

Data represented in mean (Standard error; SE). Baseline (n=51 in all the groups,); month1(n= 51 in NEP group, n=5 in NE group, n=50 in C group); month2 (n=51 in NEP group, n=50 in NE group and N=49 in C group); month3(n=51 in NEP group, n= 50 in NE group and n=48 in C group); month4 (n= 50 in NEP group, n=50 in NE group, n=48 in C group); month5 (n=49 in NEP group, n=50 in NE group, n= 48 in C group); month6 (n=48 in NEP group, N=49 in NE group and n=46 in C group).
All cost in the group and total population are in Kenya shilling (Ksh)
df: degree of freedom; Statistical significance at $p<0.05$. Data analyzed using analysis of Co- variance (ANCOVA)
All data adjusted for baseline characteristics (age, gender, and marital status, family history of diabetes and years lived with diabetes)
DC-direct cost

Total direct costs associated with managing diabetes complications such as hypertension, neuropathy, nephropathy, arthritis, foot problems, peripheral heart condition, elevated cholesterol, eye problems, oral problem and mental conditions, over the six-month period, are shown in Table 8.5. The average total cost for managing complications at baseline was not significantly different between the groups, and it ranged from Ksh.2100- ksh.2900 (Ksh.2838.3 for NEP, Ksh.2403.2 for NE and Ksh. 2394.8for C). NEP registered the highest direct cost (Ksh.2896.8) at month 3, while NE registered highest cost (Ksh.2251.9) at month 3 and C registered the highest cost (Ksh.2406.2) at month 4 however the cost was not significantly different between the groups in the months considered. There was no significant difference in mean change in total direct cost for management of complication, incurred by the participant six months' post intervention (Ksh.-119.3 in NEP, Ksh.-206.4 for NE Ksh.-268.4 for C respectively).

Distribution of indirect cost incurred by the participant per month in management of Type 2 diabetes mellitus in each group is as shown in Table 8.6. Total indirect costs considered in the current study consisted of costs incurred for transport as well as cost of sick days associated with the participants. The average total indirect cost ranged from Ksh.1100- ksh.1200 (Ksh.1200.0 for NEP, Ksh.1194.8 for NE and Ksh.1260.5 for C) for all the groups at baseline. NEP registered the highest indirect cost (Ksh.1350.2) at month 5, while NE registered highest indirect cost (Ksh.1337.2) at month 3 and Control group (C) registered the highest cost (Ksh.1260.5) at baseline. There was no significant difference in mean change in total indirect health cost incurred by the participant six month post intervention (Ksh.-12.41 in NEP, Ksh.-14.72 for NE Ksh.-83.11 for C)

Table 8. 5: Monthly distribution of cost incurred due to Type 2 diabetes Mellitus complications

Month	NEP	95% CI	NE	95% CI	C	95% CI	Total cost	95% CI	F value	P value
Baseline	2838.3(339.2)	2167.8 –3501.7	2403.2 (336.4)	1738.3–3068.1	2394.8(335.4)	1731.8 -3057.7	2545.4 (193.6)	2163.8 –2927.1	0.55 (2,145)	.058
Month1	2799.1 (329.5)	2147.8 – 3450.4	2318.51 (330.0)	1666.2– 2970.8	2084.4 (326.7)	1439.6- 2729.1	2400.6 (188.3)	2028.4 –2772.9	1.21(2 ,144)	0.30
Month 2	2642.6(309.4)	2013.0 – 3236.1	2404.1(310.2)	1790.9 - 3017.2	2113.1 (312.7)	1495.1–2731.2	2380.6 (178.1)	2028.5– 2732.7	1.04 (2,142)	0.36
Month3	2896.8 (326.2)	2251.9 – 3541.7	2376.9(327.0)	1730.3 – 3023.45	2167.1 (333.1)	1508.6–2825.6	2480.3 (188.5)	2107.6– 2852.9	1.29 (2,141)	0.28
Month4	2741.6 (331.9)	2085.5 – 3397.7	2406.8 (330.6)	1753.2-3060.3	2612.1 (336.5)	1946.9–3271.3	2586.8 (191.3)	2208.6 –2965.1	0.26 (2,140))	0.77
Month5	2905.2 (330.8)	2251.2 – 3559.2	2343.0(325.4)	1699.6 – 2986.4	2238.7 (335.4)	1575.5–2901.8	2495.6(189.7)	2120.6 –2870.6	1.15 (1,138)	0.32
Month6	2786.1(318.1)	2157.1 – 3415.1	2156.6(319.1)	1528.6 – 2790.5	2304.4 (326.1)	1659.6–2949.2	2416.7 (184.0)	2052.8 –2780.6	1.04 (2,135)	0.36
Change in CC	119.3(157.9)	-19289-431.49	-206.4(158.4)	-519.55-106.85	-268.4(161.8)	-588.39-51.53	-118.5(91.30)	-299.06-62.08	1.69(2,135)	0.18

Data represented in mean (Standard error; SE). Baseline (n=51 in all the groups,); month1(n= 51 in NEP group, n=5 in NE group, n=50 in C group); month2 (n=51 in NEP group, n=50 in NE group and N=49 in C group); month3(n=51 in NEP group, n= 50 in NE group and n=48 in C group); month4 (n= 50 in NEP group, n=50 in NE group, n=48 in C group); month5 (n=49 in NEP group, n=50 in NE group, n= 48 in C group); month6 (n=48 in NEP group, N=49 in NE group and n=46 in C group).
All cost in the group and total population are in Kenya shilling (Ksh)
df: degree of freedom; Statistical significance at $p<0.05$. Data analyzed using analysis of Co- variance (ANCOVA)
All data adjusted for baseline characteristics (age, gender, and marital status, family history of diabetes and years lived with diabetes)
CC –complication cost

Table 8. 6: Monthly distribution of indirect cost incurred by Type 2 diabetes mellitus (T2DM) patient

Month	NEP	95% CI	NE	95% CI	C	95% CI	Total cost	95% CI	F value (2,146)	P value
Baseline	1212.0(62.9)	1015.6-1344.4	1194.8(62.4)	1071.4-1318.2	1260.5(62.2)	1087.5-1333.5	1208.4(35.8)	1137.6-1279.3	0.41 (2,145)	0.96
Month1	1277.0(65.4)	1147.8-1406.3	1245.6(65.5)	1116.1-1375.0	1166.9(64.7)	1039.0-1294.9	1229.8(37.4)	1156.0-1303.7	0.76 (2,144)	0.47
Month 2	1218.8(70.7)	1079.1-1358.6	1337.2(70.9)	1197.1-1477..3	1221.5(71.4)	1080.3-1362.7	1259.2(40.7)	1178.7-1339.6	0.90 (2,142)	0.41
Month3	1306.8(64.3)	1179.8-1433.9	1241.5(64.7)	1114.1-1368.9	1224.8(65.6)	1095.0-1354.5	1257.7(37.1)	1184.3-1331.1	0.44 (1,141)	0.62
Month4	1313.3(63.4)	1188.0-1438.6	1262.9(63.1)	1138.1-1387.7	1211.3(64.3)	1084.3-1338.3	1262.5(36.5)	1190.3-1334.7	0.64 (2,140)	0.53
Month5	1350.2(70.2)	1211.4-1489.0	1271.0(69.1)	1134.5-1407.5	1222.0(71.2)	1081.2-1362.7	1281.0(40.3)	1201.5-1360.6	0.83 (2,138)	0.44
Month6	1192.2(60.1)	1073.4-1311.1	1179.5(59.1)	1062.7-1296.33	1158.2(61.1)	1037.9-12778.87	1176.7(34.45)	1108.5-1244.77	0.08 (2,135)	0.92
Changes in IC	-12.41(62.99)	-137.0-112.2	-14.72(61.92)	-137.2-107.8	-83.11(63.94)	-209.6-43.3	-36.74(36.10)	-108.16-34.66	0.40(2,135)	0.67

Data represented in mean (Standard error; SE). Baseline (n=51 in all the groups,); month1(n= 51 in NEP group, n=5 in NE group, n=50 in C group); month2 (n=51 in NEP group, n=50 in NE group and N=49 in C group); month3(n=51 in NEP group, n= 50 in NE group and n=48 in C group); month4 (n= 50 in NEP group, n=50 in NE group, n=48 in C group); month5 (n=49 in NEP group, n=50 in NE group, n= 48 in C group); month6 (n=48 in NEP group, N=49 in NE group and n=46 in C group).
All cost in the group and total population are in Kenya shilling (Ksh)
df: degree of freedom; Statistical significance at $p<0.05$. Data analyzed using analysis of Co- variance (ANCOVA)
All data adjusted for baseline characteristics (age, gender, and marital status, family history of diabetes and years lived with diabetes)

8.5 Discussion

Type 2 diabetes mellitus (T2DM) is costly to manage due it associated complication. Total health care expenditure for management of T2DM has been estimated at USD 727 billion globally (IDF, 2017). North American and Caribbean region have the highest expenditure on diabetes of USD 383 billion for persons aged 20-79 years, corresponding to 52% of the total amount spent globally. Additionally, according to IDF (2017), Africa had the least expenditure of 6 % on diabetes in 2017, but this could be higher as it is the region with highest prevalence of undiagnosed diabetes. Cost of care due to diabetes complications is on the rise, with cardiovascular disorders contributing to the highest economic burden, followed by eye problem (IDF, 2016, 2017). This is in support of the current study.

In the current study hypertension was the leading cause of co- morbidity with a prevalence of 55-75% in the three groups at baseline and 45-58% six months' post-intervention. This reduction in prevalence was however, not significant. Retinopathy was the second co morbidity associated with T2DM and peripheral artery disease 3rd in all the groups in the months considered for the study. This is consistent with reports that hypertension, retinopathy and peripheral heart problem are on the increase in T2DM patient and have been reported to have a significant effect on quality of life (IDF, 2017; WHO, 2016). Studies have reported prevalence of hypertension of above 50- 70 % in Type 2 diabetes patients (Lastraet al, 2014; Mohammed, 2014; Tadesse et al., 2018). A study by Onyando et al (2019) reported a high prevalence of hypertension as well as increased cost of care in T2DM patients with hypertension and is in support of our study. The increasing rise in hypertension, retinopathy and peripheral artery disease in T2DM patient leads, to increased economic burden and overall reduced quality of life (IDF, 2017; Okoronkwo et al., 2015). The current study reported high direct cost in purchase of anti-hyperglycemic drugs, antihypertensive drugs and eye care management drugs, supporting the evidence of increased burden associated with hypertension and retinopathy in T2DM patients.

The total cost of care for each participant for T2DM managed ranged from Ksh 4653 to Ksh.5151; an average of Ksh.4821 (per month translating to an average annual cost

of 580 USD (Table 8.3). Total cost considered in the study comprised of direct and indirect cost. Direct health cost incurred by the participant was the highest with cost of complication contributing the highest percentage associated with this cost. Most of the direct cost incurred by the participant in the current went to purchase of drug as well as management of type diabetes and complications. Kenya expenditure on diabetes management is estimated at USD 154 per person (IDF, 2017) which was far below what was reported in our study (USD 540). Comparing the result of the current study with a study carried in public hospital in Kenya (Kilifi and Bungoma) by Oyando et al (2019) as well as a study by Subramanian (Subramanian et al., 2018), the cost was below that reported in their studies. The difference might have been due to the fact that the current study did not take into consideration the loss of productivity for care giver and cost of food or accommodation while seeking care which was the case in Oyando et al (2019a). Additionally, the disparity in cost could also have been contributed by the fact that only patient with T2DM and without complication were included in the study

Compared to cost of T2DM care in other African country, the total cost of care was low. A study by Okoronkwo et al (2015) in Nigeria on cost of care for diabetes reported a total cost of USD 56 425 with cost of drug being USD 7702 and that of diabetes related disease being USD 2894 which is far above the tabulated total cost in the current study. Another study in South Africa reported a total annual cost of USD 276,900 translating to USD 23,075 month with direct cost being USD 198, 784 (USD 16,565) per month. The difference might be due to factors considered in the Nigeria study and South African study. This Nigeria study factored cost for diet that was the highest (USD 28524) cost of self-monitoring, coat of a house helper and insurance premium that were not factored in our study while the South Africa study also included cost of equipment, dialysis, stroke, kidney transplant and stroke management that were not factored in the current study.

Additionally, majority of the study participant monitored their blood glucose at facility during visit of care and not as per recommended and this might be one factor also contributed to the low cost of care in the current study.

The current study showed that change in health cost (total cost, cost of complication, direct cost as well as indirect cost) incurred by the participant post intervention was not significant. The highest cost of care in the current study both pre- and post-intervention was for managing complications. Although lifestyle interventions employing nutrition education and diabetes self-management education have been associated with decreased direct costs incurred by T2DM patients (Boren et ai., 2009), this was not the case in the current study.

The World Health Organization (WHO), ADA and IDF recommend comprehensive care for management of Type 2 diabetes (ADA, 2018, 2019; IDF, 2017; WHO, 2016). This includes routine check for blood glucose, blood pressure, nutrition status, physical examination (eye and foot included), and biochemical test that looks at kidney function, liver, cholesterol, HbA1c, and cardiovascular risk assessment (ADA, 2018, 2019). Although Thika level 5 Hospital, supported by the Kenya Ministry of Health (MOH) adopted this concept in 2010, a gap still exists in its management of care for T2DM patients (Mwavua, 2016). The only available routine checkup that is done on each hospital visits by a patient is random blood glucose checkup, blood pressure and body mass index done at a cost of Ksh. 200. All other checkup for co-morbidities associated with T2DM like foot care management, eye care, kidney function checkups are usually based on the clinician request after symptom appears or on patients' request. Also compliance of some participant to requested test or a treatment is poor and this is mostly associated with increased financial burden considering that most Kenyan live below 1 dollar per day. This eventually leads to reduced rate of diagnosis of complication in some patient hence treatment is not given. These factors usually affect cost of care and might be the cause of low cost pre and post intervention.

Additionally most studies conducted on tT2DM in Kenya reports screening for only diabetes and hypertension while other condition are left out (Ebere et al, 2017; El-Busaidy et al., 2014; Subramanian et al., 2018). This might also explain the reason for low cost per person of diabetes care as compared to other countries where majority of care is given (Moucheraud et al., 2019; Okoronkwo et al., 2015; Seuring et al., 2015). Moreover, some of the treatments like eye care are very expensive therefore most patients postpone treatment and only go for care if the situation worsens or when

services are available for free. This has been attributed to low social economic status in the studied population as well as other T2DM patient in the country (Ebere et al., 2017). Furthermore, majority of the participants only rely on blood glucose checkup at the hospital with no self-monitoring

8.6 Conclusion

The current study reported a total average cost of USD 482 that was far below cost reported elsewhere. This cost was not affected by the intervention. Studies determining all factor associated with cost of care for T2DM need to be further explored before and after implementation of nutrition education with or without peer to peer support\

CHAPTER NINE

GENERAL DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

9.1 General Discussion

Type 2 diabetes Mellitus (T2DM) is a global health challenge with increasing prevalence (IDF; International Diabetes Federation, 2015, 2017). Poor management of T2DM leads to microvascular and macrovascular complications (IDF, 2017; WHO, 2016). Additionally, metabolic syndrome (MetS) is on the increase in T2DM patients, with high prevalence of above 70 % having been reported (Lira Neto et al., 2017; Pokharel et al., 2014; Tan et al., 2013; Todowede & Sartorius, 2017; Yadav et al , 2013). An increasing trend of related complications associated with T2DM has also been reported (IDF, 2017). The increased prevalence's of T2DM, and metabolic syndrome in T2DM have been associated with risk factors such as unhealthy diets, physical inactivity, obesity (Chaudhuriet al., 2016; Fareed et al., 2017; Naveed et al., 2016; Tawaet al., 2011) and non-adherence to treatment modification (Alharbi & Alsubhi, 2016; Ganiyu et al., 2013; Saleh et al., 2014; Shankar & Ramya, 2012). This has led to increased cost of care with a health expenditure of 720 billion going of diabetes care (IDF, 2017)

Patient demographic and economic characteristics have also been shown to be key in T2DM development as well as management (Kugbey et al., 2015; Mau etal., 2013). Understanding their association with glycemic control as well as metabolic risk factors is very important, as this forms the basis of some of the preventive strategies. Such preventive strategies aimed at improving glycemic control as well as reducing complications and associated metabolic disorders have been advocated (IDF, 2017; WHO, 2016). Some of these strategies that have shown good outcomes included diabetes self-education, nutrition education; peer to peer support programme, exercise programme as well as lifestyle programmes. These strategies have been employed alone or in combination using different implementation models.

Randomized control trial models have been utilized to study the effects of these strategies in T2DM patients and have been shown to be effective.

Despite the good benefit in such strategies, most of these studies have been done in developed countries with limited studies done in low income, developing countries and sub-Saharan Africa, Kenya included. This calls for a need of such programmes, tailored for developing countries like Kenya.

The main objective of this study was to determine the effect of a nutrition education programme with peer to peer support component on metabolic syndrome management in patients with T2DM at Thika Level 5 Hospital in Kenya. It was hypothesized that there was no significant association between T2DM patient characteristics and MetS, MetS indicators and glycemic control indicators; that the nutrition education had no significant effect on knowledge levels of patient with T2DM; that the nutrition education had no significant effect on the MetS and MetS indicators among T2DM patients; that the nutrition education had no significant effect on adherence to lifestyle modification among patients with T2DM; and that nutrition education had no significant effect on health care cost incurred by the patients with T2DM.

The hypothesis that there was no significant association between T2DM patient characteristic and Mets, MetS indicators and glycemic control was rejected. The current study reported a prevalence of above 85% using the harmonised (Alberti et al., 2009) and WHO criteria (WHO, 1998) was reported among the participants in the study (Thuita, et al., 2019). Additionally, the current study showed an association of some patient demographic characteristic with some MetS, Mets risk factors. Participants with high income were significantly associated with increased odds to elevated blood pressure as well as increased odds to MetS while those who lived in the urban areas were significantly associated with increased odds to reduced HDL and elevated blood pressure.

Furthermore, participants who had attained secondary indication had significant increased odds to elevated blood pressure, elevated TG and obesity compared to those with primary education. Moreover, participants who had lived with T2DM for longer years were significantly associated with increased odds to elevated TG while female participants and those who were married associated with significant higher odds to reduced HDL. Participants who were taking alcohol, had a family history of diabetes

had significant higher odds to obesity. The current study is supported by Mavarez-Martinez et al (2016) that reported that increased income levels have been associated with behaviour adaptation like unhealthy dietary choices and sedentary lifestyle, which leads increased metabolic risk in T2DM. A study by Ogunsina et al (2018) reported an increased odds of overweight/obesity, diabetes and hypertensive in adults with increased social economic status supporting the evidence that increased social economic status is associated with increased risk to metabolic disorders.

Furthermore, family history and alcohol intake was associated with obesity. The results of the study are supported by a study by Venkatachalam et al (2013) that showed a positive association of alcohol intake and diabetes. Additionally, family history of diabetes and increased years with diabetes are key risk factors in T2DM patients as shown in the current study as it predisposes them to related metabolic risk like dysilipedimia as well as obesity. This has been supported by Gopalakrishnan et al (2017).

Patient with T2DM have been encouraged to maintain a HbA1c of <7%. This has been shown as a good indicator of prevention of complication associated with poor glycemic control. However, this was not the case in the current study as it reported a higher mean of HbA1c > 7% with 77.8% of the participants having a HbA1c >7%. Several factors in T2DM patients need to be put into consideration in order to achieve good glycemic control. These factors include environmental factor, patient characteristics as well as metabolic factors. Poor glycemic control in the current study was associated with increasing age (>50years) as well as significant higher mean TC and LDL.

Additionally, family history of diabetes (FHD), elevated fasting blood glucose (FBG), elevated TG, elevated SBP were also associated with poor glycemic control as reported in Thuita et al (2019). A study by Hu et al (2016) support the current study as it reported an association of uncontrolled dyslipidemia and high BP with poor glycemic control, while for older age this was true as it reported an association of poor glycemic control for young age which was not the case in the current study. Moreover, a strong relationship was seen after moderating FBG with FHD an indication that FHD might be an important predictor of FBS. Furthermore, advanced education (tertiary

education) showed a positive association with good glycemic control (HbA1c >7%). As people advance in education their knowledge of care increase and these might have contributed to the positive relationship with advance education. The result of the current study supports the evidence that understanding patient characteristics is key in management of T2DM, since they play an important role in its development as well as control of complication. Additionally, FHD needs to be considered on diagnosis as it has been shown to be an important predictor of FBG a key factor that had a positive relationship with HbA1c in the current study.

The current study employed a nutrition education programme with peer to peer support and one with only nutrition education. The study hypothesized that nutrition education package has no significant effect on knowledge levels of patients with T2DM. This hypothesis was rejected because the study reported a significant improvement in knowledge score after implementation of the nutrition education package post intervention. Significant improvement of between 33-42% in overall knowledge score was seen in NEP group and between 31-38% was seen in the NE group post intervention. The highest score of 42.5% and 38.3% was seen immediately after the intervention in the NEP and NE group which reduced as time elapsed. Comparison of the group after intervention showed significant difference between NEP and C, NEP and NE as well as NE and C, an indication that nutrition education in T2DM patients leads to improved knowledge with peer to peer support enhancing this further. The results of the current study are supported by Liu et al (2015) study, that reported a significant improvement in diabetes knowledge post intervention in the peer support group after employing a peer support model in there study. Another study by Muchiri et al (2016) which employed a nutrition education model in the management of T2DM patients showed increased mean in knowledge score 6 months and 12 months' post intervention, and is in support of the current study which also showed improved knowledge score in the NE and NEP groups.

Additionally, the hypothesis that nutrition education has no significant effect on the MetS and MetS indicators among T2DM patients was rejected. The current study showed significant reduction in MetS prevalence in T2DM patients six months' post evaluation (Table 6.6) in the NE group. The MetS prevalence reduced significantly in

NEP on inclusion of peer to peer support to the nutrition education model while it increased in the control group (Table 6.3). Likewise, the current study also reported significant reduction of proportion of participants with elevated WC, elevated TG, reduced HDL as well as improvement of normal BMI by in the NEP group compared to NE and C (Table 6.3). The significant reduction in MetS prevalence and prevalence in MetS outcomes in NEP and NE could support the evidence that nutrition education can successfully be employed in T2DM patients in their management which could be enhanced by incorporation of peer to peer support model. Studies have reported that nutrition education given to T2DM using different model have been shown to improve metabolic outcomes and MetS significantly and are in support of the current study (Aalaa et al., 2017; Bayat et al., 2013; Dennis-bradshaw, 2015; Mardani, Shahraki, & Piri, 2010; Muchiri, Gericke, & Rheeder, 2015; Sachmechi et al., 2013; Taheri et al., 2019). In the current study, participants in the NEP group showed greatest improvement in weight lost, reduction in BMI, WC and WHR and an increase in HDL as compared to the other groups supporting the benefit of nutrition education with that peer to peer support in T2DM patients' management. The result of reduced metabolic outcome the current study is supported by Athena et al (2011) and Cherrington et al (2015). Surprisingly, NE group showed significant improvement in mean DBP (Table 6.2) as well as reduced prevalence in BP in NE (Table 6.3) as compared to NEP and C. The result in improved DBP and reduced prevalence of participant with elevated BP in NE are unique in the currently study as literature have reported improved mean SBP outcome after application of nutrition education (Bayat et al., 2013 & Adachi et al, 2013) with limited data on DBP as well as reduced BP prevalence on inclusion of peer to peer support in nutrition education as compared to nutrition education alone (Johansson et al., 2016)

The study also hypothesized that nutrition education had no effect on adherence to lifestyle modification of T2DM patients. The hypothesis was rejected because the current study showed significant improvement in adherence to diet and physical activity after the intervention in participants in the NE and NEP group compared to control group that only received standard care. The improvement in NEP was significantly higher compared to NE. The result of the current are supported by a study by Kumari et al (2018) that showed an improvement in diet and physical activity

adherence after administering a lifestyle intervention, that had a nutrition and physical activity education component. Another study by Asaad et al (2016) is also in support that a nutrition education programme can be used to improve adherence and metabolic outcome. The result of the current study supports the evidence that nutrition education can be used as a model for improving adherence as was the case in the current study.

The hypothesis that nutrition education programme has no significant effect on health care cost incurred by patients with T2DM was accepted. The cost of care incurred by the participant post intervention remained constant with no significant difference between the groups six months' post intervention in all the cost considered. Most of the drugs given to the patient remained the same with only few changes occurring in the drug regime and this could be one of the factors associated with the no significant difference in the cost incurred by the participants. For example, Metformin 1g was used by approximately 88.7 -96.5% of the participant in all group throughout the study while insulin (Mixtard 30) by around 36-40% of the participant in the entire groups. Additionally, majority of the participants reported cost of consultations, blood sugar assessment as well as blood pressure assessment only, that were incurred during the hospital visit during treatment. This is because the participants relied on blood glucose checks in the hospital. Routine blood glucose check at home was a challenge as participants considered this to be unmanageable due to high cost associated with glucometer purchase, blood glucose strips as well as blood pressure motoring machines. These were only done and charged if the participant came to the hospital for treatment, hence this was the cost considered.

Furthermore, costs for HbA1c and lipid profile determination, as well as routine blood glucose check during group meetings, was not factored in determination of cost. This was catered for by the principal investigator hence not considered in the analysis. Moreover, cost of care of co morbidities like retinopathy, neuropathy, nephropathy, peripheral artery disease as well as oral care was low in all the groups throughout the study compared to cost of diabetes care and hypertension. This might be attributed to the fact that only few participants' self –present themselves to the clinicians with these cases as well as limited self-individual checks of the participants.

The current study was unique as it studied the association of patient characteristics with MetS, HbA1C and cardiovascular risk factors, with strong associations shown between some patient characteristics and specific cardiovascular risks in T2DM patients, which miss out in several studies. Several studies done in T2DM population and general population have reported association of patient characteristics with MetS but not individual risks factors. A study by Kaduka et al (2012) at in Kenyan population reported presence of Mets being associated with increasing age, socioeconomic status, and education while a study by Tadewos et al (2017) reported a positive association of MetS with gender (female), nutrition status(overweight and obesity). Study on association of patient characteristics with individual cardiovascular risks in T2DM patient are limited in Kenya as well as in developing world, hence the strength of the current study. It also showed effectiveness of a nutrition education programme on T2DM patient on MetS, MetS risk factor, adherence to lifestyle intervention and improved knowledge retention on diabetes care and management

9.2 Conclusion and Recommendations

9.2.1 Conclusions

High prevalence of MetS above 86%, as well as high prevalence of poor glycemic (HbA1c>7%) control above 77 % in T2DM patients was reported in the study. The current study also indicated some association of different patient demographic characteristic with MetS indicator as well as HbA1c> 7 %. These included income, education, gender, years lived with diabetes, occupation as well as family history of diabetes was associated with elevated BP, occupation was associated with high WHR. Education level was associated with obesity as well as elevated TG while family history of diabetes and alcohol intake showed some positive association with obesity. Moreover advanced years in living with T2DM was associated with elevated TG while reduced HDL was associated with gender, marital status as well as area of residence.

The current study also showed that poor glycemic control was associated with family history of diabetes as well as advanced age. Elevated blood pressure, elevated LDL and elevated TG as well as high fasting blood sugar were also associated with poor

glycemic control. Elevated blood pressure, elevated LDL and elevated TG as well as high fasting blood sugar were also associated with poor glycemic control (HbA1c).

The current study reported a low level of knowledge below 50% in general management of diabetes as well as importance of diet, physical activity and glycemic index in management of T2DM. However on application of NE knowledge score increased significantly >75% with incorporation of peer to peer support increasing knowledge score further. Additionally, knowledge retention was high immediately after intervention that dropped as the months elapsed.

The result of the current study showed that application of nutrition education with peer to peer support component reduced the prevalence of MetS significantly as well as MetS risk factors which reduced further on incorporation of peer to peer support, an indication that nutrition education with peer to peer support can be utilized in management of T2DM.

The current study also reported low adherence rate (below 15%) to diet as well as physical activity adherence below 50%, which both improved significantly upon application of nutrition education; and this was further enhanced by peer to peer support; indicating that nutrition education had a role to play which was further improved by peer to peer support.

The current study also reported a significant improvement in knowledge score in the study participants due to nutrition education, which improved further with inclusion of peer to peer support. The cost of care averaged at Ksh. 4820 before the intervention. Application of nutrition education with peer to peer support and nutrition education without peer to peer support showed no significant changes in cost of care incurred by the participants' withT2DM six month after the intervention.

9.2.2 Recommendations

i. The current study advocate use of nutrition education with peer to peer support in management of T2DM as positive result in improvement of

MetS, MetS indicators, adherence to lifestyle modification as well as improved knowledge score were seen.

ii. The current study advocates for screening for MetS, Mets risk factor as well as HbA1c regularly at least twice a year in all patients with T2DM and establishment of association of patient characteristic with MetS, MetS risk factor as well as HbA1c. Studying T2DM patients' characteristics is important as it lays a foundation on the strategies that can be used for setting up preventive measures.

iii. The current study also recommends periodic screening of patients' dietary intake and physical activity as well. Periodic studies for determining adherence to lifestyle modification (diet and physical activity) need to be done

iv. Assessment of the effectiveness of the nutrition education strategy to glycemic control, MetS, metabolic risk, adherence to treatment regime as well knowledge retention need to be enhanced in T2DM patients.

v. Future studies applying different education model in management of T2DM at community level as well as hospital need to be conducted and their effectiveness on T2DM care done to supplement already existing structure in the DCC.

vi. Future studies on cost effectiveness of use of education model to the care of T2DM both at community and hospital level also need to be done and result communicated to policy makers.

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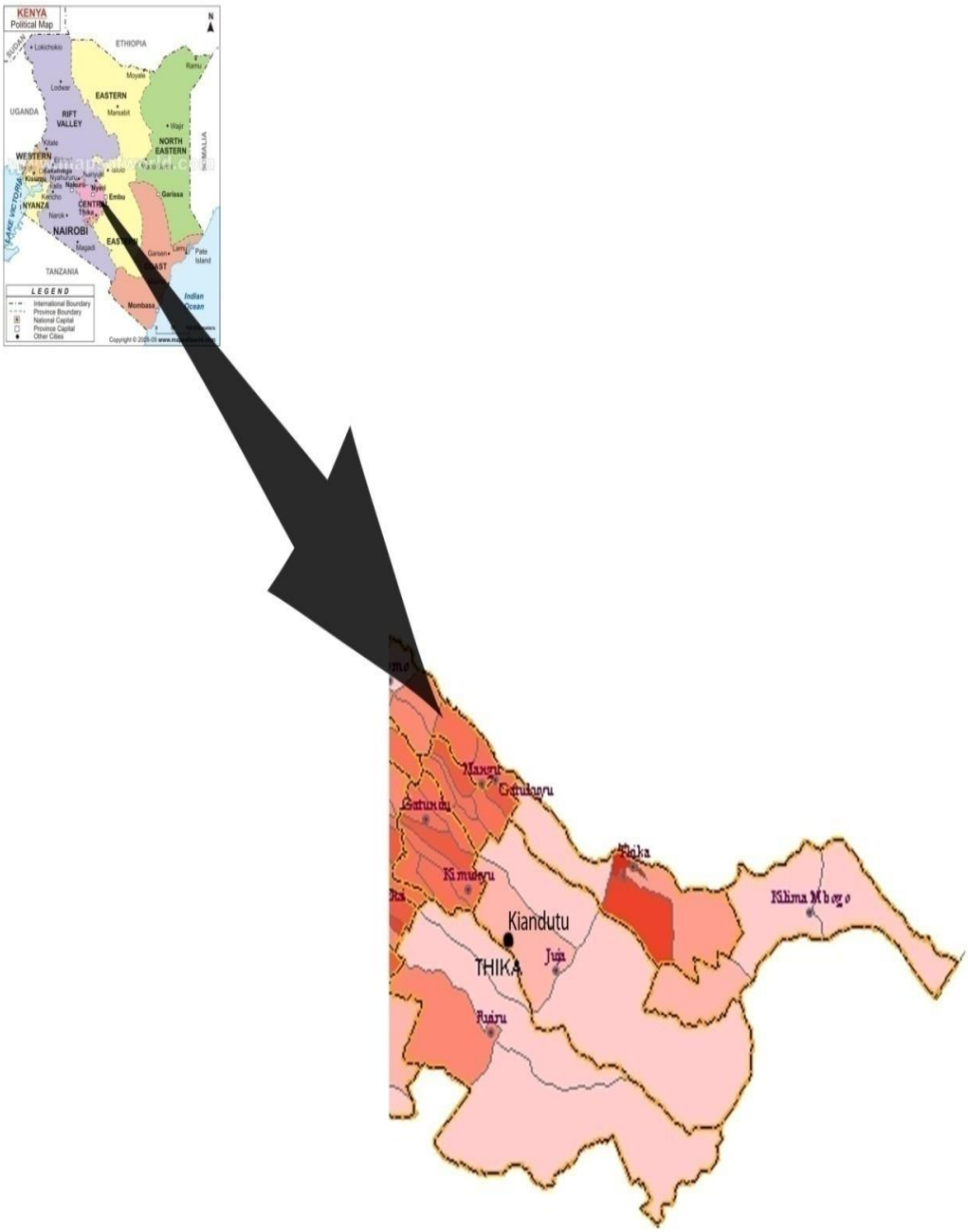
APPENDICES

Appendix I: Study Area Map



Appendix II: Additional information on Research Methods

1.1 The study site

The study was conducted at Thika Level 5 Hospital (TL5H) in Kiambu County, Kenya. The hospital is a government based facility with a 300 bed capacity. The hospital which is the largest hospital in the county was purposively selected as it operates an out-patient diabetic clinic daily; Diabetes Comprehensive Care Center (DCC) and an in-patient facility where medical care for T2DM patients is provided throughout the week. Diabetic patients, self and non-self-referred from the county and nearby areas attend the clinic on appointment days. The clinic serves both male and female with diabetes T1DM and diabetes T2DM. The clients are mainly from low and middle income social economic background Thika Level 5 Hospital (TL5H) is located in Thika Sub County, Kiambu County, that lies between latitudes 3' 53" and 1' 45" South of the Equator and longitudes 36' 35" and 37' 25" East and act as a referral hospital as well as treatment site for the entire population of the larger Thika environment and neighboring Sub-Counties. The Diabetes Comprehensive Care Clinic (DCC) attends to approximately one hundred patients per week and has an average of one thousand patients (MOH, 2012).

1.2 Study design

The study was be a randomized controlled clinical trial (RCT) consisting of a control group and 2 multi arm experimental groups with pre and post- test administration to test the effect nutrition education on metabolic syndrome management, in patient with T2DM attending medical care at TL5H The study involved development of a nutrition education programme that was pre tested in a small sample (10%) of the patient who were not participant in the study. The intervention was implemented to the selected sample of the T2DM patients (NE and NEP groups)

The study utilized a cross sectional study design to collect baseline data that included data on demographic and economic characteristics of the patients, medical and clinical history, diet and physical activity prior the study

1.3 Target population

The target populations were patients diagnosed with T2DM attending TL5H diabetes comprehensive care clinic (DCC).

1.4 Inclusion and exclusion criteria

1.4.1 Inclusion criteria

Patients suffering from T2DM aged between 20-79 years attending the DCC in TL5H included in the study. International diabetes federation (IDF) and WHO organization have reported prevalence of T2DM as from 20 years to 79 years (IDF, 2015, 2017; WHO, 2016). Other studies on T2DM patient have also used the age group of between 20-79 years. For example a study by Asakari et al.(2013) on T2DM also used the age 14-87 years in their study participants, while a study by Ganz et al (2014)used an age ≥18 years T2DM patient in their study. Additionally, a study by Lade et al (2016) also included T2DM aged 18 years and above in their study. The participants included in the study, signed an informed consent and visited the clinic monthly for six months.

1.4.2 Exclusion criteria

Patient with T2DM, with complication like renal failure, congestive Heart failure, Stroke were excluded from the study during recruitment. These were verified from the patients' medical record by the researcher and a physician, who was present during recruitment of the participants. These patients were excluded as they need a more intense medical care on top of lifestyle modification to avoid further complication. Patient with renal failure undergoes dialysis which requires further diet modification and supplementation other than a normal diet due to renal impairment. In addition they needed close medical attention. For patient with CCF they also required specialized treatment than normal diabetes patient in drug administration, diet modification and other forms of treatment hence their exclusion. Pregnant women and HIV patients with diabetes were be excluded. A pregnant woman mostly presenting with T2DM requires specialized care and there energy requirement is high. A lot of medical cares need to be taken during their

management, to prevent complication of the mother and the baby and ensure healthy babies are born hence the exclusion in the study. For HIV/AID patient with T2DM , there management is different from a normal T2DM patients as most of them are on ARV hence a balance on HIV care and T2DM care must be reached thus they were excluded.

1.5 Sampling frame and randomization

Thika Level 5 Hospital (TL5H) was purposively selected because it is one of the hospital in Kiambu with high prevalence (43%) of T2DM (MOH, 2015) and operates diabetes comprehensive diabetes care (DCC) for patients with diabetes. Patients attending the clinic with T2DM were informed about the study during their routine visit. All procedure of the study was explained to the patient. Convenience sampling method was used to recruit the study participants who met the inclusion criteria daily until the required sample was gotten. Those patients recruited for the study were given the consent form to sign. Before signing the consent form it was explained by the researcher to the participant and once they understand it they were requested to sign. After signing the consent form baseline data was collected from the participant and an appointment date given to the patient when blood sample for lipid profile and HbA1c analysis will be done as well as the date actual intervention was to begin. This continued until the required sample size was obtained. During the 1st appointment all the participant received standard education in the form of lectures that review T2DM and its symptoms, treatments, and associated complications. Once the lecture for first appointment was over, the participant were then randomly assigned to 3 groups (2 intervention groups; nutrition education-NE group, and nutrition education peer to peer support group-NEP and one control groups). The researcher wrote number 1-3, mixed them using lottery and request participant in each group to pick a number. After the participants had picked the numbers they were placed into three groups' i.e group1, 2&3. After this the researcher wrote 3 ballots NE, NEP& C mix them using rotary system and requested a volunteer from each of the three groups to volunteer and pick a ballot each. The one who picked NE, there member were allocated into NE group, NEP the members were allocated into NEP group the one who picked C there member

were allocated in to the control group. Equal ratio of sample size was used for all groups. The study hypotheses were not communicated to the participants. . Since this is an education trial the researcher and research assistant were aware as they were taken through the training of the intervention but the hypothesis of the study was not communicated to research assistant. After randomization of the participant they were given different appointment dates for the interventions and monthly appointments after the intervention. The researcher ensured that was taken through the same package after the six month follow up as the NE group.

1.6 Sample size determination

The formula for calculation of sample size for randomized control trial will be used (Armitage et al., 2012, and Lwanga & Lemeshow, 1991).

$$n = \left[\frac{Z_\alpha \sqrt{2\bar{p}\bar{q}} + Z_\beta \sqrt{p_1 q_1 + p_2 q_2}}{p_1 - p_2} \right]^2$$

P_1 =0.86 The estimated population proportion 1 (non-exposed/ control group)

P_2 =0.56 The estimated population proportion 1 (exposed/ Intervention group)

Q_1=1-P_1=0.14

Q_2=1-P_2 = 0.44

P= $\frac{P_1+P_2}{2}$ is the estimated average of p_1 and p_2 = 0.71

Q= $\frac{Q_1+Q_2}{2}$ is the estimated average of q_1 and q_2 = 0.29

Z_α is the value corresponding to the alpha error (at $\alpha = 0.05$ or $significance\,level = 5\%$, the value of $Z_\alpha = 1.96$)

Z_β is the value corresponding to the beta error (at $\beta = 0.20$ or power = 90%, the value of $Z_\beta = 1.282$)

The required sample size per arm is

$$n = \left[\frac{Z\alpha \sqrt{2pq} + Z\beta \sqrt{p1q1 - p2q2}}{p_1 - p_2} \right]^2$$

$$= \left[\frac{1.96\sqrt{2 \times 0.71 \times 0.29} + 1.282 \sqrt{(0.86 \times 0.14) + (0.56 \times 0.44)}}{0.30} \right]^2$$

$$\left(\frac{1.258+0.7764}{0.3}\right)^2$$

=45.99

=46

To confer 90% power at 5% level of significance to detect an absolute effect size of 25% improvement on adherence to lifestyle modification (i.e. from 86% to 56% with intervention), we need to include 46 study participants per group. This was calculated using the formula by Armitage *et al.,* 2012 and Lwanga & Lemeshow, 1991).The sample size was subjected to a correction factor of 10% to cater for attrition (10% of 46=4.6 approximately 5), hence each arm will have a sample size of 51 participants (46+5) for a total sample size of 153.

1.7 Study procedure

The participants were recruited on normal clinic days. Patients attending there appointment were informed about an upcoming study in the morning as they received health talks. Those willing to be involved in the study were requested to volunteer themselves. Once they volunteered they were informed on the procedures of the study in details which included baseline data collection on demographic profile, medical, nutrition and physical activity history as well as dietary patterns, biochemical data that was done with no charges which included fasting blood glucose , glycated hymoglobin (HbAIc) and lipid profile (total triglycerides, HDL,LDL total cholesterol) and clinical data (blood pressure); intervention that lasted for eight weeks 2 hours each, and there after monthly follow up and data collection for a period of six months . Details of the intervention were given to each group separately after randomization. They were also informed that for baseline biochemical data collection, monthly fasting blood glucose determination and post intervention biochemical data; blood samples was withdrawn from each participant. Those willing to participate and met the inclusion criteria were given an informed consent form to sign as participant. After signing baseline data questionnaire was administered and participant given appointment dates for blood sample collection. During appointment day they were required to come in the

morning having not eaten something as fasting blood sample were required. After blood withdraw by laboratory technologist (Mr. Nduati) a snack was given. Recruitment continued on clinic day until the required sample size was reached. Recruitment of the participant was done by researcher and two qualified registered nutrition officer who had been recruited by the researcher, trained and taken through the procedure of the study. The research assistant were registered licensed nutrition officer who holds a bachelor of science degree in nutrition and had an experience of at least two years in diabetes patient management

1.8 Standard of care

The standard care was provided to the participant in the control group.The standard of care during the study included registration of the partcipants in the clinic in the morning on arrival, and after registration a general health talk on diabetes management was given wasgiven. After the health talk patient care profilewas taken that included blood pressure, fasting blood glucose and nutrition status (weight, height and BMI computation, waist circumfrence and hip circumfrence).

The patrticipnts were then seen by the clinician who may request on other test urea and erectrolyte depending on patient baseline profile and physical examination and treated them accorndingly.

1.9 Peer to peer support component

Previous studies have highlighted the importance of peer support (Bahun & Savic, 2011; Fisher et al., 2014; David Simmons et al., 2013). The peer to peer support component in the NEP group adopted a face to face self-management (FFSM) and peer coach (PC) approach model (Heisler, 2010). The FFSM aimed at combining discussion on key self-management issues participants are facing on diet and physical activity through goal setting and discuss these goals, exchange ideas in the group and each group leader acted as peer leader. This ensured enhanced support that aimed at behavior change as well as strengthening participants' diabetes care self-efficacy, problem solving skills and efforts; emotional support and encouragement as well as informational support and experience sharing. To deliver

the peer to peer support component, participants in the NEP group were grouped in small support group of 5-10 participants each depending on the location they come from as well as age cohort. They were encouraged to set and share with other each other weekly goals for specific changes in their eating and physical activity behavior aimed at making healthy food choices, reduction of portion sizes and being active. Participants reported on their progress at the beginning of the next session, and adjustment of goals made if not met. This aimed at enhanced information delivery as well as promoting behavior changes geared at adopting healthy lifestyle. Each small group was headed by a leader who guided the other.

Additionally, a peer educator (Coach) also guided the participant in the peer to peer process and encouraged the participants. The peer educator was a diabetes patient who was a trained peer coach from KDDA. He had lived with diabetes for 13 years; hence he had gained enough experience in self-management of diabetes. He also led the participant in the problem solving session together with the researcher. After the eight weeks training sessions the participants were followed and there goal presented to other members on monthly basis for six month. The researcher together with the peer educator helped the participants review their goals and if there was any adjustment required done. Also individual counseling where necessary was given on each visit. The peer to peer support session was done after the trainings and lasted 30 minutes during the weekly meeting as well as during monthly follow up. The researcher together with the peer educator guided the participant throughout the peer to peer support implementation. A model of the peer to peer support is attached in Appendix 10

1.10 Follow up

The intervention ran for eight weeks. After the end of the eight weeks intervention the patients were requested to be coming to the hospital monthly on selected days for monthly follow up. Each group had a separate day. At the start of the study the participants were given appointment cards developed by the researcher indicating the day they are supposed to come for the appointment. After each visit appointment day for next visit was always indicated. The researcher also got phone numbers for

the participants which assisted her in follow up. A reminder short message was sent to the participant two weeks before the appointment day. There after a was given to the participant reminding them on the appointment day one week to the appointment day and two days to the appointment day to ensure they availed themselves. During monthly follow up session data on weight, height, waist circumference, height circumference, blood pressure, fasting blood glucose and data on cost incurred by the participants was collected. Data on lipid profile (TC, TG, LDL-c and HDL-c) and HbA1c data was collected after month 6 of follow up, while data on adherence to lifestyle modification (diet and physical activity) was collected at month 1, at month 3 and at month 6 of follow up. Also during monthly follow up data on knowledge level was collected immediately after the intervention, at month 1 of follow up, at month 3 of follow up and at month 6 of follow up. Additionally, during follow up participant requiring medical attention were attended. Peer to peer support component for NEP also continued monthly follow up. A physician and a Clinician were also present during the study follow up period to manage any patient requiring medical treatment.

1.11 Clinical support

During the study period the physician, clinician, nurse, a physiotherapist and a laboratory technologist were available to provide clinical support to the patient. The physician and the clinician were available to manage any patient requiring medical treatment. Some patient on examination present with High blood glucose, high HbA1c, high blood pressure, neuropathy, general weakness among other which required a medical intervention and the physician and clinician were available to review the participant and manage accordingly. The nurse assisted in physical examination including foot examination of the patient and also worked with the researcher in blood pressure determination which is key in management of diabetes. The laboratory technologist assisted in fasting blood glucose determination, glycated hymoglobin (HbA1c) determination and lipid profile determination. He was the one who withdrew blood samples from the participant and carried out the analysis. He was a registered laboratory technologist with a Bachelor degree in medical laboratory. A physiotherapist who holds a diploma in Physiotherapy was

also available. Together with the researcher he took the participants in the intervention groups (NE and NEP) through the physical activity lessons and advised them on the most ideal activity they can do how to do them, and how to prevent hypoglycemia during exercise. The entire health care provider identified were taken through the procedure of the study, without revealing the hypothesis before actual study begins and were informed to maintain participant confidentiality throughout the study.

1.12 Biochemical assessment

Biochemical data that include lipid profile, fasting blood glucose level, HbA1C was analyzed by a qualified registered medical laboratory technologist. The Biochemical tests were analyzed at Thika Level 5 Hospital laboratory which has been assessed and awarded a 4 star (2015) in quality control and quality assurance. The laboratory uses human quality assessment services (HuQAS) for its external quality assessment (EQA). HuQAS is a Kenya registered non-profit organization that offers professional and integral proficiency testing (IPT) services since 2000 to clinical laboratories. The laboratory also runs internal quality control (IQA) daily using normal, low and pathological control in a multi-calibrator system and has an officer appointed to ensure Quality assurance and quality control are maintained. An auto chemistry auto analyzer Dirus 300CS was used for all the biochemical analysis. For all the analysis standard operating procedure developed as per international standards were followed.

1.12.1 Quality control

Human control sera (HBC01 or HBCO2) was used to monitor the performance of the assay procedures. This control were run in every time before start of the analysis. If a control value was found outside the defined range, the instrument, reagent and calibrator were checked if there is a problem and corrected before analysis starts.

1.12.2 Blood Sample collection

Blood samples was collected from each participant while in a seated position after fasting for at least 8-12 h. Ten (10) ml of blood was drawn through venipuncture procedure into vacuum collection tubes containing EDTA anticoagulant and shaken to mix well. Each sample was accompanied with a requisition form that identifies each participant using a unique number. The tubes were labeled by the laboratory technologist according to the unique numbers created for each patient in order to reduce any confusion and the test required specified.

Risk:- contamination of patient or laboratory technologist infection poses a major risk during phlebotomy. To ensure the risk is reduced the laboratory technologist collecting the sample ensured that they are collected in a sterile condition. Alcohol wipes (70% isopropyl alcohol) was used to clean venipuncture site and vacuum collection tubes used. Sterile gauze sponge was applied with a strapping on the site where sterile needle for withdrawing blood sample is withdrawn to protect the venipuncture site to draw blood to minimize contamination. The laboratory technologist wore latex gloves to minimize cross infection and dispose them on infection waste bin. Sterile disposable needle and syringes was used for blood sample collection and disposed of at designated sites; i.e. a sharp box was used for placing used syringes after blood withdraw. Confidentiality was ensured on patient samples and result

1.12.3 Blood Sample Transportation

After the samples have been collected they were then be put in a cool box maintained at 4^0c for transportation to the laboratory for analysis. The samples were collected at the study site (DCC) and transported to the laboratory

1.12.4 Analysis of the sample

In the laboratory the samples were refrigerated to 4^0c awaiting analysis. Levels of serum TG, total cholesterol (TC), high density lipoprotein (HDL-c), low-density lipoprotein cholesterol (LDL-c), were determined by enzymatic method (Allain et

al., 1974; Assmann et al., 1983; Bucolo & David, 1973; Friedewald et al., 1972; Robinet et al., 2010; Stępień & Gonchar, 2013; Wu et al.,1989).

Glycated Hemoglobin (HbA1c) and blood glucose were determined using high-performance liquid chromatography and glucose oxidase method respectively (Beach & Turner, 1958; Klenk et al., 1982).

This data was collected on recruitment and after six months of the study for both groups of patients. In addition, fasting blood glucose was collected every month after the intervention for a period of six months. The analysis of the sample for fasting blood glucose was done immediately after sample collection and result availed to the participant after one hour. Analysis of the blood samples for HbA1c and lipid profile (HDL-c, LDL-c, TG and TC) was done the following day after sample collection and result given to the participant on the following appointment.

1.12.4.1 HbA1c analysis procedure

Biorad D-10 hemoglobin testing system was used to analyze blood sample for HbA1c. This is an automated analyzer intended for percent determination of HbA1c in human blood using high performance liquid chromatograph (HPLC). The samples were automatically diluted on D-10 and injected into analytical cartridge that separates hemoglobin based on their ionic interactions with the cartridge material. Separated hemoglobin was then passed through flow cell of filter photometer where change in absorption at 510 nm is measured. A sample report and a chromatogram was generated.

1.12.4.2 Lipid profile determination

The plasma was separated from the blood under sterile condition and stored at 4^0c ready for analyses.

1.12.4.2.1 Total cholesterol analysis

To analyze total cholesterol enzymatic –colorimetric test was used. The principle for this method is that cholesterol and its esters are released from lipoprotein by

detergents. Cholesterol esterase hydrolyses the esters and hydrogen peroxide (H_2O_2) is formed in the subsequent enzymatic oxidation of cholesterol by cholesterol –oxidase as per equation below. During the reaction a red dye quinonimine dye is formed of which the intensity is proportional to the cholesterol concentration. The reagents that was used includes phenol, cholesterol esterase (CHE), cholesterol oxidase (CHOD), peroxidase, 4-aminoanitypyrine (4-AP) and cholesterol aqueous as a standard

$$\text{Chol. Ester} + H_20 \xrightarrow{\text{CHE}} \text{Cholesterol \_+fatty acid}$$

$$\text{Cholesterol} + O_2 \xrightarrow{\text{CHOD}} 4\text{Cholestenon} + H_2O_2$$

$$2H2O2 + \text{Phenol} \xrightarrow{\text{POD}} \text{Quinonimine} + 4H_20$$

Before analysis the colorimeter was adjusted to zero using distilled water. Then 10µl of the sample (plasma), blank (distilled water was used) and standard was placed into 1cm light path cuvette by a pippete and 1ml of reagent added to each. They was then mixed and incubated for 37^0c for 10 minutes. They were then placed at the colorimeter at wavelength of 510 nm and then the absorbance read.

Table 1.2: Analysis of total cholesterol

	Blank	**standard**	**Sample**
Standard	--------	10µl	-------
Sample	---------	-------	10µl
Reagent	1ml	1ml	1ml

Cholesterol, concentration was calculated using the formula below,

Cholesterol concentration (mg/dl) = absorbance of sample/absorbance of standard x200 (standard concentration conversion factor.

This method is linear up to 750mg/dl. During the analysis if the value reading of the sample exceeds 700mg/dl they were diluted with saline in the ratio of sample: saline= 1:2. After dilution the test was repeated and result multiplied by 2.

1.12.4.2.2 High density lipoprotein (HDL) analysis

1.12.4.2.2.1 Principle of the method

In the analysis of HDL, polyethylene glycol, average MW 6000, in aqueous solution was used to precipitate lipoprotein VLDL and LDL. After centrifugation a clear supernatant containing HDL fraction was used for enzymatic determination of HDL.

1.12.4.2.2.2 Test procedure

Precipitation Step: Five hundred (500) µl of sample plasma was placed to a centrifuge tube using a pippete and 500µl of polyethelenglycol 16 %(with a non - reactive additive and stabilizer) added to the sample. They were then be mixed by inversion, incubated for 5 minutes at 37^0c and then centrifuged at 3000 g/minute for ten minutes. After centrifuging the supernatant was separated and used as the sample for quantitative step.

Quantitative step

Twenty five (25) µl of blank, standard and sample prepared in previous step was placed in cuvette using a pippete and 1 ml of the reagent added to each,. They were then be mixed and incubated at 37^0c for 5 minute and absorbance of the standard and sample read against the blank using a spectrophotometer at a wavelength of 510nm, light path of 1cm and at 37^0c. After obtaining the value HDL cholesterol will be calculated as;

HDL cholesterol mg/dl =absorbance of sample (AX)/absorbance of standard (AS x standard value x 2

This method is linear up to 700mg/dl. During the analysis, if the value reading of the sample exceeds 700mg/dl they were diluted with saline in the ratio of sample: saline= 1:9. After dilution the test was repeated and result multiplied by ten.

1.14.2.3 Triglyceride determination

Triglyceride was determined using enzymatic colorimetric GPO-PAP method. The principle for this method is that the triglyceride was determined after enzymatic hydrolysis with lipoprotein lipase. A coloured phenazone is formed from hydrogen peroxide, 4 -Aminoantripyrine and 4-chlorophenol under the catalytic influence of peroxidase.`

Triglycerides + $3H_20$ —LPL→ Glycerol + 3 RCOOH

Glycerol +ATP —GK, Mg^{2+}→ Glycerol -3-phosphate + ADP

Glycerol -3-phosphate +O_2 —GPO→ Dihydroxyacetone phosphate + H_20_2

$2\ H_20_2$+ 4 –Aminoantripyrine + 4-chlorophenol —POD→ 4-(p- 4Benzoquinone-monoimino)-phenazone +$2H_20$ +HCL

The reagent to be used for analysis includes pipes buffer pH 7.0 40mmol/l, 4-chlorophenol 5mmol/l, magnesium ione 5mmol/l, ATP 1mmol/l, peroxidase 1U/ml, glycerol kinase 1U/ml, 4 –Aminoantripyrine 0.4mmol/l, Glycerol -3-phosphate 3.5U/ml sodium azide 0.05%and a standard 200mg/dl. The reagent are stable and need to be stored at between $+2^0$c and+ 8^0c but need to be protected to light.

The procedure for analysis is as shown in table 3.2. 10µl of the sample and standard was put in the cuvettes using a pippete and then 1000µl of reagent added to each respectively. They were then be mixed and incubated for five minutes at 37^0c. After this absorbance was read against reagent blank at a wave length of 510nm.The concentration of triglycerides was computed as follows;

Triglyceride concentration (mg/dl)= absorbance of the sample/absorbance of the standard

Table 1.3 Procedure for triglyceride analysis

	Blank	Sample	Standard
Standard	-------	----------	10µl
Sample	-------	10µl	------
Reagent	1000µl	1000µl	1000µl

1.12.4.3 Low density lipoprotein determination

LDL cholesterol was calculated automatically using Friedwald equation

LDL (mg/dl) = (Total cholesterol-HDL)- (Triglycerides/5)

1.12.5 Fasting blood glucose determination

The blood glucose was determined using glucose oxidase method. Glucose oxidase will be used to catalyze oxidation of glucose to hydrogen peroxide and D-gluconate. Phenol + 4AAP + hydrogen peroxide in the presence of peroxidase produce a quinoneimine dye that was measure at 510nm. The absorbance at 510nm is proportional to the concentration of glucose in the sample. The principle is summarized in the formula below;

$$\text{D-GLUCOSE} + H_20 + 0_2 \xrightarrow{\text{Glucose oxidase}} H_20_2 + \text{D-Glucose}$$

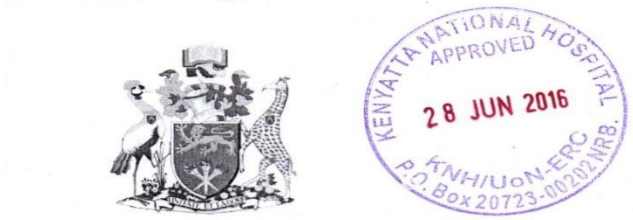
$$H_20_2 + \text{4-AAP} + \text{Phenol} \xrightarrow{\text{POD}} \text{quinoneimine dye} + H_20$$

The reagent composition includes glucose oxidase (microbial) 12,000u/l, peroxidase 1000u/l, 4-AAP 0.3Mm, phenol 4Mm, buffer Ph.of 7.4, non -reactive stabilizer.1. ml 0f reagent was placed in well labeled test tube for sample, standard and blank. The 0.01 ml of sample and standard was put to the test tube labeled sample and standard containing the reagent. They were then be mixed and incubated for 5 minutes at 37^0c. After incubation the reagent blank was used to zero the

spectrophotometer and absorbance of the sample and standard read at 510nm. After reading the absorbance, calculate the concentration of glucose as follows;

Glucose concentration (mg/dl) =absorbance of sample/absorbance of standard x concentration of standard (mg/dl)

Appendix III: Ethical Clearance



UNIVERSITY OF NAIROBI
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Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/232

28th June, 2016

Anne Watetu Thuita
Dept.of Food Science and Technology
JKUAT

Dear Anne

REVISED RESEARCH PROPOSAL: "EFFECT OF NUTRITION EDUCATION AND PHYSCAL ACTIVITY ON METABOLIC SYNDROME, ADHERENCE TO LIFESTYLE MODIFICATION AND HEALTH CARE COST OF INDIVIDUALS WITH TYPE TWO DIABETES ATTENDING THIKA LEVEL 5 HOSPITAL " (P167/02/2016)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH-UoN ERC) has reviewed and **approved** your above proposal. The approval period is from 28th June 2016 – 27th June 2017.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH-UoN ERC before implementation.
c) Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
f) Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
g) Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

For more details consult the KNH- UoN ERC website **http://www.erc.uonbi.ac.ke**

Protect to Discover

Yours sincerely,

PROF M.L. CHINDIA
SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Deputy Director, CS, KNH
The Assistant Director, Health Information, KNH
The Chair, KNH- UoN ERC
Supervisors: Dr. Beatrice Kiage, Dr.Arnold Onyango, Prof. A.O. Makokha

Appendix IV: NACOSTI Research Permit

Permit No. : NACOSTI/P/16/83452/10118
Date Of Issue : 4th July,2016
Fee Recieved :ksh 2000

THIS IS TO CERTIFY THAT:
MS. ANN WATETU THUITA-WAMBUGU
of JOMO KENYATTA UNIVERSITY OF AGRICULTURE AND TECHNOLOGY, 5136-506 NAIROBI,has been permitted to conduct research in Kiambu County

on the topic: EFFECT OF NUTRITION EDUCATION AND PHYSICAL ACTIVITY ON METABOLIC SYNDROME, ADHERENCE AND HEALTH CARE COST OF INDIVIDUALS WITH TYPE TWO DIABETES ATTENDING THIKA LEVEL 5 HOSPITAL

for the period ending:
4th July,2017

.....
Applicant's Signature

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

CONDITIONS

1. You must report to the County Commissioner and the County Education Officer of the area before embarking on your research. Failure to do that may lead to the cancellation of your permit
2. Government Officers will not be interviewed without prior appointment.
3. No questionnaire will be used unless it has been approved.
4. Excavation, filming and collection of biological specimens are subject to further permission from the relevant Government Ministries.
5. You are required to submit at least two(2) hard copies and one(1) soft copy of your final report.
6. The Government of Kenya reserves the right to modify the conditions of this permit including its cancellation without notice

REPUBLIC OF KENYA

National Commission for Science, Technology and Innovation

RESEARCH CLEARANCE PERMIT

Serial No.A 9864

Appendix V: Research Approval; Ministry of Interior and Co-Ordination of National Government; Kiambu County

OFFICE OF THE PRESIDENT

MINISTRY OF INTERIOR AND CO-ORDINATION OF NATIONAL GOVERNMENT
COUNTY COMMISSIONER, KIAMBU

Telephone: 066-2022709
Fax: 066-2022644
E-mail: countycommkiambu@yahoo.com
When replying please quote

County Commissioner
Kiambu County
P.O. Box 32-00900
KIAMBU

Ref.No: **ED.12/1/VOL.IV/92**

23rd August, 2016

Ann Watetu Thuita Wambugu
Jomo Kenyatta University of agriculture
P.O. Box 62000-00200
NAIROBI

RE: RESEARCH AUTHORIZATION

Reference is made to National Commission for Science, Technology and Innovation letter Ref No. **NACOSTI/P/16/83452/10118** of **4th July 2016**.

You have been authorized to conduct research on ***"Effect of nutrition education and physical activity on metabolic syndrome, adherence and health care cost of individuals with type two diabetes attending Thika Level 5 Hospital".*** The data collection will be carried out in ***Kiambu County*** *for a period ending* ***4th July, 2017.***

You are requested to share your findings with the County Education Office upon completion of your research.

J. A. RATEMO
FOR: COUNTY COMMISSIONER
KIAMBU COUNTY

Cc County Director of Education
KIAMBU COUNTY

National Commission for Science, Technology and Innovation
P.O. Box 30623-00100
NAIROBI

The County Coordinator of Health
KIAMBU COUNTY

Deputy County Commissioner (***For information and record purposes***)
THIKA WEST SUB COUNTY

"Our Youth our Future. Join us for a Drug and Substance free County".

Appendix VI: Research Approval; Minstry of Education; Kiambu County

MINISTRY OF EDUCATION SCIENCE & TECHNOLOGY
State Department of Education

Telephone: Kiambu (office) 020-2044686
FAX NO. 020-2090948
Email:directoreducationkiambu@yahoo.com

COUNTY DIRECTOR OF EDUCATION
KIAMBU COUNTY
P. O. Box 2300
KIAMBU

When replying please quote
REF: KBU/CDE/HR/4/VOL.II/ (138)

15TH AUGUST, 2016.

ANN WATETU THUITA WAMBUGU
JOMO KENYATTA UNIVERSITY OF AGRICULTURE
AND TECHNOLOGY
P.O BOX 6200 - 00200
NAIROBI.

RE: RESEARCH AUTHORIZATION

Reference is made to the National Commission for Science Technology and Innovation letter Ref. No NACOSTI/P/16/83452/10118 and dated 4th July, 2016.

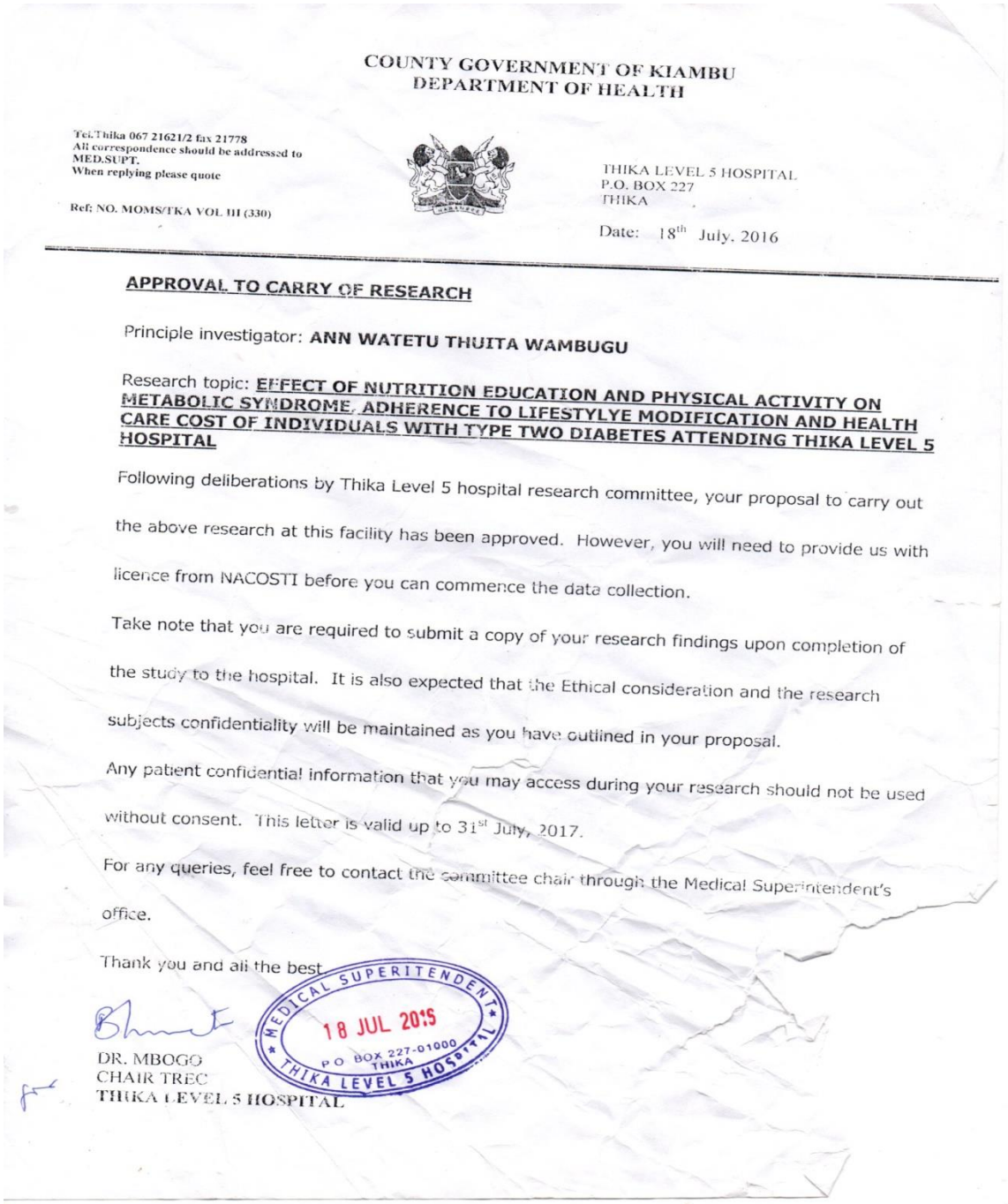
The above named has been authorized to carry out research on ***"Effects of nutrition education and physical activity on metabolic syndrome, adherence and health care cost of individuals with type two diabetes attending Thika Level 5 Hospital"*** for a period ending **4th July, 2017**.

We expect that the findings of your research will be shared with this office to help in making our county better.

COUNTY DIRECTOR OF EDUCATION
KIAMBU COUNTY
P O BOX 2300-00900 KBU.
TEL 020-2044686
FAX 020-2090948

EMILY NYAGA
FOR: COUNTY DIRECTOR OF EDUCATION
KIAMBU

Appendix VII: Research Approval (TL5H)



COUNTY GOVERNMENT OF KIAMBU
DEPARTMENT OF HEALTH

Tel.Thika 067 21621/2 fax 21778
All correspondence should be addressed to
MED.SUPT.
When replying please quote

Ref: NO. MOMS/TKA VOL III (330)

THIKA LEVEL 5 HOSPITAL
P.O. BOX 227
THIKA

Date: 18th July, 2016

APPROVAL TO CARRY OF RESEARCH

Principle investigator: **ANN WATETU THUITA WAMBUGU**

Research topic: **EFFECT OF NUTRITION EDUCATION AND PHYSICAL ACTIVITY ON METABOLIC SYNDROME, ADHERENCE TO LIFESTYLYE MODIFICATION AND HEALTH CARE COST OF INDIVIDUALS WITH TYPE TWO DIABETES ATTENDING THIKA LEVEL 5 HOSPITAL**

Following deliberations by Thika Level 5 hospital research committee, your proposal to carry out the above research at this facility has been approved. However, you will need to provide us with licence from NACOSTI before you can commence the data collection.

Take note that you are required to submit a copy of your research findings upon completion of the study to the hospital. It is also expected that the Ethical consideration and the research subjects confidentiality will be maintained as you have outlined in your proposal.

Any patient confidential information that you may access during your research should not be used without consent. This letter is valid up to 31st July, 2017.

For any queries, feel free to contact the committee chair through the Medical Superintendent's office.

Thank you and all the best.

MEDICAL SUPERITENDENT
18 JUL 2016
P O BOX 227-01000
THIKA
THIKA LEVEL 5 HOSPITAL

DR. MBOGO
CHAIR TREC
THIKA LEVEL 5 HOSPITAL

Appendix VIII: Study Registration

08 October 2019

To Whom It May Concern:

RE: Effect of Nutrition Education Programme on Metabolic Syndrome, Adherence to Lifestyle Modification and Health Care Cost Incurred by Patients with Type 2 Diabetes Attending Care at Thika Level 5 Hospital in Kenya

As project manager for the Pan African Clinical Trial Registry (www.pactr.org) database, it is my pleasure to inform you that your application to our registry has been accepted. Your unique identification number for the registry is **PACTR201910518676391**.

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

Please note that it is now a WHO requirement to include, at a minimum, summary results or a link to summary results within the trial registration record. This should be done within 12 months of the study completion date.

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

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

Yours faithfully,

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

PACTR
PAN AFRICAN CLINICAL TRIALS REGISTRY

The South African Medical Research Council
Cochrane South Africa | PO Box 19070, Tygerberg, 7505

Appendix IX: Participant's consent form

English version

Introduction

My names are Ann Thuita, a PHD student from Jomo Kenyatta University of Agriculture and Technology. I am conducting a study on **the 'Effect of a nutrition education programme on the management of metabolic syndrome in patient with T2DM; a randomized control trial'.** The information gathered from this study will be used for planning strategic intervention programs to enhance the management of diabetes in the hospital, Kiambu County and in the ministry of health.

Procedures to be followed

Type 2 diabetes patient attending Thika level5 hospital will voluntary choose to participate in the study and will be required to visit the clinic for eight weeks during diabetes education intervention and thereafter once a month for a period of six months If you agree to take part in this study, you will be asked to take part in a one to one conversation during baseline data collection and the information you give will be recorded in a questionnaire. I will ask you questions about your demographic profile, diabetes, you diet intake at home, physical activity as well as take you anthropometric (weight, height, hip circumference and waist circumference) and your blood pressure. In addition, you will be required to provide blood sample at Thika level five hospital laboratory at the beginning of the study and thereafter every month for a period of six months. The blood sample (10ml) will be for analysis of HbA1c and lipid profile (HDL, LDL, Triglycerides and total cholesterol) at the start and after six months and fasting blood sugar monthly. These biochemical tests are key for diabetes management. After baseline data collection an intervention in form diabetes education lesson of eight weeks will be given and there after monthly follow –up for six months. During the eight weeks diabetes education lessons, you will be required to visit the clinic weekly and there after monthly for six months as per appointment dates given. During monthly follow anthropometric and blood pressure measurement will be done. Also you will be asked question on your food consumption patterns, type of exercises

and cost incurred on management of diabetes every month. You may withdraw from the study at any stage without being victimized by anybody and your care in the clinic will continue normally. The result of all the tests done will be availed to you and management given according to result of the test. Feel free to ask any questions which are not clear to you regarding this study any time even after consenting. During the study you will continue with your regular treatment and may come for consultation in the clinic any time you feel unwell.

Research benefits

The information gathered from this study will be used for planning strategic intervention programs and policies which will go a long way in improving diabetes management and quality of life. The biochemical test will be done free with no charges and they will assist you in the management of diabetes. At the end of the study you will be given handouts with information on diabetes management for your reference. In every visit a snack will be provided to the participants.

Discomforts and risks

There are no risks involved in participating in this study. Some of the questions you will be asked may be uncomfortable to you. If this happens, you may decline to answer these questions if you so choose. Nobody will victimize you for this you may also stop the interview at any time. The interview will take some of your time. A snack will be provided immediately after blood sample withdraw to prevent hypoglycemia

Confidentiality

The data and information collected from you will be held strictly confidential and will not be used for any other purpose outside the objectives of this study. The names will be substituted with code numbers for confidentiality purposes. The study finding will be communicated back to the participant after analysis and a copy of the report will be made at the clinic library for reference. Your name will not appear in any part of the report from this study.

Communication line

Any form of communication or clarification about the study or complain can be directed to the following;

Investigator: Ann Thuita- 0721783766, or email; awambugu78@gmail.com
Thika Level Five Hospital physicians, Dr. Mbogo -0722613432
Dr. Kiage Beatrice, Prof. Anorld Onyango and Prof. Anselimo Makokha (Supervisors)
Kenyatta National Hospital-University of Nairobi- Ethical review committee (KNH-UoN-ERC)-

Participant statement

I, the undersigned have understood the above information which has been fully explained to me by the study team. I have agreed to voluntarily consent to participate. I was given the chance to ask questions and I received satisfactory response.

Name of the participant/respondent…….
Signature of the respondent…….
Date…….
Researcher name Ann Thuita Contact +254721783766
Signature…… Date……
Feel free to ask any questions which are not clear to you regarding this study any time even after Consenting.

Participant consent (Kikuyu version)

Njitaguo Ann Watetu Thuita na ndi murutuo wa PHD Jomo Kenyetta University. Ndireka githomo gia kurora bata wa mirire miega na mathako hari murwaru wina murimu wa cukari wa Type 2. Githomo giki, kugika na guthomithia uhoro wa murimu wa cukari kahinda ka wiki inyanya na thutha wa guthomithia ndimururire o mweri kwa mieri itandatu. Maumirira ma mathomo maya ni makahuthirwo ni Thirikari ya Ugima wa Mwiri (Minstry of Health) mibangoini yao ya guteithia arwaru aria mena murimu wa cukari.

Mutaratara uria ukurumirwo

Arwaru aria mena murimu wa cukari wa Type 2 nimakorio merutire hatari kuringiririo. Akorwo niukuirutira gukorwo githomo-ini giki, niukurio ciuri cia miikarire yaku, uria urigititwo kahinda karia ukorotwo na murimu uyu, uria uriaga, irio iria uriaga na mathako maria wikaga. Niugucoka uthimwo kiro, uraihu, njohero na uria thakame yaku iratengera mwiriini waku. Niukurutuo thakame ya kurora muigana wa cukari mwiriini waku, maguta (cholesterol, HDL, LDL, Triglycerides) na uria cukari ukorotwe kahinda ka mieri itatu (HbA1c). Ithimi ici niagocokerwo thutha wa mieri itandatu twarikia mathomo. Ni uriheagwo maumirira ma ithimi ici na ugataririo wega maumirira maya. Niurithimagwo cukari waku, kiro, urahu, njohero na uria thakame iratengera mwiriini o mweri woka kuringana na thiku iria ukuheo. O muthenya uyu woka niuriuragio mathako maria uthaka ta kurima, irio iria uriaga na kana niurumagirira mataro maria uhetwo hindi ya mathomo ma wiki inyanya. Kahinda karia ugukorwo gitthomo ini giki niukurio urimagirira cliniki yaku o uria wathitwo ni dagitari.

Mawega ma githomo giki

Ithimi iria ciothe uguthimwo ni iguteithia miroreini yaku ya murimu uyu wa cukari na urithimagirwo hatari marihi gwa kahinda karia ugukorwo githomo-ini giki. Niukaheo mandiko ma githomo kiria ugathomithio (handauti). Mandiko maya ni mariguteithagia kwiririkania maundu maria ubataire gwika niguo uhote kumenyerera wega murimu

uyu wa chukari. Nimariguteithia kuririkana maundu maingi megii murimu uyu. Thutha wa mathomo niureheagwo chai na snaki nigetha ndukahute.

Ugwati

Hatiri ugwati o wothe ungiumira wetikira gukorwo githom-ini giki. Urirutagwo thakame oo wega na no karuo kanini uriiugua. Ukiurio ciuri uingigua kuri itari njega nu utigane na cio na hatiri mundu ugukuria kana akurugamia guthii na mbere.

Thiri

Maundu maria mothe ukuheana na maumirira ma ithimi ciaku matikuiru mundu ona uriku, makuhuthirwo mari magithomo giki tu na ritwa riuaku ritikuandikwo hando oo hothe. ,Ni ukuheo namba iria irihuthagirwo nginya turikie mathomo maya. Ungikorwo ukiigua uru niurineaga ndagitari maumirira ma ithimi niguo uthondkwo na ndariraga mundu una urika maumirira ma ithimi iaku.

Namba cia thimu na mitambo iria ungihuthira ukikorwo na kiuria

Murutwo

Ann Watetu Thuita 0721783766 (awambugu78@gmail.com)

Ndagitari na aruti wira a thibitari

Dr David Mbogo (Ndagitari) -0722613432

Mr Stephen Kanyi (physiotherapist)- 0714806654

Mr. David Ngaruma (Nduati) (laboratory manager)- 0722662894

Arimu

Dr. Kiage Beatrice

Prof. Anorld Onyango

Professor Anselimo Makokha

Kenya National Hospital-University of Nairobi Secretariat-

+254-020 2726300 Ext 44355 UoN), +254-020-76300-9 uonknh-erc@uonbi.ac.ke

Angikorwo niwathomo, wanyita na waiganira marai watarirwo uhoro wa githomo giki ningukuria na gitio wandiki ritwa riaku na ukire saiini(siginature) kana kirore haha kianda kuga niwetikira gukurwo uri umwe wa githomo giki.

Ritwa riaku----------

Saiini (signature)----------Mweri ----------
Mbeere ya Muthomi

Ann Watetu Thuita

Saiini (signature)…… Mweri ----------

Angikorwo wina kiuri uhoro wa githomo giki nourie ohindi yothe na niugucokerio

Appendix X: Questionnaires

Title of the study

This is a study to find out the "**effect of nutrition education on management of metabolic syndrome in T2DM patients attenind care Thika Level 5 Hospital**."

You're requested to voluntary answer the questions and you are assured that the data will be used for the purpose of this study and will be treated with confidentiality and care.

Baseline data: Diabetes Care Profile

Questionnare No._ __ __ __ __

Demographics section

Please answer each of the following questions by filling in the blanks with the correct answers or by choosing the single best answer.

1. Age: __ __ years old
2. Birth date: __ __ / __ __ / __ __

(Month / Day / Year)

3. Sex [Tick√ appropriate].
   a. □ Male b. □ Female
4. What is your marital status? (Tick√ appropriately]
   a. □ Never married b. □ Married c.□ Separated/Divorced
   d.□Widowed
5. What is your residence? [Tick√ appropriate]
   a. □ Rural b. □ Urban
6. Where do you live? (tick√ appropriate)
   a. □Your own house b. □ Rental house c. □ Home of a relative/friend
   d. □ Retirement home e. □ other (specify) _____
7. Do you have any children? [Tick√ appropriate]
   a. . □ Yes b. □ No
8. If yes how many ……..
9. How many people live with you? [Tick √ appropriately]
   a. □ I live alone
   b. □ 1 person
   c. □ 2 people

d, □ 3 people

e, □ 4 people

f. □ 5 or more

10. How much schooling have you had? (Years of formal schooling completed) [Tick √ appropriately]

a. □Primary

b.□ Secondary

c.□ College graduate (degree, diploma or certificate)

d.□ No education

11. What is your occupation? [[Tick √ appropriately]

a. □ Formal employment. b.□. Casual employment. c. □ Housewife

d.□ Farminge. e. □ Unemployed f.□ Business g.

□ Others (specify)…….

12. How much income does the family make in a month? [Tick √ appropriately]

a. □ < 1000 Kshs b. □ Ksh. 1000 to 4999 c. □ Ksh. 5000 to 9999d. □ Ksh. 10,000 to 20,000 e. □ Over 20,000 Kshs

13. Do you own any of the following? [tick√ appropriate]

a. □ Radio b.□ Television c. □ Mobile phone

d. □ Bicycle e.□ Motorized vehicle

Medical history

14. Is there anyone else who has diabetes in your family? [Tick √ appropriately]

a. □ Yes b. □ No

15. If yes, in No. 14 who? [Tick √ appropriately]

a. □ Sibling

b. □ Parent

c. □ Uncle/aunt

d. □ Grandparent

e. □ Son/daughter

f. □ other (specify)……

16. What was your age at diagnosis? ……[Indicate year when you were diagnosed with Type 2 diabetes mellitus]
17. How long is it since you were first diagnosed with diabetes?..... years.
18. Were you put on a management program immediately upon diagnosis? [Tick √ appropriately]

    a. □ Yes b. □ No

19. . If yes which one? [Tick √ appropriately]

    a. □Medication alone

    b. □Medication and diet

    c. □Medication, diet and physical activity

    d. □Any other (specify)…….

20. What prompted you to go to hospital the first day you were diagnosed with type 2 diabetes? [Tick √ appropriately]

    a. □ Complications

    b. □ Routine investigations

    c. □ Unrelated complaints

    d. □ Was feeling unwell

    e. □ Other (specify)…….

21. How did you feel when you were first diagnosed with diabetes? [Tick √ appropriately]

    a. □ Shocked

    b. □ Angry

    c. □ Anxious

    d. □ Depressed

    e. □ Helpless

    f. □ Hopeless

    g. □ Surprised

22. How do you feel now? [Tick √ appropriately]

    a. □Fear future complications

    b. □Still worried about being sick

    c. □Fear social disabilities

    d. □Fear social and psychological burdens

23. How has the disease affected your life? [Tick √ appropriately]

a. □ Unable to work as well as before

b. □ Unable to work completely

c. □ Family life

d. □ Socially

e. □ Other (specify)…….

24. Why did you come to the clinic today? [Tick √ appropriately]

a. □Am feeling unwell

b. □ I had an appointment

c. □ To have my blood glucose checked

d. □ Other (specify)…….

25. Do you have any complication resulting from diabetes at the moment? [Tick √ appropriately]

a. □ Yes b. □ □ No

26. If, yes which ones? [Tick √ appropriately] [to be confirmed from hospital record in presence of clinician].

a. □ Retinopathy

b. □Hypertension [to be confirmed by blood pressure assessment or drugs taken and certify in hospital records]

c. □ Nephropathy

d. □ Neuropathy

e. □ Peripheral vascular disease

f. □ Foot disease

g. □Arthritis

h. □ Other (specify) ……..

27. Do you suffer from any other chronic illness? [Tick √ appropriately]

a. □ Yes b.□ No

28. If yes, which ones? [Tick √ appropriately]

a. □ Oral problem

b. □ Eye problem

c. □ Arthritis

d. □Other (specify)…….

29. Have you received all of the following recommended screening exams? [Tick √ appropriately]
    a. □ HbA1C in the last six months
    b. □Eye exam in the last 1 year
    c. □Feet exam in the last 1 year
    d. □ Lipid profile checked in the last six month
    e. □ All the four services received in the last 1 year.
30. Do you monitor your blood glucose? [Tick √ appropriately]
    a. □ Yes b. □ No
31. What are your current treatment modalities? [indicate a tick √ for the ones you have received]
    a. □ Oral medication
    b. □ Moderate exercise
    c. □ Medical nutrition therapy
    d. □ Oral medication and insulin injections
    e. □ Insulin injections
    f. □ Nutrition and exercise
32. Does the clinician provide you with adequate explanation before changing your medication? [Tick √ appropriately]
    a. □ Yes b. □ No
33. Are you willing to adapt to future changes in your treatment regimen if necessary? [Tick √ appropriately]
    a. □ Yes b. □ No c. □ Don't know

Lifestyle survey

Nutrition history

1. What do you eat for your normal meals? List below
   a. ……
   b. ……..
   c. ……..
   d. ……..
   e. …….
   f. …….
2. What time of the day do you eat the food listed above [tick√ appropriate]?

Foods eaten	Morning(6-8am)	10.00am	Lunch(12noon to 2 pm)	4.00pm	Supper(6-9pm)

3. What kind of nutrition information have you ever received? List below
   a. …….
   b. …….....
   c. …….
   d. …….
   e. ……
4. Where did you receive the nutrition information? [Tick √appropriately]
   a. □ Hospital
   b. □ Church
   c. □ Media
   d. □ Group gathering
   e. □ Any other (specify)
5. Have you ever made a change in what you eat?

a. □ Yes b. □ No

6. If yes in question 5 above, what changes have you ever done in what you eat? list below

a. ……

b. ……

c. ……

d. ……

7. Who usually advice you on dietary choices? [Tick √appropriately].

a. □ Doctor

b. □ Nutritionist

c. □ Nurse

d. □ Relative

e. □ Media

f. □ Any other(specify)

8. Are you following any type of meal plan? [Tick √appropriately].

a. □ Yes b. □ No

9. If yes in question 8 above, which one? [Tick√ appropriate].

a. □ Low fat diet

b. □ Vegetables and fruit rich diet

c. □ Refined carbohydrate diet

d. □ High protein diet

e. □ Low cholesterol diet

f. □ Low sodium diet

g. □ Any other (specify)

10. How many of the time are you able to follow your meal plan indicated above? [Tick√ appropriate].

a. □ Daily b. □ Rarely c. □ Sometimes d. □ Often

e. □ Weekly

11. Who usually does the cooking? _____

12. Who usually does the shopping? _____

13. How many times each week do you eat away from home? _____

14. Which meals are usually eaten from home? [Tick√ appropriate].

a. □ Breakfast b. □ Lunch c. □ 10.00am snack d. □ 4.00pm snack e. □ dinner

15. Which type of food do you eat away from home? [List below].

a. ……..

b. …….....

c. …….

d. ……

e. …….

16. Do you drink alcohol? [ick √appropriately]

a. □ Yes b. No

17. If yes in No.16 which type do you take? [tick √appropriately], *Photo of example to be used.*

a. □ Beer b. □ Wine c. □ Liquor/spirit

18. How often? …….

19. How much? …….

20. Is there any day of the week you have missed your meal? [Tick√ appropriately].

a. □ Yes b. □ No

21. If yes in No.20 when?.....

22. Do you have "trigger" food that often cause you to overeat? [Tick√ appropriately]

a. □ Yes b. □ No

23. If yes in No.22, list the reason below

a. …….

b. …….

c. ……

d. ……

24. Do you eat for other reasons than hunger? [Tick√ appropriately]

a. □ Yes b. □ No

25. If yes in No. 24, please describe reason why……

Weight History

1. Height (confirm by measuring) …….Present Weight (confirm by measuring) …….. Usual Weight ……..
2. Has your weight changed over the past year? [Tick√ appropriately]
   a. □ Yes b. □ No
3. If yes, please describe how: ……..
4. How do you feel about your weight right now?.....
5. What has been your weight range as an adult? …….....
6. What would you consider to be a healthy weight for you? …….
7. Would you feel comfortable at that weight? [Tick √ appropriately]
   a. □ Yes b. □ No
8. Have you ever tried to change your weight before? [Tick√ appropriately]
   a. □ Yes b. □ No
9. If yes, what have you tried [list below]
   a. ……..
   b. ……...
   c. ……
10. Have you been successful? [Tick√ appropriately]
    a. □ Yes b. □ No
11. Are you interested in working to change your weight? [Tick√ appropriately]
    a. □ Yes, right now
    b. □ Yes, but I can't right now
    c. □ No, but I will think it over
    d. □ No, not now
    e. □ No, I'm not interested
    f.

Physical Activity History

1. What type of activities do you do regularly and how much time each week do you spend doing them? Examples include walking, dancing, digging, biking, aerobics, and swimming.

Type of activity	Times per week	Minutes per activity

2. Do you like doing these activities alone or with others? [Tick√ appropriately]

   a. □ Alone b. □ with others

3. Do you view exercise as potentially exacerbating illness i.e.as negative physical reactions such as physical weakness, body pain, sickness or ageing? [Tick√ appropriately]

   a. Yes [ ] b.No [ ]

4. Are you interested in becoming more physically active? [Tick √ appropriately]

   a. □ Yes, right now

   b. □ Yes, but I can't right now

   c. □ No, but I will think it over

   d. □ No, not now

   e. □ No, I'm not interested

5. If yes in No.4, what type of physical activity could you see yourself doing regularly? [Explain].

.....

.....

6. If no in No. 4 why? [explain]

Follow up

Adherence to lifestyle modification recommendation

This section contains questions to establish whether or you were adhering to lifestyle modification recommendations (diet and exercise) in the last one month under review Please tick√ the appropriate option inside the box.

Exercise

Definition: Vigorous activities make you breathe much harder than normal e.g. when digging while Moderate physical activities make you breathe somewhat harder than normal and may include carrying light loads, bicycling at a regular pace. Walking will be considered separate.)

1. In the last one month did you follow to any form of exercise recommendations? [i.e. Did you exercise for a minimum of 30 minutes per day for at least 3 days/week] [Tick√ appropriately]

   a. □ Yes b. □ No If NO, please proceed to question

2. If yes in No. 1 was it vigorous or moderate [global physical activity (GPAQ]show card used to illustrate the activities] [if vigorous proceed to question3, and if moderate proceed to question 4] [Tick √ appropriately]

   a. □ Vigorous b. □ Moderate

3. If you participated in vigorous activities indicate the activities done, number of time the activity was done per week and minute spent per day per activity in the table below.

1. 1	2	3	4
Type of activity	Times per week	Minutes per activity per day	Total minutes per activity [to be gotten by multiplying column 2 and 3

4. If you participated in moderate activities in the last one month, indicate the activities done, number of time the activity was done per week and minute spent per day per activity in the table below

1. 1	2	3	4
Type of activity	Times per week	Minutes per activity per day	Total minutes per activity [to be gotten by multiplying column 2 and 3

5. During the last one month, how many days per week did you walk for at least 10 minutes at a time? ……

6. How much time did you usually spend walking per day on one of those days? ……

7. If No in number. 2 please indicate the reason why you did not exercise following list below the reason(s) for non-adherence to exercise. [Tick √ appropriately]

a. □ Too busy schedule

b. □ Weather (especially during winter)

c. □ Lacking exercise partner/spouse

d. □ Specific locations away from home (e.g. Cattle post, trips)

e. □ Criticism (presence of others make you uncomfortable)

f. □

Others…….

8. How much time do you spend sitting on a typical day? [Indicate time in hours].....

9. Did exercise to play a role in your management of type 2 diabetes mellitus in the last one month? [Tick√ appropriately]

a. □ Yes b. □ No

10. If No in number 9, please proceed to question 12.

11. If yes explain how?

……

……

12. In the last one month did you follow any form of healthy dietary habit recommendations? [Tick √ appropriately]

a. □ Yes b. □ No

If yes go to question number 13 and if no go to question number 15

13. If YES, what kind of healthy dietary habit recommendations are you following? [Tick √ appropriately]

a. □ High starch and fiber diets
b. □ Low saturated fat and caloric intake
c. □ Fruits & vegetables
d. □ Regulated alcohol intake and smoking cessation
e. □ Eat more of sugar, Carbohydrate and fat meals
f. □ Include unsaturated fat in my meal
g. □ Exchange lists
h. □ Calorie counting
i. □ Carbohydrate counting
j. □ Low fat diet
k. □ Low sodium diet
l. □ Others …….....

14. How often did you follow healthy dietary habit recommendations?

a. □ Daily b. □ Weekly c. □ At least thrice weekly
d. □ monthly

15. If NO, please indicate reason (s) for not following dietary habits/prescriptions. [Tick √ appropriately]

a. □ Eating out (restaurant, ceremonies, work, family & friends‟ homes)
b. □ Inappropriate dietary habits (e.g. eating snacks in-between meals)
c. □ Financial constraints (to procure ideal healthy diets)
d. □ Poor self-control
e. □ Granting self-permission (e.g. just this once, a little won’ t hurt)

f. □ Another’ s home (e.g. Cattle post, on trips)

g. □ Situations at home (e.g. I eat non-healthy diets when alone)

h. □ Other……

16. Do you try to control the amount of carbohydrate you eat? [Tick √ appropriately]

a. . □ Yes b. □ No [ ]

17. If yes, why do you control? [Explain] ……...

18. On average over the past one month, how many days per week did you follow the diet or eating healthful eating plan? [tick √appropriately]

□ 0days □ 1day □ 2days

□ 3days □ 4days □ 5days

□ 6days □ 7days

19. On how many days per week over the last one month did you eat three to five or more servings of fruits each day? [tick √appropriately]

□ 0days □ 1day □ 2days

□ 3days □ 4days □ 5days

□ 6days □ 7days

20. On how many days per week over the last one month did you eat three to five or more servings of vegetables each day? [tick √appropriately]

□ 0days □ 1day □ 2days

□ 3days □ 4days □ 5days

□ 6days □ 7days

21. On how many days per week over the last one month did you eat high fibre food such as oatmeal, high fibre cereals, whole brown bread each day? [tick √appropriately].

□ 0days □ 1day □ 2days

□ 3days □ 4days □ 5days

□ 6days □ 7days

22. On how many days per week over the last one month did you eat carbohydrate-containing foods with a low Glycemic Index? (Example: dried beans, lentils, whole maize flour ugali, whole wheat flour chapatti) [Tick √ appropriately]

□ 0days □ 1day □ 2days

□ 3days □ 4days □ 5days

□ 6days □ 7days

23. On how many days per week of the last month did your meals for the day include high fat foods like fatty meat, skin on chicken, highly fried foods etc? [tick √appropriately].

□ 0days □ 1day □ 2days

□ 3days □ 4days □ 5days

□ 6days □ 7days

24. On how many days per week over the last one month did you eat fish or other foods high in omega-3 fats? [Tick √ appropriately]

□ 0days □ 1day □ 2days

□ 3days □ 4days □ 5days

□ 6days □ 7days

25. On how many days per week over the last one month did you eat foods high in sugar, such as cakes, cookies, desserts, candies, etc ? [Tick √ appropriately]

□ 0days □ 1day □ 2days

□ 3days □ 4days □ 5days

□ 6days □ 7days

26. On how many days per week over the last one month did you space carbohydrates evenly throughout the day? [Tick √ appropriately]

□ 0days □ 1day □ 2days

□ 3days □ 4days □ 5days

□ 6days □ 7days

27. On how many days per week in the last one month did include low sodium or limit sodium diet in your meal? [Tick √ appropriately]

□ 0days □ 1day □ 2days

□ 3days □ 4days □ 5days

□ 6days □ 7days

28. On how many days per week of the last one month did your meals for the day include low fat foods in your diet? [tick √appropriately]

□ 0days □ 1day □ 2days

□ 3days □ 4days □ 5days

□ 6days □ 7days

29. On how many days per week in the last one month did you eat food which contained or was prepared with canola, walnut, olive, or flax oils? [Tick √ appropriately]

□ 0days □ 1day □ 2days

□ 3days □ 4days □ 5days

□ 6days □ 7days

30. Do you feel that healthy dietary habit had a role to play in the management of type 2 diabetes mellitus? [Tick √ appropriately]

a. Yes [ ] b. No [ ]

31. If yes explain how?

Health care cost questionnaire Baseline

1. On average how often ~~did~~ you visit the health facility per month before joining this programme? [Indicate no. of times].
2. Other than diabetes what other condition were you being managed before the programme? [list the condition] [confirm with the condition listed in medic al history]
    a. ……..
    b. ……...
    c. ……...
    d. ……
3. What drugs have you been using per month before the programme? [list the drugs]
    a. ……..
    b. ……
    c. ……
    d. ……

(To be administered monthly)

4. In the last one month how many times did you come to the diabetes clinic for treatment other than the programme [indicate no. of times] ……..
5. Why did you come to the hospital? [indicate condition treated]
    a. …….
    b. ……..
    c. ……..
    d. …….
    e. …….
6. . How much were you charged for the following services?

a. Consultation and clinical assessment [indicate amount paid] ……

b. Drugs (specify the drugs)

…….

……

……

c. Laboratory procedures (indicate the test requested

…….

……

……

d. Other, specify……

7. Which other condition other than diabetes are you suffering from now?
   a. Nephropathy
   b. Neuropathy
   c. Hypertension
   d. Lower extremity problem
   e. Oral disease
   f. Arthritis
   g. Mental problem
   h. Others(specify)……

   ……

   ……..

8. How many time in the last one month have you visited the hospital because of the condition listed above?.....
9. What kind of treatment were you given
   a. …….
   b. ……
   c. ……
   d. ……..
10. How much did it cost you to be treated of the condition?
    a. Consultation and clinical assessment [indicate amount paid] ……
    b. Drugs (specify the drugs)

    …….

    …….

    …….

c. Laboratory procedures (indicate the test requested

……

……..

……..

d. Other, specify……

11. On average how Many days in the last one month were you unable to perform daily activity due to your illness [indicate number of days]……..
12. Do you have any eye problem? [tick yes or no]

a. □ Yes b. □ No

[If yes in question 12 proceed to No.13 and if no to No.15]

13. Which eye condition were you suffering from? [list below]

a. .....

b. …….

c. ……

d. ……

14. How much did it cost you to treat the condition [estimate cost and confirm from hospital records] Ksh……..
15. Do you have any dental problem?

a. □ Yes b. □ No [If yes in question 15 proceed to No.16 and if no to No.18]

16. Which dental condition were you suffering from?.....
17. How much did it cost you to treat the condition [indicate amount KShs.]……
18. Where do you get cash for your treatment?

a. □ Own earnings b. □ From relatives c. □ From friends

d. □ Insurance (specify type e.g. NHIF, KCB ….)

e. Other (specify) ……..

19. Where do you come from [name the place] ……
20. How far is your home from the facility [estimate distance] …….
21. How much fare do you use when coming for treatment at the facility [indicate amount] .KShs……..

Anthropometric and biochemical data

Anthropometric data: These parameters will be investigated for all groups at baseline, and after the intervention six months. They will include Hb1Ac and lipid profile. blood glucose levels will be done monthly

a. **Record of nutrition status for six month**

Month	**Weight**			**Height**			**BMI**			
	Wt 1	**Wt 2**	**Avg**	**Ht 1**	**Ht 2**	**Avg**		**WC**	**HP**	**Waist hip ratio**
Baseline										
1										
2										
3										
4										
5										
6										

LABORATORYINVESTIGATION

These parameters will be investigated for all groups at baseline, and after six months. They will include Hb1Ac and lipid profile, blood glucose levels will be done monthly,

Participant ID	**Months**	**(FBS)**	**Hb1Ac**	**Lipid profile**			
				LDL	**HDL**	**Triglycerides**	**Total cholesterol**
	Baseline						
	1						
	2						
	3						
	4						
	5						
	6						

CLINICAL INVESTIGATION

1. **Blood pressure of the patient: this was done at baseline and monthly for six month after intervention**

Participant id	MONTH	**Diastolic blood pressure**		**Systolic blood pressure**	
		1st reading	**2nd reading**	**1st reading**	**2nd reading**
	Base line				
	1				
	2				
	3				
	4				
	5				
	6				

Knowledge assessment questionnaire [to be administered before the intervention, after the intervention, one mont6ht after the intervention, 3 month after the intervention and six month after the intervention] [for each question tick appropriate answer]

General diabetes knowledge

1. What is Type 2 diabetes [Tick √ appropriately]
    a. A condition characterized by high blood glucose due to lack of insulin or insufficient insulin production
    b. A condition that occur after eating a lot of food

c. A condition characterized by high blood pressure

d. I don't know

2. Which of the following is not common with diabetes mellitus?
    a. Increased blood glucose level
    b. Neuropathy
    c. Renal problem
    d. Meningitis

e. I don't know

3. When diabetes is not under control the blood glucose ….
    a. Can be low
    b. Can be high
    c. Can be normal
    d. I don't know
4. Glycated hemoglobin (HbA1c) values reflect the two to three months average endogenous exposure to glucose including postprandial spikes in the blood glucose level.
    a. True
    b. False
    c. I don't Know
5. To control diabetes, you need
    a. To balance regular intake of medication, diet and exercise
    b. to go to the hospital regularly

c. to take plenty of food

d. I don’t know

Physical activity

6. For someone with diabetes regular exercise or physical activity…
   a. Improves cardiovascular fitness and blood lipid levels
   b. Is of no importance
   c. Lead to increased risk to complication
   d. Makes one tired and more sick
7. A person with diabetes should
   a. Exercise for at least 150 minutes per week of moderate activity
   b. Not exercise at all
   c. Exercise only when blood glucose is high
   d. Only exercise when told by a health worker
8. You can use any type of shoes while exercising
   a. True
   b. False
   c. I don’t know
9. Exercise for people with type 2 diabetes are the same for all ages
   a. True
   b. False
   c. I don’t know
10. For people with diabetes it always good to monitor the blood glucose and assess their feet before exercising
   a. True
   b. False
   c. I don’t know

Knowledge on Diet

11. Heath eating for a person with diabetes is....
   a. Eating a lot of vegetables, less animal and plant protein and less starch
   b. Eating a lot of starch
   c. Eating food fried with saturated fat

d. □ Eating snacks like cakes with sodas.

e. □ I don’t know

12. It is very important to control the portion size of each food when eating?

a. □ True

b. □ False

c. □ don’t know

13. Which foods contain omega 3 fatty acids? .[Tick[√] appropriately]

a. □ Flax seeds / oil

b. □ Potatoes

c. □ Salmon and tuna

d. □ Walnuts

14. Tick [√] from the list below the foods that are rich sources of carbohydrate:

a. □ Hamburger patty
b. □ Apple
c. □ Cookie
d. □ Bread
e. □ potato
f. □ milk
g. □ orange juice
h. □ sugar
i. □ olive oil
j. □ butter

15. Tick [√] from the following foods those that are high in saturated fat.

a. □ Butter
b. □ Olive oil
c. □ Lard
d. □ Corn oil (elianto)
e. □ solid fats like kimbo, kasuku,
f. □ milk
g. □ meat

16. Tick [√] from the following foods those that high in monounsaturated fat.

a. □ Butter
b. □ Olive oil
c. □ Lard
d. □ Corn oil (Elianto)
e. □ solid fats like kimbo, kasuku,
f. □ milk
g. □ meat

17. Replacing saturated fat with unsaturated fat. [Tick [√] appropriately]

a. □ Has a beneficial effect to insulin sensitivity

b. □ Is not beneficial at all

c. □ Increases risk to diabetes

d. □ Is not recommended

e. □I don’t know

18. Serving dish rich in green vegetables. [Tick [√] appropriately]
    a. □ Increases risk to diabetes complication
    b. □ Reduces risk to diabetes complication
    c. □ Has no beneficial effect
    d. □ Increases glycemic index of food
    e. □ I don’t know
19. Serving red meat, milk and food rich in fat daily leads to...
    a. □ a relative increase in risk to diabetes
    b. □ to reduced risk to diabetes
    c. □ Is very beneficial to diabetes patient
    d. □ Has no benefit at all
    e. □ I don’t know
20. What is the recommended serving for fruits and vegetable for a type 2 diabetes mellitus patient? [Tick [√] appropriately]
    a. □ 6-11 servings a day
    b. □ 3-5 servings a day
    c. □ 2-3 servings a day
    d. □ 1 serving a day
    e. □ I don’t

Knowledge on glycaemic index

21. High glycaemic index diet increases risk of diabetes by... [Tick [√] appropriately]
    a. □ True
    b. □ False
    c. □ I don’t know
22. Food of low glycaemic index may lead to high glycaemic load if eaten in excess [Tick [√] appropriately].
    a. □ True
    b. □ False
    c. □ I don’t know
23. Whole meal bread, oranges and oat meal are high glycaemic index foods [Tick [√] appropriately].

a. □ True

b. □ False

c. □ I don’t know

24. You can lower glycemic index of a food by the following except [Tick [√] appropriately]

a. □ Eating a food of high glycemic index with fibre rich food

b. □ Using fat in food preparation

c. □ Combining a protein and a carbohydrate rich food

d. □ Eating food that are very ripe

25. The glycemic index of a food is not affected by degree of ripeness, processing, type of food and cooking method. [Tick [√] appropriately]

a. □ True.

b. □ False

c. □ I don’t know

Appendix XI: Training of Research Assistants

Objectives of the training:

1. To explain the objectives of the study
2. To explain the methodology of the study
3. To impart knowledge on nutrition management of T2DM
4. To impart knowledge on peer to peer support model and its use in management of T2DM
5. To train the research assistants on skill used in adult education and their application for effective learning.

Duration of training

The training took five days. The principal investigator a qualified nutritionist (MSc in Applied Human Nutrition) conducted the training.

Mode of training

The research assistants' knowledge on nutrition and physical activity as well as role pf peer to peer support in management of T2DM was pre-tested before the training to establish the existing knowledge gaps. The training to the research assistant was done through use of different models that included; lectures, discussions, brainstorming, role-plays and demonstrations using locally available materials. Additionally, the research assistant was also taken through practical sessions to increase their knowledge and ensure they deliver the content to the required standards

Standardization of research assistants' performance:

1. A written pretest and posttest was given to the research assistant before and after the training. This was to ensure they were adequately knowledgeable on nutrition management of TDM as well as use of the peer to peer support model.
2. role plays and demonstration were done by the research assistant during the training to ensure they had acquired adequate teaching skills

Emphasis was put on

- Importance of seeking consent for the participant
- Respect for the participants
- Confidentiality in the whole process of the research

Appendix XII: Training Curriculum

NUTRITION EDUCATION PACKAGE FOR MANAGEMENT OF TYPE 2 DIABETES MELLITUS

Goals of the Program:

i. To provide a basic understanding of diabetes
ii. To provide a basic understanding of the relationship between Diabetes and nutrition.
iii. To improve recognition of the food groups and increase awareness of the importance of combining foods for improved diabetes control.
iv. To improve diabetic meal planning skills.
v. To improve physical activity levels of the participant

INTRODUCTION WEEK

OVERVIEW OF DIABETES MELLITUS

Objective

At the end of the session the patient should be able to explain;

i. What is diabetes
ii. Symptom of type 1 and type 2 diabetes mellitus
iii. Differentiate between hyperglycaemia and hypoglycaemia as well as how to manage
iv. Risk factors to diabetes
v. General management of diabetes
vi. How to care for foot and eyes

2. . What is diabetes?

Diabetes is chronic disorder characterized by hyperglycaemia (high blood glucose >6.1mmol/l) that occurs due to lack of insulin in the body or failure of the body cells to respond to circulating insulin (ADA; American Diabetes Association, 2014; MoPHS, 2010b).

3. Classification of diabetes mellitus

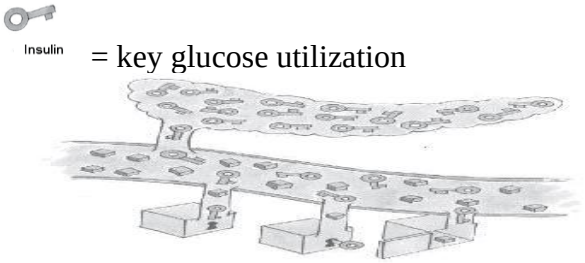
Diabetes is classified to:

i. Type 1 diabetes mellitus
ii. Type 2 diabetes mellitus
iii. Gestational diabetes

4. Insulin action

The participant will be explained by the trainer how insulin works through a picture as shown below

In simple terms insulin acts as a key that unlocks the liver and muscle to allow glucose to get in.



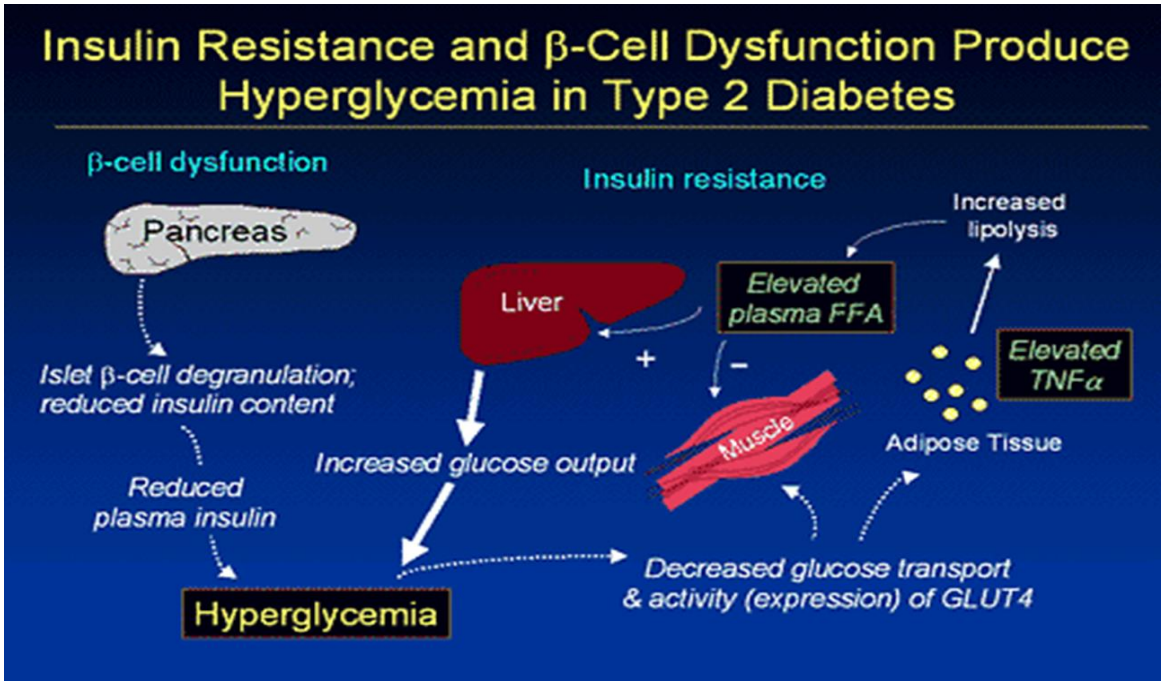
= key glucose utilization

Insulin helps control blood glucose levels by signaling the liver and muscle and fat cells to take in glucose from the blood. Insulin therefore helps cells to take in glucose to be used for energy. If the body has sufficient energy, insulin signals the liver to take up glucose and store it as glycogen. However, insulin insufficiency due to dysfunction of Beta cells of the pancreas and/or Insulin resistance leads to hyperglycemia as elaborated in the figure 1.

5. Type 2 diabetes Mellitus

This is characterised by insulin resistance (failure of insulin to work properly) and or abnormal insulin secretion or not being produced at all or most of the time both are present (ADA, 2014)

Pathogenesis of Type 2 Diabetes Mellitus



(Baynest, 2015; Defronzo et al, 1988; Kahn, Cooper, & Prato, 2014)

Figure 1: Pathogenesis of T2DM

Demonstration using locally available material on how resistance occur will be done; this will aim at making the participants understand more about insulin resistance (volunteer participants will be requested to push a wall with all their strength; they will be told to tell the members how the task will. Resistance band will also be used where participant will be requested to pull the band and share the experience with the others. This will be geared at giving a clear understanding of resistance)

Signs and symptom of Type 2 Diabetes Mellitus /Hyperglycemia

Table 1 Signs and symptom of Type 2 Diabetes Mellitus

Serial No	**Symptom**	**Serial No**	**Symptom**
1	Frequent urination	**5**	Irritability
2	Excessive thirst	**6**	Blurred vision
3	Unexplained weight loss	**7**	Slow healing of cuts and wounds
4	Increased fatigue	**8**	Numbness and burning sensation

Flip charts will be used to elaborate (Flip Chart no. 1 attached at the end of the curriculum)

Risk factors OF Type 2 Diabetes Mellitus

Table 1: Risk factors OF Type 2 Diabetes Mellitus

Serial No.	Risk factors
1.	Obesity
2.	Unhealthy diet
3.	physical inactivity
4	Family history

Flip charts will be used to elaborate (Flip chart no 2 attached at the end of the curriculum)

Complication Associated with Type 2 diabetes Mellitus

- Hypoglycaemia (short term)
- Eyes problem- cataracts, glycoma, retinopathy
- Diabetes foot and poor healing of wounds
- Hypertension-elevated blood pressure
- Nephropathy (Kidney problem)
- Neuropathy (Nerves problem)

Flip charts will be used to elaborate (Flip Chart no. 3 attached at the end of the curriculum)

6. Hypoglycemia

This occurs when your blood glucose (sugar) levels have fallen (gone down) low enough that you need to take action to bring them back to your target range. This is usually when your blood sugar is less than 70 mg/dL. Some of the causes and symptoms are listed below:

Table 2: Causes and Symptoms of Hypoglycemia

Causes of hypoglycaemia		**Symptom of Hypoglycaemia**	
1	Skipping meals,	**1**	Dizziness
2	Wrong timing of medication,	**2.**	Hunger headache
3.	Drug overdose	**3.**	Nausea irritability
4.	Excessive physical activity	**4.**	Fainting
5.	Side effect of medication (Overdose)	**5.**	Dizziness

Flip chart will be used to elaborate (Flip chart NO. 4 to be used to elaborate Symptoms of hypoglycaemia)

WEEK ONE

SESSION 1: PRINCIPLE OF HEALTH EATING AND FOOD GROUPS (CEREALS, ROOT AND TUBERS)

Session 1: part A: Principles of Health Eating

At the end of the session the participants will be able to;

i. Define what is healthy eating
ii. Explain the benefits of health eating
iii. State the basic nutrient, defining the role of each
iv. State the basic principles of a healthy diet
v. Identify healthy food choices

What is healthy eating?

Health eating means;

i. Eating varieties of food from most of the food groups like vegetables, starch, cereals, fruits
ii. Eating food high in fibers like whole grain bread, whole grain rice, vegetable and fruits
iii. Including vegetables and fruits in a meal
iv. Cutting fatty pieces from meat
v. Choosing unsaturated fat instead of saturated
vi. Choosing food with low glycemic index
vii. Reducing intake of salt **(salt will be used to demonstrate)-**participant were advised to reduce intake of processed food like smokes, sausages as they are high in salt
viii. Reducing intake of sugar and sugar base product **(example will be given-cakes, sugar, juices, sodas)**

Note: Food groups and glycemic index will be discussed in later sessions

Signal system in health eating

(DHHS; Department of Health and Human Services, 2014; Health, BH, & VSG, 2014; USDH; United State DePartment of Health and Health Services, Programme, & CDC; Centre for Disease Control and Prevention, 2008)

To elaborate further on health eating we will use the signal System. It is a guide that will help you understand well the principle of healthy food choices and cooking methods

The system uses the traffic light concept of red for 'stop' which also denotes danger, yellow for 'go slow' or cautious, and green for 'go' or safer road. This method is used to guide patient on food selection and cooking method. It uses universally understood symbols which makes it simple and highly useful way for a patient to make an informed choice.

Traffic light sign will be shown to the participant in form of flip charts to help them understand the concept of the colours and food choices

Red		Stop(Danger)
Yellow		Go slow (be cautious)
Green		Go(Safe)

Figure I: Signals sign in health eating

Importantly signal system focuses attention on processing and cooking, lays stress on the Glycemic Index (GI) of food, fiber content of food, the amount and type of fat used and the mode of cooking. It removes negative feelings about being on a diet and avoiding certain foods. It empowers the patient to make a behavior change towards healthy eating.

Table 3: Principles of Healthy Food Choices, Signal system

Principles	Green	Yellow	Red
Refined cereals and sugars	Low	Moderate to high	High
Saturated fat	Low	Low	High
Total fat	Low	Moderate	High
Glycemic index	low	Moderate high	High GI
Fiber	High	Low	Negligible
Cooking method	Steaming, boiling, roasting, grilling, tandoor, dry heat, less fat in cooking	Pan fried, sautéed, stir fry; moderate amount of fat in cooking	Deep fried, extra butter, ghee added, rich sauce/dressing, rich in added sugar
Processing	Rich fiber, parboiled, hand pounded.	Low fiber, refined, milled	Low fiber processed, ready to eat

Additionally, fresh food bought in the morning during training days was used to elaborate the points

Benefits of healthy eating

Q. What are the benefits of health eating?

Healthy eating;

i. Helps keep your blood glucose in your target range
ii. Help you reduce weight if overweight and maintain good weight for those who are not overweight.
iii. Help reduce blood pressure
iv. Help reduce cholesterol levels
v. Help you to be active throughout the day
vi. Lower your risk for serious health conditions, from heart disease to and other complications.

Maintaining a healthy blood Glucose (Sugar)

How do you maintain healthy blood glucose using diet?

Note: Maintaining a healthy blood glucose level is very important to Type 2 diabetes mellitus management. This can be done

i. Having variety of food in your diet and doing food combination
ii. Timing of your meal
iii. Spacing your carbohydrates throughout the day

Timing of meals

What do we mean by timing of a meal as one way of achieving health eating?

This means eating food at the same time of the day

It is very important that you eat at approximately the same times each day and never ever skip meals.

i. Timing your meal (setting time for your meals) on regular schedule will result in improved glucose control throughout the day, and over time, evidenced by improved HbA1c values and improved insulin sensitivity.
ii. Eating on regular times of the day leads to energy stabilization and regulation
iii. Eating on regular time help to control hunger and appetite

Note: Explanation to assist principal investigator

Research has shown that regular daytime eating patterns help regulate the release of leptin a hormone produced by adipocytes, resulting in reduced hunger scores and cravings(Sofer, Stark, & Madar, 2015)***. Gherlin, a hormone produced by the gastrointestinal tract, also plays a significant role in appetite regulation***(Sofer et al., 2015)***. Gherlin levels are stabilized with regular daytime eating*** (Sofer et al., 2015)***. Hormonal stabilizing, resulting in appetite stabilizing, results in reducing of food intake and proven changes in overall weight and weight-related measurements (body mass index, abdominal circumference, body fat percentage)***(Sofer et al., 2015; Takahashi et al., 2018)**.**

Food combination (Variety)

What is food combination? Participant were asked to explain what is food combination

It is always good to combine your foods each time you eat a meal or a snack. Combining food means to always have food with different nutrients at a meal. Some of the nutrients you can include are carbohydrate, fats, protein, vitamins and minerals.

We will discuss which foods are carbohydrates and which are proteins in a few minutes

This can be achieved by having a variety of different food in a meal

Fresh food bought from the market will be used to explain variety and how to include them in a meal.

This combination is important, because food is broken down and digested in the body at different rates. If you only eat carbohydrates your blood glucose will increase rapidly, but then will decrease rapidly before next meal, and you may experience a low blood glucose reaction. Protein foods will breakdown at a slower rate in the body and produce less rapid increase blood glucose and fat is the slowest to breakdown with the least rise in blood sugar. If you combine a carbohydrate, a protein and a fat each time you eat – you will get a steady moderate rise in blood sugar that will carry you over to the next meal or snack.

Session 1: Part B Food Nutrients

Now we will discuss the nutrient contained in food

Our body's requires nutrient for survivals. These nutrients include carbohydrates, proteins, vitamins and minerals, fats and water.

1. **Carbohydrates**

What are carbohydrates?

Carbohydrates are energy giving foods and key component of a healthy diet

- They should be included in the meal plan and usually provides 50-60% of the total calories (energy).
- Sources includes;

- Cereals & grains e.g. maize, rice, ugali, wheat, and wheat products,
- Roots e.g. arrow roots (Nduma), Irish potatoes & sweet potatoes, cassava etc.
- Legumes
- Vegetables
- Fruits

Note: cereals, root and tuber are high in carbohydrates, followed by legumes. Fruit and vegetable have small quantity of carbohydrates and are high in fibre so include them in a meal

The food listed will be shown to the participant for them to visualize them better

- In the body carbohydrates are converted to glucose and absorbed in the blood
- The amount of carbohydrates eaten is very important in blood glucose control

Note: The total amount of carbohydrate in meals or snacks is more important than the source or type because it affect blood sugar level

Dietary fibre

These are also carbohydrates. This is the indigestible portion of plant foods that pushes food through the digestive system, absorbing water and easing defecation. Dietary fiber comes from the thick cell wall of plants.

Dietary fiber can be:

- Soluble (able to dissolve in water)
- Insoluble (not able to dissolve in water).

Sources of Dietary Fiber

- Whole grains are the best source of insoluble fiber.
- Oats, barley, beans, fruit (but not fruit juice), and some vegetables contain significant amounts of both forms of fiber and are the best sources of soluble fiber.

Note: **We will discuss the i*mportance of carbohydrates and dietary fibre in blood glucose (sugar) control to be discussed during meal planning lesson***

2. Proteins

i. Proteins are body building foods.

ii. It is recommended that 10-20% calories (Energy) should come from protein (approximately 0.8g protein/kg body weight)

iii. Include protein in your diet as it assist to slow glucose (sugar release in the blood)

iv. Diet high in protein and low in carbohydrates is not recommended.

Sources of proteins are;

- *Animal sources* –
  - meat and meat products,
  - milk and milk products,
  - fish,
  - poultry (chicken, turkey, ducks)
  - eggs,
  - *Plant Sources* –
  - dry legumes e.g. beans, peas, lentils etc.

Note: Protein foods do not directly affect blood glucose and can help you feel satisfied, although they do add calories, hence include them in your diet

Fresh food samples bought from the market will be used to allow participant visualize protein sources

3. Vitamins and minerals

i. Are needed by the body for vital functioning.

ii. Most of these nutrients are required for metabolism (breakdown) of macronutrients (carbohydrates and proteins).

iii. They are constituents of major foods e.g.
  - Vitamin B12 is found in meats and grains,
  - calcium is high in milk and milk products as well as sea foods,
  - iron is present in red meats, eggs, organ meats and nuts

Major sources

- Fruits - mangoes, bananas, oranges, lemons and tangerine
- Vegetables - spinach cabbage, carrots green beans and peas, indigenous vegetables etc.
- Vegetables and fruits are major sources of fiber which is a major dietary component of glycemic control

Note: We will discuss fruits and vegetables in details vegetables in lesson 4 during week

4. Dietary fats

Details of different types of fat to be done in the food group section for fats and oils during week five)

i. These are high energy giving foods.
ii. All Fats provide more energy per gram than other foods (9 call/g)
iii. It is recommended that less than 30% of total energy calories should be provided by fat

<u>Fats and oils are classified into:</u>

i. Monounsaturated: sources are canola, peanut, and olive oils; avocados; nuts such as almonds, and seeds such as pumpkin and sesame seeds.
ii. Polyunsaturated: sources include: Sunflower, corn, soybean, and flaxseed oils, and also in foods such as walnuts, flax seeds, and fish.
iii. Saturated: (solid at room temperature) sources are whole milk, butter, cheese, and ice cream; red meat; chocolate; coconuts, coconut milk, coconut oil and palm oil
iv. Trans fats: sources include margarines; vegetable shortening like kasuku, cow boy, kimbo among others, deep-fried foods; many fast foods; some commercial baked goods

FOOD GROUPS

Q. What are food groups?

Objective

At the end of session two, three, four and five the patient will be able to

i. Classify food in food groups
ii. Make health food choices in the food groups by
    - Including varieties of food in the meal
    - Including high fibre food in meal (non-refined cereals like whole grain maize flour,
    - Including vegetables and fruits in meals
    - Cutting fatty pieces from meat
    - Choosing unsaturated fat instead of saturated
iii. Understand the carbohydrates, protein, fat and energy content of different foods
iv. Space carbohydrates throughout their meals
v. Do carbohydrate counting

Session 1: Part C: Cereals

i. This group of food consists of the cereals like maize, millet, sorghum, rice and product made from these cereals like bread, ugali (African Corn Mash), chapatti, pasta (spaghetti) among others.
ii. They classified as refined and none refined
iii. Examples of refined foods included cakes, white bread, white rice, refined maize flour like jogoo, Mama, refined chapati flour like ndovu, pembe maize meal, while unrefined cereals consist of whole maize meal flour, millet flour, sorghum flours, whole maize wheat flour, oats, among others

(Example of real foods to be used for demonstration)

iv. A serving of cereals provides 15 grams of carbohydrates, 8 grams of proteins, 2 grams of fat and 80kcals.

(Example of serving for cereals using different food to be given during the training)

v. One serving of this group (one ounce) size equals:
    - 1 slice of bread

- ½ cup of cooked cereal (*cooked maize was used to demonstrate*)
- ½ cup of cooked rice or pasta (*cooked rice was used to demonstrate*)
- 1 cup of ready eat cereal (*wheat bix was used to demonstrate*)

vi. For a person with diabetes 6--11 servings per day of are recommended for diabetes patient.

Participant will be taught on how to include cereals in a health way in the diet

Note:

- Choose from unrefined source; they are rich in fibre which slows carbohydrates digestion and absorption.
- Space food from cereal sources throughout the day

Demonstration of serving of cereals, roots and tubers will be done by the principal investigator

Session 1 Part D: Roots and Tubers.

i. This consists of potatoes, yams, arrowroot, yams, cassava and green bananas. They are grouped together with cereals.

ii. Foods from this group are sources of carbohydrate and energy in the diet.

iii. A serving of food from these group gives 15 grams of carbohydrates and Kilocalories

Note For a person with Type 2 diabetes mellitus 6--11 servings of selected form cereals, root and tubers per day of are recommended.

WEEK TWO

SESSION 2: LEGUMES, NUT AND SEEDS

Session 3 Part A: Legumes

In your understanding, what are legumes?

i. They are good sources of protein, carbohydrates and energy

ii. Food from this group includes beans**,** pigeon peas, dry peas, black peas or dolicos (njahi), chicken peas. Their protein is plant based

iii. They require to be complemented with cereals because most of them are deficient with some essential amino acids.

iv. A serving of legume gives 12 grams' carbohydrates, 7 grams' protein and 80 kilocalories **(we will learn about serving in week 6)**

v. Food from this group is also rich in fibre that delays release of carbohydrate in the body.

vi. Soak them before cooking to reduce ant-nutrient that often cause flatulence

vii. Choose from food from this food group and include them in a meal

Flip chart No. 7 gives some examples of legumes

Note:

Participants will be urged to include them in a meal as they are good source of protein and fibre but should eat them in moderation because they also contain carbohydrates

Beans, pigeon peas, dry peas, chick peas and dolicos will be availed for demonstration)
Cooked beans will be used to demonstrate a serving of legumes

Session 2 Part B: Nuts and Seeds

i. Nuts and seed are good source of proteins, fat, carbohydrates and energy.
ii. Nuts are high in ant-nutrient hence require prior processing before eating
iii. Some of the methods you can use to prepare nuts includes roasting and frying
iv. Nuts and seeds are mostly used as snacks
v. Examples of nuts: These include ground nuts, cashew nuts, macadamia nuts,
vi. Examples of seed that can be consumed included simsim seeds, pumpkin seeds, chia seeds.

Note:

Raw and processed nuts and seed will be used for demonstration
Nuts and seed are sources of carbohydrate, protein and fat, hence should be used sparingly, preferably as a snack

Examples used for demonstration included:

i. Ground nuts (raw and roasted); cashew nuts (raw and roasted); simsim seeds (roasted), macadamia nuts (raw and processed), Chia seeds
ii. Participants will be advised that if using chia seed they should soak them at least 1 hour before use. A demonstration of the same will be done
iii. For nuts participants will be informed on how they can use the as snack and a handful is enough as shown below.

Note: Example of a serving of nuts will be shown using the palm of the hand. Participants were requested to practice. This gave them a clear understanding.

WEEK THREE

SESSION 3: MILK AND DAIRY PRODUCTS, MEAT AND MEAT PRODUCTS

Session 5 Part A: Milk and Dairy Products

i. These foods include milk and its products
ii. This food is a combination of a carbohydrate and protein food.
iii. 2-3 servings per day recommended.
iv. One serving equals:
- 1 cup of milk or yogurt
- 1 ½ ounces of natural cheese
- 2 ounces of processed cheese

	Avoid:	**Choose More:**
o	Whole milk	Skim milk
o	2% milk	1 % milk
o	Regular high fat	cheese Low fat cheese
o	*Regular evaporated milk*	*Evaporated Skim milk*

A250 ml glass is the ideal serving of milk and its products

Session 5 Part B: Meat and Meat products

This consists of meat, poultry, fish, dried beans, eggs.
The provide protein and fats
One serving equals:
- 2 1/2 –3 ounces of meat or meat substitute.
- 1 egg = 1 ounce of meat.

This food group is a protein.

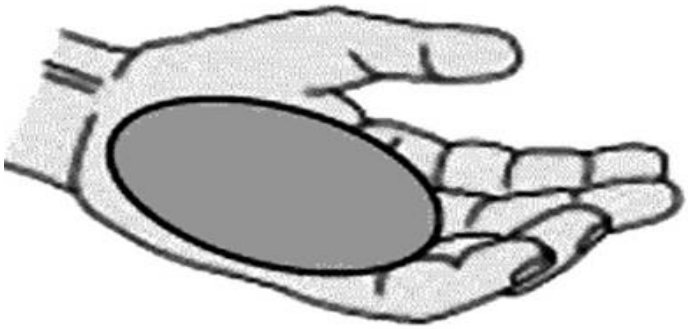


Figure II: Serving of meat/ meat product using hands
Size of your palm is the ideal source of a serving of meat

WEEK FOUR

SESSION 4: VEGETABLES AND FRUITS

Session 4 Part A: Vegetables.

i. Vegetables provide vitamins, minerals, and fiber.
ii. They are low in carbohydrat**e**.
iii. Include both the Green leafy, yellow or orange and other coloured vegetables in your diet.
iv. A serving of vegetables provides 5 grams' carbohydrates and 25 kilocalories.
v. 3-5 servings per day are recommended.
vi. You can use vegetables as salad
vii. Use oil sparingly while frying vegetables
viii. Examples include lettuce, broccoli, spinach, peppers, carrots, green beans, tomatoes, celery, kales, cabbage, traditional vegetables such as amaranth, mrenda, managu, among others. One serving includes
ix. Examples of vegetable serving include
    - ½ cup of chopped raw or cooked vegetable
    - 1 cup of leafy raw vegetable

Note:

i. Fresh cabbage and kales as well as cooked cabbages will be used to demonstrate a serving of vegetables

ii. Different fresh varieties of vegetable will be used for demonstration. They includes spinach, kales, cabbages, carrots, cucumbers, godget, broccoli, cauliflower, celery, onions tomatoes, capsicum (red, yellow and green,) leek onion, traditional vegetables like amaranth, pigeon peas leaves, pumpkin leaves, managu, mrenda among others.

iii. A flipchart with different varieties of vegetable that will be shown to the participant (Flip Chart No. 8).

iv. Demonstration of different serving sizes of vegetables will be done but details will be covered in week 6

A sample of vegetables is shown below.

Figure III: Illustration of fresh vegetibles

Green vegetables: cauliflower, brocolli, cerelly,succhin(godget),green pepper, corriander
Coloured: carrots, tomattoes, purple cabbage, pumpkin
Participant will be grouped into groups of ten and practice serving of Vegetables. They will also make different type of salads using vegetables availed

Figure IV: Hand estimate of vegetable that can be included in a meal.(Mash & Content, 2010)

Note:

i. ***The participant will use their hand to estimate vegetable portion and place the vegetable from their hands into a plate.***
ii. ***This will make them visualize the portion of vegetable one can include in a meal***

Session 5 Part B: Fruits

i. Fruits provide you with carbohydrate, vitamins, minerals, and fiber.
ii. It is recommended that a person with Type 2 diabetes should eat fruits daily
iii. Use fruits in season to cut on cost
iv. Avoid overripe fruits because they are high in sugar.
v. You can also blend the fruit and take them as juice that is not sieved, but fresh fruits are recommended because they are high in fibre
vi. Examples includes apples, oranges, pineapples, melons, passion, grapes, pomegranate tree tomatoes among others and their products
vii. This is a carbohydrate food
viii. 3-5 servings of fruits are recommended per day.
ix. One serving equals:
    - 1 piece of medium size fruit or melon wedge
    - ¾ cup (6 oz.) of juice
    - ½ cup of canned fruit
        - ¼ cup of dried fruit

Note:

- ***Fresh fruits from the market will be used for demonstrate***
- ***Serving of fruits will be demonstrated to the participant the principal investigator and research assistants.***
- ***Participant will be grouped into groups of ten and practiced serving of fruits***

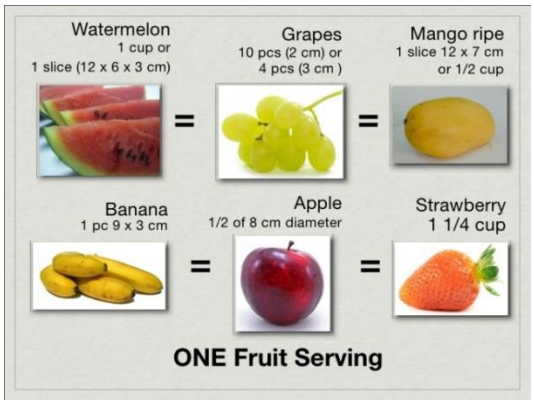


Figure V: Serving of a fruit (Elaboration using a fist) ***A fist (size of a tennis ball) is equivalent to a serving of vegetable. A tennis ball will also be availed led to elaborate further***

Figure VI: Fruits available in Kenyan market that can be used by Type 2 diabetes patient

They can be eaten as salad or whole fruit as shown above

Note:

- ***i. Participant will be urged to always choose different varieties of fruits guided by colour, size and use fresh fruits***
- ***ii. Flip Chart No. 8 will be used to give more demonstration of different food in Kenya***

WEEK FIVE

SESSION 5: DIETARY FAT AND OILS

These are high energy giving foods. It is recommended that fat intake should not exceed 30% of total calorie intake per day. The total fats depend on many factors. However, the type of fat an individual eats is more important than total fat. All Fats provide more energy per gram than other foods (9 kcal/g) but only differ in their action on the cholesterol metabolism. Therefore, it is important to watch portion sizes as well.

Fats are classified as;

i. Saturated fat

They are mainly found in food of animal origin, however, coconut and palm oils belong to this category. They are solid at room temperature with the exception of coconut and palm oils. They adversely affect serum cholesterol levels.

***Note: One of the important diabetes nutrition guidelines is to eat less than 7% of calories from saturated fa*t.**

Foods containing saturated fat include:

- High-fat dairy products such as full fat cheese, cream, ice cream, whole milk, sour cream. High-fat meats like regular ground beef, hot dogs, sausages bacon
- Lard
- Butter
- Fatback and salt pork
- Cream sauces
- Gravy made with meat drippings
- Chocolate
- Palm oil and palm kernel oil
- Coconut and coconut oil
- Poultry (chicken and turkey) skin

Note; eat in moderation.

ii. **Unsaturated Fats**

These are divided into;

a. Trans-unsaturated Fats

Like Saturated fat, Trans-fat tends to increase blood cholesterol levels. Trans-fats are produced when liquid oil is made into a solid fat through the process called hydrogenation.

Sources are re

- Processed foods like snacks (crackers and chips)
- Baked goods (cookies and cakes) with hydrogenated oil or partially hydrogenated oil
- Margarine
- Shortening
- Some fast food items such as French fries

b. *Monounsaturated Fats*

Monounsaturated fats are called "good or healthy" fat because they can lower the low density lipoprotein (LDL). To include more monounsaturated fat, try to substitute peanut butter instead of butter, margarine or shortening when cooking. Sprinkling a few nuts or sesame seeds on a salad is an easy way to eat more monounsaturated fats. Nuts and oils are high in calories, like all fats. If trying to lose or maintain your weight, eat small portions of these foods.

Sources of monounsaturated fat

- Avocado
- Canola oil
- Nuts like almonds, cashews, pecans, and peanuts
- Olive oil and olives
- Peanut butter and peanut oil
- Sesame seeds

c. Polyunsaturated Fats

Polyunsaturated fats are also "healthy" fats. It is recommended that you include these in your diet as well as monounsaturated fats.

Sources of polyunsaturated fats are:

- Corn oil
- Cottonseed oil
- Soya beans oil
- Salad dressing
- Sunflower oil
- Walnuts
- Pumpkin or sunflower seeds
- Mayonnaise

Serving of fat

- 1 table spoon of margarine or butter
- 1 tablespoon of mayonnaise
- 1 table spoon of vegetable oil

Avoid:	**Choose More:**
Shortening	Canola oil
Lard	Olive oil, corn oil, sunflower oil
Butter/Margarine	

Sample of different oils and fat will be displayed during training for the client to visualize them. Flip chart no. 10 has more examples

Healthy tips

- Try to eliminate Tran's fats from diet. Check food labels for Trans fats; limit fried fast foods.
- Limit intake of saturated fats by cutting back on processed and fast foods, red meat, and full-fat dairy foods. Try replacing red meat with beans, nuts, skinless poultry, and fish whenever possible, and switching from whole milk and other full-fat dairy foods to lower fat versions.
- In place of butter or margarine, use liquid vegetable oils rich in polyunsaturated and monounsaturated fats in cooking and at the table. You can also use peanut for spreading on breads.
- Eat one or more good sources of omega-3 fats every day—fatty fish, walnuts, soybean oil, ground flax seeds or flaxseed oil

SUGARS

NOTE:

i. Sugar, sweets and sweetened water(juices): These food in the signal system are represent with colour red; avoid them, they cause a raise in blood glucose
ii. Use them sparingly

Table 4: Summary table of the food groups, required servings and servings sizes

Food group	**Number of servings**	**What is a serving?**
Starches and breads	6-11	1 Slice bread ½ cup cooked rice, cereal ¼ cup dry cereal, ½ cup pasta 3 biscuits (eat whole-grain, fortified or enriched starches, bread, and cereals)
Vegetables	3-5	½ cup vegetables cooked 1 cup vegetables raw
Fruits	2-4	1 cup fruit juice (fresh, frozen or canned without sugar) 1 medium piece fresh fruit
Milk and milk products	2-3	1 cup skim / low fat milk / ¾ cup plain or artificially sweetened yogurt
Meat and meat substitutes	2-3	57-85 g cooked lean meat fish or poultry 28.5 g meat is equivalent to: - 1 egg 28.5 g cheese ¼ cup fish (Omena, tuna, salmon or cottage cheese
Fat	Use sparingly	1 teaspoon margarine 1 teaspoon salad dressing 1 teaspoon oil or mayonnaise 1 tablespoon peanut-butter

NB: Serving of each food in the food group will be done practically; this will assist the participant be able to visualize the portion sizes of different foods

WEEK SIX

SESSION 6: MEAL PLANNING

As discussed earlier health eating is important in blood glucose control. To be able to eat healthy you need to plan your meal. We will discuss more about meal planning in this lesson

Learning objectives

By the end of this lesson you will be able to;

i. Describe what meal is planning.
ii. Discuss the principles of meal planning.
iii. Use the common tools in meal planning.
iv. Plan a meal

Planning a meal

Note: It is very important to plan your meals before as it assist you to remain focused and always eat a health meal

NB: Individualized meal planning will be done

Meal planning

What is meal planning?

Meal planning is the use of foods, food groups and nutrients to facilitate variations for individual/group preferences, cultural habits, health status and socio-economic factors to achieve specific objectives.

i. It is an interactive process between the client and the health care provider.
ii. The process requires input from the client, including financial, religious and cultural considerations.
iii. It involves distribution of foods to be taken in an individual's daily diet.

What is a meal plan?

Principle of Meal planning

What principles do you consider before planning your meal?

The principles include the point given below;

i. Adequacy in all nutrients

If you can remember we discussed nutrient in our first lesson. Therefore, adequacy in all nutrients means the diet you plan should be able to provide all nutrients (i.e. Proteins, carbohydrates, fat, vitamin and mineral) you require in right amount for you to remain health.

ii. **Balance of foods and nutrients in the diet**

The meal you plan should have a balance in different type of foods and nutrients. This means not over consuming any one food. The art of balance food means that you use enough but not too much or too little of each type of the food groups; that is or for example use some meat or meat alternatives for iron, use some milk or milk products for calcium and save some space for other foods. The concept of balance encompasses proportionality both between and among the groups.

iii. **Nutrient density**

This refers to the relative ratio obtained by dividing a food's contribution to the needs for a nutrient by its contribution to calorie needs. This is assessed by comparing the vitamin and mineral content of a food with the amount of calories it provides. A food is nutrient dense if it provides a large amount of nutrient for a relatively small amount of calories.

iv. **Energy density**

This refers to the amount of energy in kilocalories in a food compared with its weight. Examples of energy dense foods are nuts, cookies, and fried foods. Low energy density foods include fruits, vegetables and any food that incorporates a lot of water during cooking. They contribute to satiety without giving many calories.

For high energy dense food reduce their portion and increase the consumption of low energy dense food like fruits and vegetables.

v. **Moderation in the diet**

Always moderate your diet. This mainly refers to portion size. Plan your whole day meals so as not to under/over consume any one food. In planning the diets, the goal should be to moderate rather than eliminate intake of some foods.

We will learn about portion size in a while

Flip chart no.11. Elaborate well on portion

vi. **Variety in food choice**

This in meal planning means choosing a number of different foods within any given food group rather than eating the same food daily. You should vary your choices of food within each class of food from day to day. This makes your meals more interesting, helps to ensure a diet contains sufficient nutrients as different foods in the same group contain different arrays of nutrients and gives one the advantage of added bonus in fruits and vegetables as each contain different phyto chemicals. We discussed variety in detail in the first lesson

Flip chart no.5 elaborate well on variety

Tools of meal planning

Q. Which tools do you can use in meal planning?

We will discuss this in a while, but they include:

1. Plate method
2. use of hands
3. use of food pyramid
4. Use of food exchange list
5. Use of glycemic index and glycemic load (This we will discuss in Lesson seven, Week Seven)

Remember

Eating doesn't have to be boring. It's all about finding the right balance that works for you.

NOTE:

i. Your choice of food and how much you eat is relative to your blood glucose level.

ii. If you eat more than you need, your blood glucose will rise. To help manage your diabetes, having a good sense of portion control is an important skill

a. Use of hands for portion control

How do you use hand to plan your portion?

Visualizing food portion size": It's in your hands, but how?

Below is an illustration

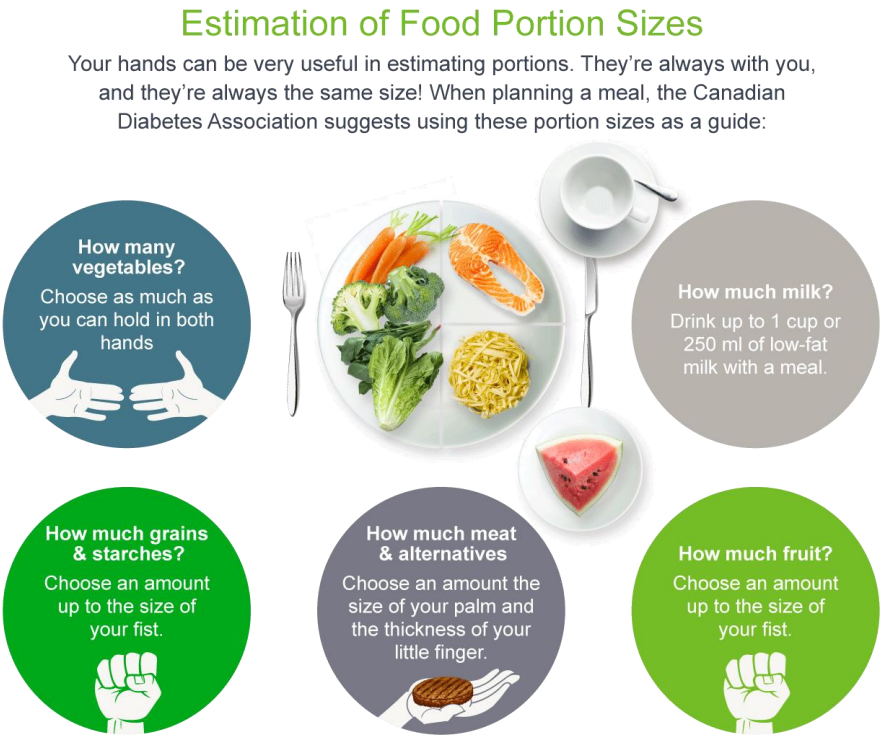


Figure VII: Portion size of different food groups (Adapted from Canadian Food Guide(AHS; Aberta Helath Services, 2016)**)**

b. Food exchange list

i. This is a simple grouping of common foods according to generally equivalent nutritional values. It is used in diet planning and in situation requiring caloric and food value control and helps in achieving kilocalorie control and moderation.

ii. All the foods listed together are approximately equal in proteins, carbohydrates and fat value.

iii. .In the food exchange any food on the list can be exchanged or traded for any other food on that same list without affecting the total kilocalories. The foods are organized to starches (group one), milk (dairy group- group 3), vegetables (group 2), fruits (group 3), meat and legumes (group five),

iv. Fats (group six) and sugars (group six also).

v. The system organizes food into seven exchange lists and the number of kilocalories associated with each food is an average for the group. The energy

in kilocalories (Kcl) is calculated given the number of grams of CHO, fats and proteins in starches food (1gcarbohydrates =4kcl, 1g protein= 4kcal,1g fat =9 kcal).

c. Portion control

We will discuss portion control in a while.

i. In this planning portion sizes will be used.
ii. Portion sizes are strictly defined so that the amount of energy provided by any food item is the same as that of any other item within a given list.
iii. Portion sizes are very important for staying within your calorie level for the day and for meal planning.
iv. Always ½ cup is the portion size for any starchy vegetable, regular vegetable, cooked cereal or canned fruit.
v. For dairy products 1 cup is a serving and meat portions should be no bigger than the palm of your hand. In addition, combine food at each meal time in order the same amount of carbohydrate and protein at each meal and balance your snack with a carbohydrate and a protein

Note: Familiarity with portion sizes is necessary for successful use of the system

d. Plate method

Note: It's easy to eat more food than you need without realizing it. To prevent this the plate method can assist?

What is plate method of meal planning?(CDC; Centre for Disease Control andPrevention, 2014; Evert et al., 2014)

i. The plate method is a simple, visual way to make sure you get enough non-starchy vegetables and lean protein, and limit the amount of higher-carbohydrates food that has the greatest potential to increase your blood glucose.
ii. In this type of planning you use a plate 9inches in diameter that is dinner plate
iii. Example of different type of plates will be used to make you familiarise yourself with different size of plates in terms of size and depth.

iv. A 12-inch ruler will be used to estimate 9 inches

How does plate method of planning work? You will learn this in a while.

i. Divide your plate into two halves''.
ii. Divide I half in to two to make a quarter
iii. Fill half of your plate with non-starchy vegetables, such as spinach, carrots and tomatoes.
iv. Fill a quarter of your plate with a protein, such as fish, lean pork or chicken, lean pork or plat alternatives like legumes, green grams.
v. Fill the last quarter with a whole-grain item, such as brown rice, whole meal maize flour ugali (African corn mash), or root tubers like arrowroot or green bananas.
vi. Include "good" fats such as nuts or avocados in small amounts.
vii. Add a serving of fruit size of tennis or a bowl of fruit or dairy (250ml) and a drink of water

Group work

i. For our practical's we will use kale mixed with spinach and tomatoes and Ugali (African corn mash) from whole maize and beans to demonstrate the portions.
ii. An orange size of tennis ball will also be used and milk
iii. Different plates will be provided to estimate size
iv. An illustration is show in the figure below and Flip chart no.11

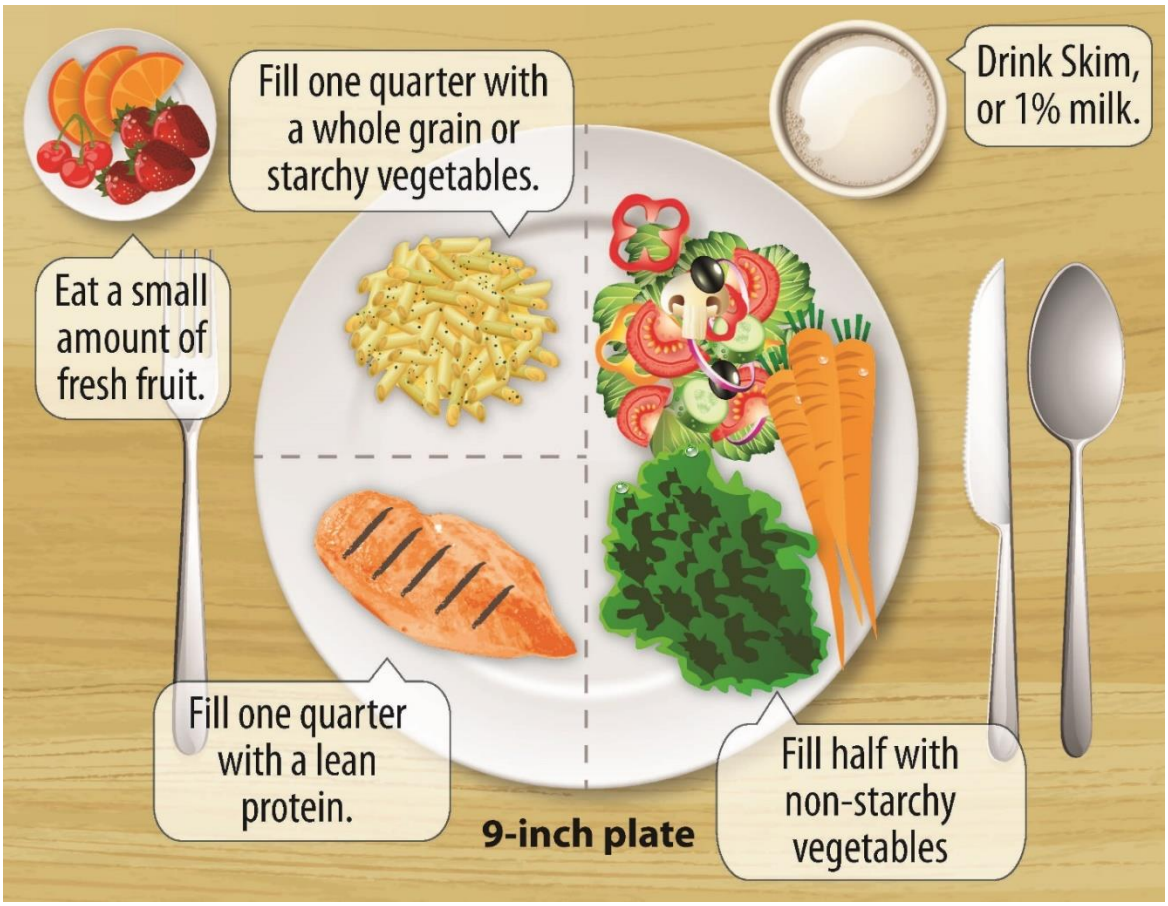


Figure VIII: Portion control using a plate(CDC; Centre for Disease Control andPrevention, 2014; Evert et al., 2014)

Carbohydrate and blood glucose

i. No matter what eating pattern you choose, it is important to know that foods that contain carbohydrate have the greatest effect on blood glucose levels compared to foods that contain protein or fat.

ii. Carbohydrate includes sugars, starches, and fiber. Foods containing carbohydrate are divided into groups based on similar carbohydrate content per serving.

iii. The amount of carbohydrate you consume is based on your diabetes treatment goals and carbohydrate tolerance.

iv. Managing carbohydrate as part of an overall healthful eating pattern not only supports good blood glucose control, but allows flexibility in meal planning, helps balance food and medication, and controls food portions to support a healthy weight.

How can you manage your carbohydrate intake? Don't worry, this you can do with carbohydrate counting?

Carbohydrate Counting — a method to Help Manage Your Blood Glucose

i. Carbohydrate counting is a flexible meal-planning tool (not a diet) that can help you understand how your food choices affect your blood glucose level.
ii. It means keeping track of how many carbohydrates you eat and setting a limit for each meal, this can help keep your blood glucose levels in your target range.
iii. The amount of carbohydrate in your meals and snacks can make a big difference in your blood glucose level. That's why it's important to be aware of the amount of carbohydrate you eat. Any carbohydrate food you eat (e.g., milk, fruit, bread and pasta) is digested into glucose, which causes your blood glucose level to increase. However, eating some carbohydrate foods throughout the day is important because they provide energy and essential nutrients for your body.
iv. To better manage your blood glucose, energy level and weight, pay attention to how much carbohydrate you eat.
v. Maintaining the right balance between carbohydrate and insulin (whether your body produces it or you take it) helps to regulate your blood glucose level.
vi. Determining when and how much you eat — and whether or not you have snacks — should be based on your lifestyle, medications and meal-planning goals.

Note:

i. Carbohydrate counting helps you keep track of how much carbohydrate you are eating.
ii. The amount of carbohydrate to eat for each meal depends on things like how active you are and the type of medicines you takes

Portion sizes and serving size

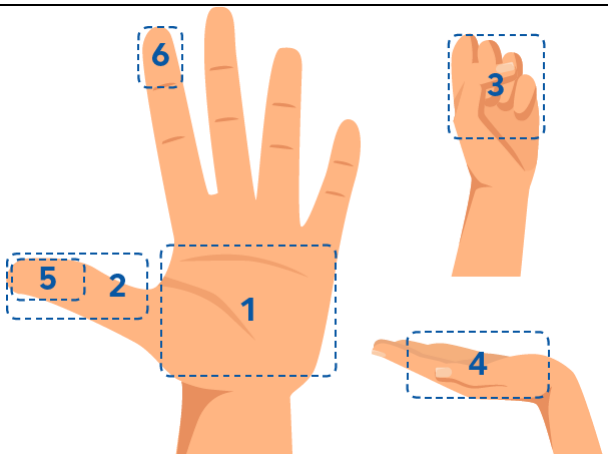
Let us now try to understand portion size

i. Portion size and serving size aren't always the same.

ii. A portion is the amount of food you choose to eat at one time, while a serving is a specific amount of food, such as one slice of bread or 8 ounces (1 cup) of milk.

iii. A portion is not a standard amount and may vary by person and occasion.

Note: We will use hand again and weight to understand portion and serving sizes

Different servings of food by weight	Different servings of food by show of hand
1. 3 ounces (85 gm.) of meat, fish, or poultry =Palm of hand (no fingers) 2. 1 ounce (28.3gm) of meat or cheese = Thumb (tip to base) 3. 1 cup or 1 medium fruit = Fist 4. 1–2 ounces (28.3-56.6gm) = Cupped hand 5. 1 tablespoon =Thumb tip (tip to 1st joint) 6. 1 teaspoon =Fingertip (tip to 1st joint)	

Note: One serving of carbohydrates =15 grams; Foods with about 15 grams of carbs:

i. A small piece of fruit.

ii. 1 slices of bread.

iii. 1/2 cup cooked oatmeal.

iv. 1/3 cup cooked pasta or rice.

v. 4 to 6 crackers.

vi. 1/2 cup black beans or other starchy vegetable.

vii. 1/4 large baked potato.

viii. 2/3 cup nonfat yogurt.

WEEK SEVEN

SESSION 7: GLYCEMIC INDEX, GLYCEMIC LOAD AND NUTRITITON FACT AND LABELS

Session 6 Part A: Nutrition fact labels

i. Understanding the Nutrition Facts label on food items can help you make healthier choices.

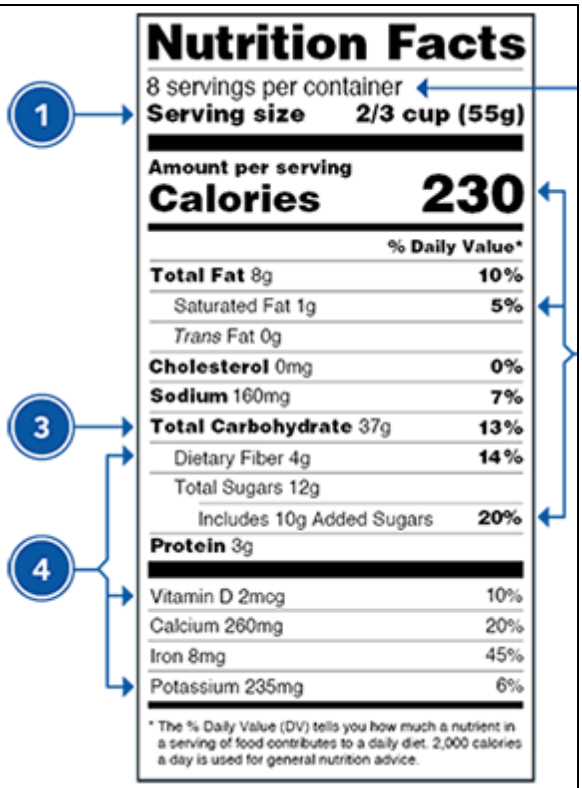
ii. The label breaks down the amount of calories, carbs, fat, fiber, protein, and vitamins per serving of the food, making it easier to compare the nutrition of similar products.

iii. Be sure to look at different brands of the same foods—nutrition information can differ a lot.

iv. For example, one brand of tomato sauce may have more calories and sugar than another brand for the same serving size.

In nutrition facts and labels

Adapted from Kollannoor-Samuel et al (2016)

1. Check the Serving size first. All the numbers on this label are for a 2/3-cup serving. 2. This package has 8 servings. If you eat the whole thing, you are eating 8 times the amount of calories, carbs, fat, etc., shown on the label. 3. Total Carbohydrate shows you types of carbs in the food, including sugar and fiber. 4. Choose foods with more fiber, vitamins, and minerals. 5. Choose foods with lower calories, saturated fat, sodium, and added sugars. Avoid trans-fat.	

This nutrition label tells you:

Nutrition Facts

2 servings per container

Serving size 1 1/2 cup (208g)

Amount per serving

Calories **240**

	% Daily Value*
Total Fat 4g	**5%**
Saturated Fat 1.5g	**8%**
Trans Fat 0g	
Cholesterol 5mg	**2%**
Sodium 430mg	**19%**
Total Carbohydrate 46g	**17%**
Dietary Fiber 7g	**25%**
Total Sugars 4g	
Includes 2g Added Sugars	**4%**
Protein 11g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 6mg	35%
Potassium 240mg	6%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Nutrition labels

This nutrition label tells you:

Serving size—1½ cups.

Servings in the container—2.

Total carb grams per serving—46.

Other nutrition information, including calories, protein, fat, vitamins, and minerals per serving.

If you eat the entire container, you've had two servings instead of one. Multiply carb grams in one serving by two to get the correct amount of carbs you have eaten: 46g x 2 = 92g.

(Kollannoor-Samuel et al., 2016)

Session 7 Part b: Glycemic index and glycemic load

What is the meaning of glycemic index and glycemic load?

i. Glycemic Index (GI) is a ranking of foods from 0-100 that tells us whether foods containing carbohydrates will raise blood sugar (glucose) levels rapidly, moderately or gradually.

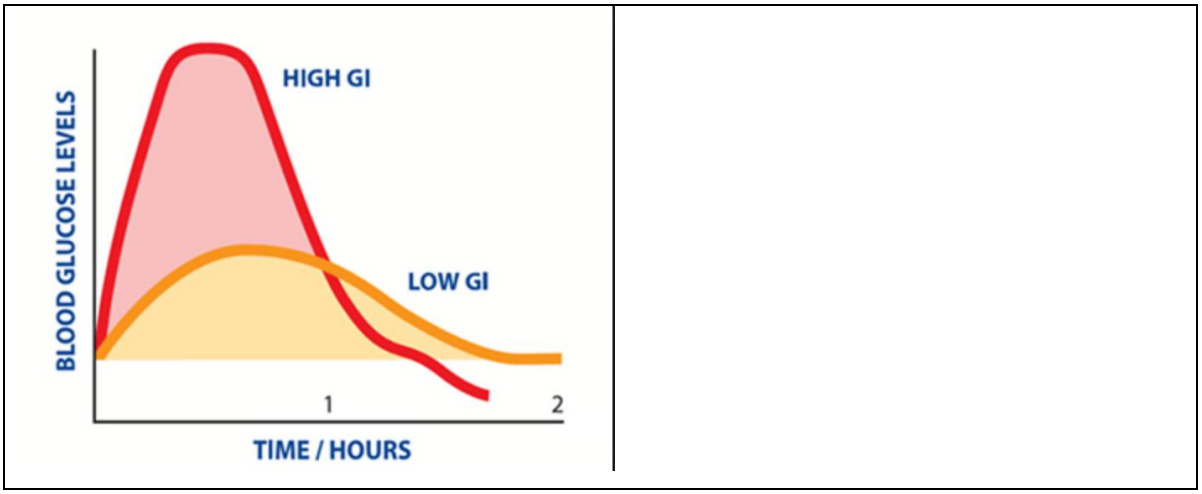
ii. The highest measure of glycemic index is pure glucose that measures a 100.

iii. Food with high glycemic index increase the post prandial glucose rapidly after consuming them

iv. Food with low glycemic index increases the post prandial glucose slowly after eating them

v. A table with a list of different food with their glycemic index is attached in ***Flip chart no.13***

Below is a graph showing how blood glucose level responds after consuming food of low glycemic index and high glycemic index.



GI: Glycemic index

Figure IX: Effect of glycemic index on blood glucose (blood sugar)

(Riccardi et al, 2008)**.**

Use of signal system in Glycemic index

Note: We can also Use signal system to understand the Glycemic index and its effect on blood glucose

i. High glycemic index (≥70) are denoted with the traffic light red that means Stop signaling you to avoid these foods

ii. Medium glycemic index (56-69) are denoted with the traffic light yellow signaling you to use these foods with caution food

iii. Low glycemic index (≤55) are denoted with the traffic light green that means go signaling you that these foods; i.e.: are ideal for you to consume

COLOUR CODE	SIGN	Effect	Signal
High (≥70)		Rapid increase in blood glucose level	Stop!!! , avoid these foods Rethink before use!!
Medium (56-69)		Moderate increase in blood glucose levle	Use with caution
Low (≤55)		Slow increase in blood glucose level	Go for it.!!!!!- ideal to consume (Vegetables, fruits, whole grain cereals, legumes belong to these category)

Figure X: Use of signal system to understand glycemic index

Group work

i. Participant will be grouped in to groups of ten and given different type of fresh food and asked to classify them in terms of their glycemic index.

ii. They will also be given white papers and requested to colour them using the traffic light and then list food in the colured chart

Factors affecting glycemic index

What are the factors that affect glycemic index?

i. Particle sizes
ii. Duration and manner of cooking
iii. Variety of plant
iv. Degree of ripeness
v. Nature of starch

- Content of fat, protein, acid or fibre in the product

Glycemic Load

What do you understand with glycemic load?

After understanding glycemic index, we will know try to understand glycemic load

i. The glycemic load (GL) is obtained by multiplying the quality of carbohydrate in a given food (GI) by the amount of carbohydrate in a serving of that food.
ii. To understand better Glycemic load, let's look at glycemic index
iii. The glycemic index (GI) compares the potential of foods containing the same amount of carbohydrate to raise blood glucose. However, the amount of carbohydrate contained in a food serving also affects blood glucose concentrations and insulin responses. For example, the mean GI of watermelon is 76, which is as high as the GI of a doughnut. However, one serving of watermelon provides 11 g of available carbohydrate, while a medium doughnut provides 23 g of available carbohydrate hence different glycemic load
iv. Therefore glycemic load (GL) is used to simultaneously describe the quality of carbohydrate contained in a food type (GI) and quantity of carbohydrate in a food serving, meal, or diet..
v. Therefore; the glycemic load of a single food is calculated by multiplying the glycemic index by the amount of carbohydrate in grams (g) provided by a food serving and then dividing the total by 100

GL_{Food} = (GI_{Food} x amount (g) of available $carbohydrate_{Food}$ per serving)/100

Example 1

GL_{pple} = (GI_{apple} x 15g) of available $carbohydrate_{APPLE}$ per serving)/100

i. For a typical serving of a food, GL would be considered high with GL≥20, intermediate with GL of 11-19, and low with GL≤10.

ii. For example, despite similar glycemic index in watermelon and a doughnut, one serving of watermelon has a glycemic load of 8, while a medium-sized doughnut has a glycemic load of 17.

Therefore, dietary glycemic load is the sum of the glycemic load for all foods consumed in the diet.

Example 2

If you have consumed

Ugali (African corn mash) 2 serving for lunch with two serving of kales fried with ¼ serving of onion and ½ serving of tomatoes with a serving of beans fried with¼ serving of onion and ½ serving of tomatoes, then the glycemic load will be given by

Total GL of the diet =GL of 2 serving of ugali (African corn mash) + GL of 2 serving of kales+GL of ½ serving of onions + GL of 1 serving of tomatoes

KEY: GL- glycemic load,

Healthy tips

- Increasing the consumption of whole grains, nuts, legumes, fruit, and non-starchy vegetables; they are low glycemic index foods.
- Decreasing the consumption of starchy high-glycemic index foods like potatoes, white rice, and white bread
- Decreasing the consumption of sugary foods like cookies, cakes, candy, and soft-drinks

Note :

The consumption of high-GI and -GL diets for several years might result in higher postprandial blood glucose concentration and excessive insulin secretion. This might contribute to the loss of the insulin-secreting function of pancreatic β-cells and lead elevated blood glucose and irreversible complication associated with prolonged duration of uncontrolled blood glucose.

WEEK EIGHT

SESSION 8: PHYSICAL ACTIVITY PACKAGE

Learning outcomes

i. Demonstrate an understanding of the importance of physical activity in diabetes patient
ii. Development and implementation of a personal physical activity plan (frequency, intensity, time, type)
iii. Help participant to develop an exercise routine program

What is physical activity?

Physical activity means "**any effort involving the muscle-skeletal system which entails higher energy consumption than that required during rest**". This definition therefore includes not only sporting activities but also simple daily activities such as walking, cycling, dancing, playing, gardening and housework.

Type of physical activity

Give the type of activities you know?

Physical activity can either be light or moderate or vigorous

i. **Light activities** are physical activities that involve large your muscle groups. While engaging in light activities, you begin to notice your breathing, but they you still talk fairly easily.
ii. **Moderate activities** are physical activities that cause breathing and heart rate to increase. While engaging in moderate activities you can breathe, but can still talk.
iii. **Vigorous activities** are physical activities that cause breathing and heart rate to increase to a higher level, making it difficult to talk.

You are encouraged to practice moderate; 30 minutes/day for 5 days a week (150 minutes per week) and/or vigorous; at least 15 minutes/day for five day(75 minutes per week)

Classification of physical activities (Colberg et al., 2016)

a. Cardiorespiratory endurance/aerobic fitness

What do you understand by cardio (**Cardiorespiratory endurance/aerobic fitness** metabolic, resistant activity and flexibility exercises?

Cardio-metabolic includes cardio as well as aerobic activities.

Cardiorespiratory endurance/aerobic fitness activities

- These are exercise that has the ability to assist the cardiovascular system (heart, blood, blood vessels) and respiratory system (lungs, air passages) to deliver oxygen and other nutrients to the working muscles and to remove wastes.
- These activities include brisk walking jogging, morning run, running, aerobic activities like jumping jack, sport activities like football, cycling, and swimming. (Elaboration done for examples were done by a physiotherapy and principal investigator.)

Note

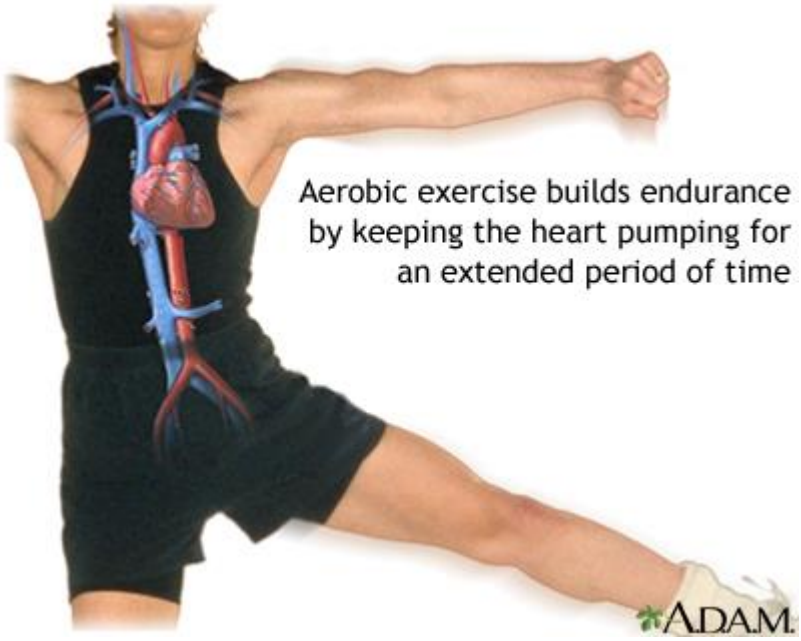
- Aerobic activity increases the oxygen demand from the body and the workload to heart and lungs, thus making blood circulation more efficient. A well-trained heart pumps a higher amount of blood without spending extra energy: 10 heartbeats less per minute mean 5,256,000 beats saved every year.
- 

Figure XI Importance of aerobic activities

b. Resistance training activities

- These activities assist in developing muscular strength and muscular endurance but can develop cardiorespiratory endurance if it is incorporated within a circuit-type workout.

i. . **Muscle strengthening activities**

- These are activities that have the ability to assist a muscle, or a group of muscles, to exert force for a brief period of time
- They include activities like weight lifting or sandstone work where you lift heavy objects like stones.
- Strength of different muscles can be measured by having a person perform weightlifting exercises and determining the maximum amount of weight the person can lift.

While,

ii. Muscle endurance activities

- The activities help muscle or a group of muscles, to sustain repeated contractions or to continue applying force against a fixed object.
- Push-ups and curl-ups are examples of these activities
- The person's endurance is expressed as the number of repetitions completed without stopping for a set period of time (often one minute).

,

Recommended

- **Muscular strength activities:** Two or three 20-minute sessions each week that include exercises for the entire major muscle groups are required. Lifting weights is one of the most effective ways to increase strength. For sedentary people, as little as two workouts per week can be beneficial.

and/or

- **Muscular endurance activities:** Two to three 30-minute sessions each week that include exercises such as calisthenics, push-ups, curl-ups, pull-ups, and light weight training for all the major muscle groups are required.
-

Note

- Use of elastic band can also assist gain muscle strength and Muscle endurance
- Flexibility exercises are those activities that have the ability to move joints through their full range of motion.
- A person's flexibility is usually expressed in how far a joint can be moved or the degrees through which a joint can be moved.
- They done mostly when one is not moving like
  i. Squats
  ii. Brisk walking
  iii. Running and jogging programs

Go go go !!!!!!It is never too late to start moving, no minimum level is required to feel the benefits: a little physical activity is better than nothing. And you feel better as soon as you start being more active.

Try to increase your physical activity every week. Here is how you can start…

If you are inactive (you rarely do physical activity)

Increase the number of daily activities at the base of the pyramid by: (Pyramid attached below)

i. Walking up the stairs instead of using the lift
ii. Hiding the television (TV)remote control and getting up from the armchair every time you change channel
iii. Walking more: around the house or yard
iv. Stretching while standing in a queue
v. Walking whenever possible.

If you are sporadic (your physical activity is not regular)

Try to become consistent by choosing activities at the middle of the pyramid:

i. Find activities you like
ii. Plan activities during the day
iii. Set realistic goals.

If you are consistent (you do physical activity at least four times a week)

Choose activities from the whole pyramid and, if you get bored:

i. Change your daily routine

ii. Try out new activities.

Figure XII: Physical activity pyramid (Mikusova et al., 2009)

How can be able to achieve physical activity? How to reach **30 minutes of moderate physical activity a day:**

i. Walking or cycling to work

ii. Avoiding motorized transport (vehicle or motorcycles) for short distances

iii. Going for a walk with friends or for a run in the park

iv. Walking up the stairs instead of using the lift

v. Getting off the bus one or two stops before yours

vi. Doing some gardening or housework

vii. Dancing or playing with kids.

Note: Example of different physical activity are attached in flip chart no.13

Importance of physical activity

How does physical activity assist you?

Regular and moderate physical activity:

- Helps you to lose excess weight
- Improves your blood pressure
- Burns fats and improves the cholesterol level in the blood
- Helps you to control glucose
- Help you to fight stress; is an excellent way to fight stress
- For those who smoke it help them to reduces cravings to smoke
- Help you to socialize; is a good way to socialize
- It is the best cosmetic.

Through regular physical activity the heart becomes stronger and more resistant to fatigue.

KEY TIPS during physical activity

- Know how to monitor intensity (e.g., talk test, rate of perceived exertion, heart-rate monitor When increasing the intensity (speed, incline, and/or resistance) or duration of exercise, keep in mind the 10 percent rule (e.g., if a person is running continuously for 10 minutes per session in week 1, then in week 2 the maximum increase recommended would be to run continuously for 11 minutes per session).
- Include a variety of activities to avoid overuse injuries or to prevent boredom.
- Include a cardiorespiratory cool-down. To prevent post-exercise peril (e.g., dizziness, light-headedness, fainting), gradually reduce the heart rate, breathing rate, and body temperature before moving on to resistance training or flexibility training. This could be accomplished by simply walking slowly for 5 to 10 minutes.

<u>Key principle in Physical activity</u>

The below listed principles will help you improve your physical activity level and become active.

a. Specificity:

- This means that the type of activity you do or decide to do should be directed specifically at improving your abilities in life.
- Therefore, choose the right kind of activities to improve each physical fitness component of your body.
- Also do the right combination of physical fitness components; combine aerobic with resistant and flexibility training for best result.
- Note if you only do strength training it result to increased muscle strength and endurance but does little to improve cardiorespiratory endurance.
- Also, train specifically for the specific activity of interest. For example, optimal running performance is best achieved when the muscles involved in running are trained for the movements required (Practice). It does not necessarily follow that a good swimmer is a good runner. Specificity also requires that one consider the speed of motion, the number of limbs moving, the direction in which they are moving, and the range over which the movement occurs.

b. Overload:

- This is a term used in exercise.
- It means that one needs to load the body more than it is usually accustomed; For example, if you walk 1 km increase to 2 km.
- However it does not refer to the idea that one needs to overexert or exert at high intensities to obtain gains in fitness ; that is if a person works often (frequency) enough, hard (intensity) enough, and long (duration) enough to load the body above its resting level, physical fitness will improve.
- If this is done regularly over a period of time, the body will gradually adapt to the increase in demands.

c. Reversibility:

- Physical fitness or the effects of a physical activity program or an exercise program cannot be stored.
- If you stop training for a period of time (three to five days, in some cases) a process of detraining will begin.

- The gains in fitness that were made begin to reverse themselves. If no exercise is done for a long enough period, your fitness levels can revert to the original starting point.
- At least three balanced workouts a week are necessary to maintain a good level of fitness.

d. Progression:

- Increasing the frequency, intensity, and/or duration of an activity over periods of time is necessary for continued improvement in physical fitness and overall metabolism. Improvements in metabolism and physical fitness are realized fairly rapidly at the onset of an exercise or training program.
- The rate of improvement will gradually slow down and level off (adaptation) if an overload is present (meaning that the load is increasing and that there is progress).
- At high levels of physical fitness, it may even be necessary to change the type(s) of exercise(s) being performed.

e. Diminishing returns:

- The fitter a person becomes, the more difficult it is to continue to become fitter at the same rate.
- Individuals who begin jogging can, over a relatively short time, improve the speed and duration of their runs.
- However, experienced distance runners may have to spend an entire training season to decrease their run time by just a few seconds.

You now know, take action and control your blood sugar with physical activity. If you have started keep it up, if you have not, it is not late, start and keep going you will really leap the benefits

What do you aim by being physically active?

- The aim of this physical activity programme is to ensure that patients accumulate a minimum of 150 min of moderate or 75 minutes of vigorous activity each week.
- This total amount of exercise consisted of a combination of aerobic, resistance training as well as normal routine work.

Actual physical activity practice during the training day

- Participant will be requested to come ready dressed for a physical activity class. Good foot ware and sport ware were encouraged.
- During the meeting days the participant will be taken through the exercise programme by trainer.
- The exercise programme will start with a warm up of 5–10 min of aerobic activity (jogging) at a low intensity level. The warm-up session aims at preparing the skeletal muscles, heart, and lungs for a progressive increase in exercise intensity.
- After a short warm-up, muscles it will stretches of 5–10 min.
- This will then be followed by a 5-10 minutes cool down aimed at bringing the heart rate down gradually.
- Use of proper foot ware will be recommended during the exercise session.
- Individuals will be taught to monitor closely for blisters and other potential damage to their feet, both before and after physical activity.
- Also proper hydration will be emphasized during exercise
- Adequate hydration prior to physical activity will be recommended (e.g., 17 ounces of fluid consumed 2 h before physical activity).
- The exercise programme will be individualized

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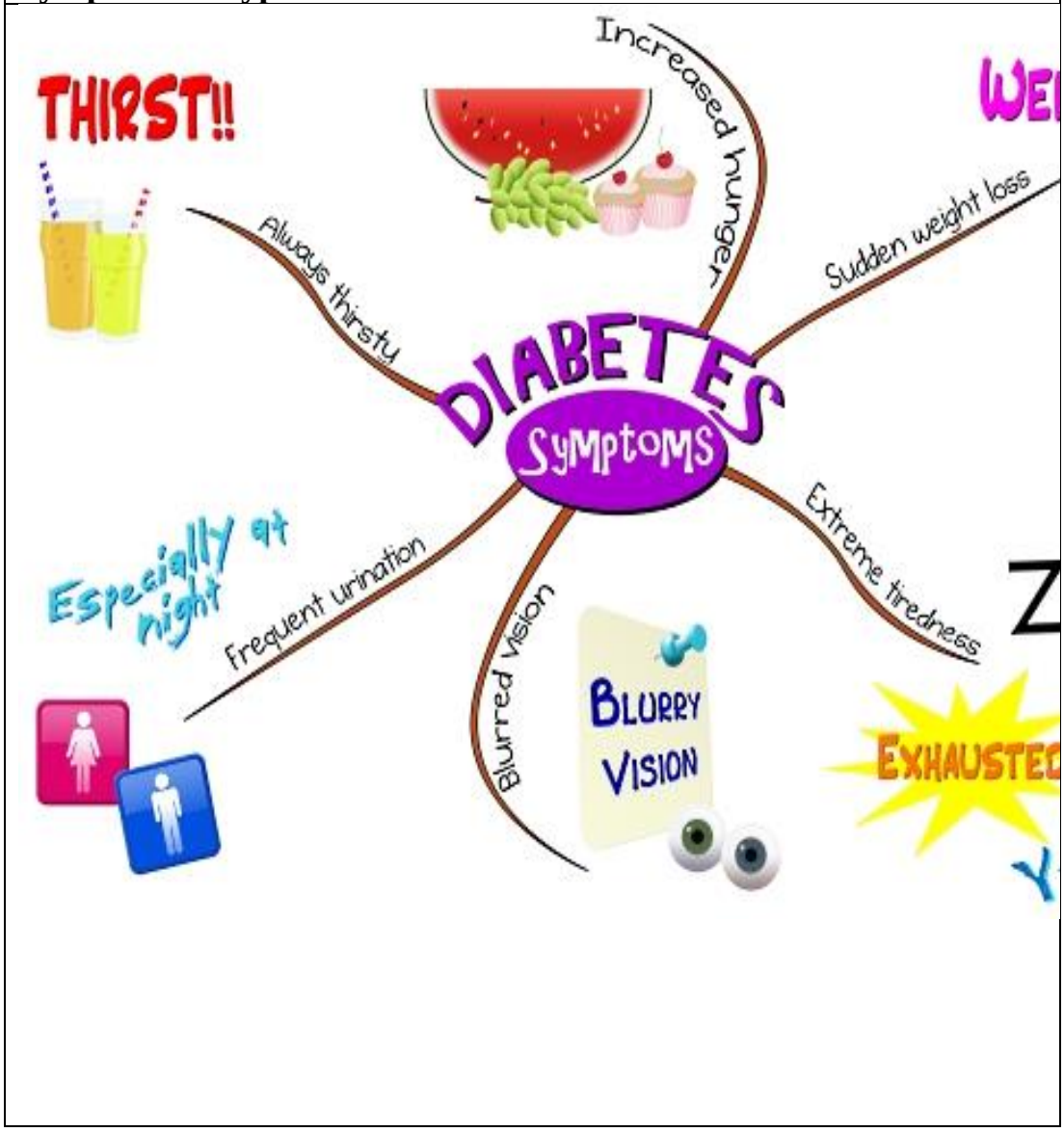
FLIP CHARTS USED IN THE TRAINING

FLIP CHATR NO. I SYMPTOMS OF TYPE 2 DIABETES

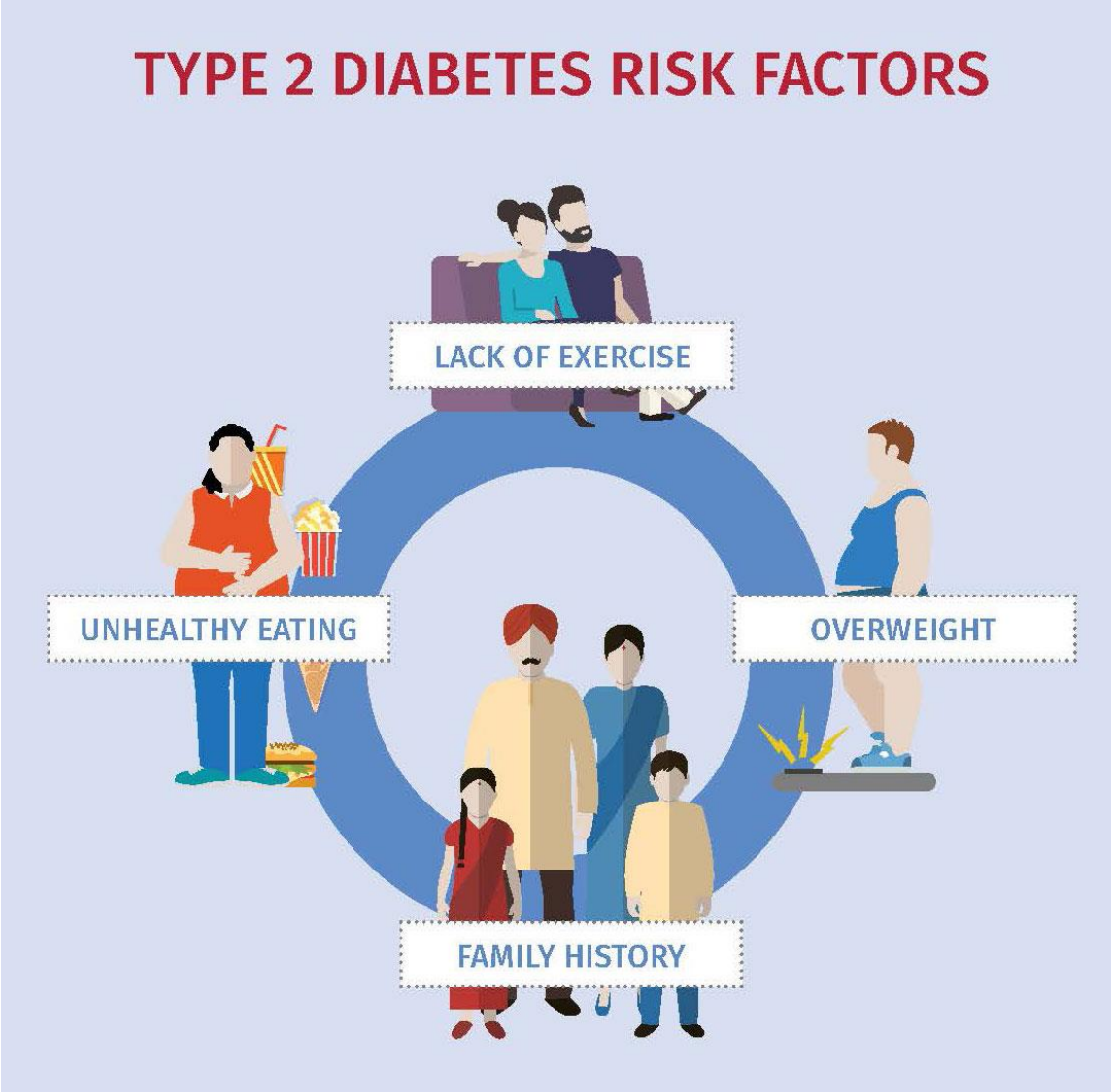
What do you see and learn from the figure below?

Symptoms of type 2 diabetes


Note: In case you have these symptoms your blood glucose is high, take charge.

FLIP CHART NO. 2: RISK FACTORs TO TYPE 2 DIABETES MELLITUS

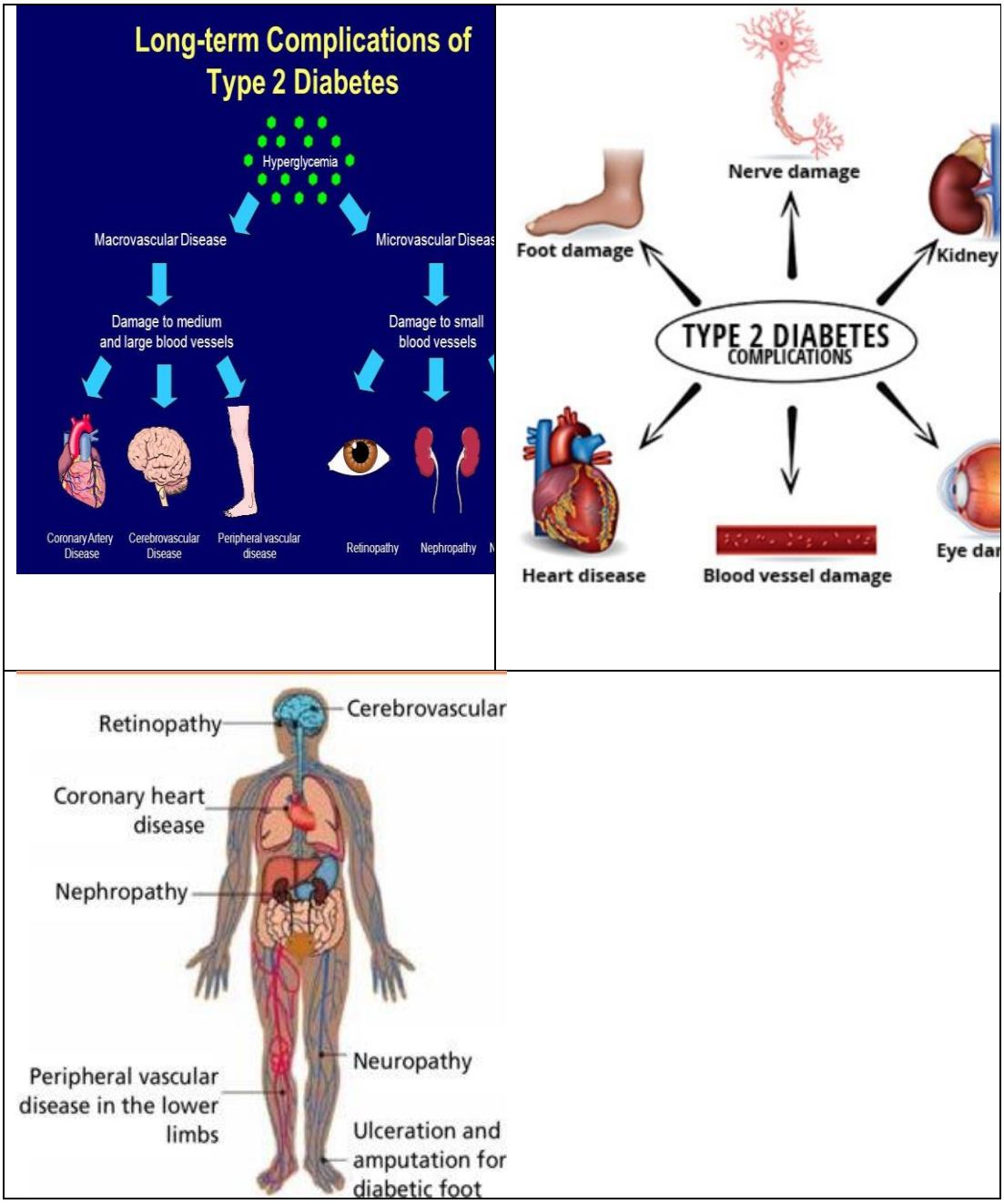
What do you see and learn from the diagram below?



NOTE: Avoid unhealthy eating, be active. This will help lose weight and avoid being overweight. Take charge.

FLIP CHART NO. 4 COMPLICATION OF TYPE 2 DIABETES

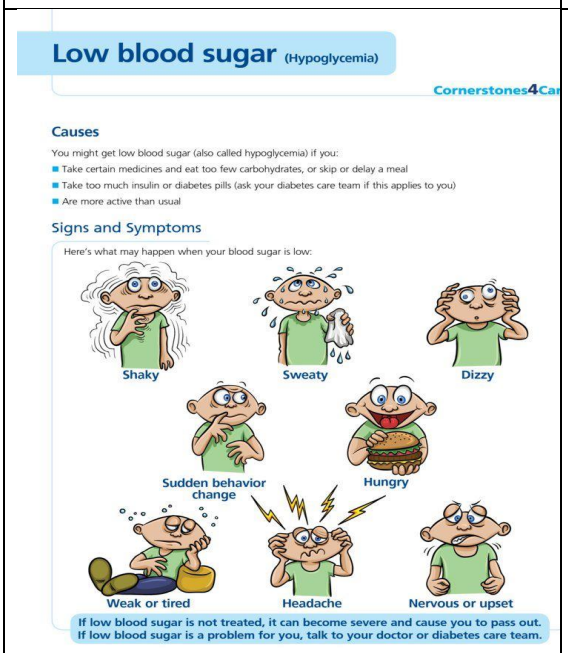
What do you see in the figure below?



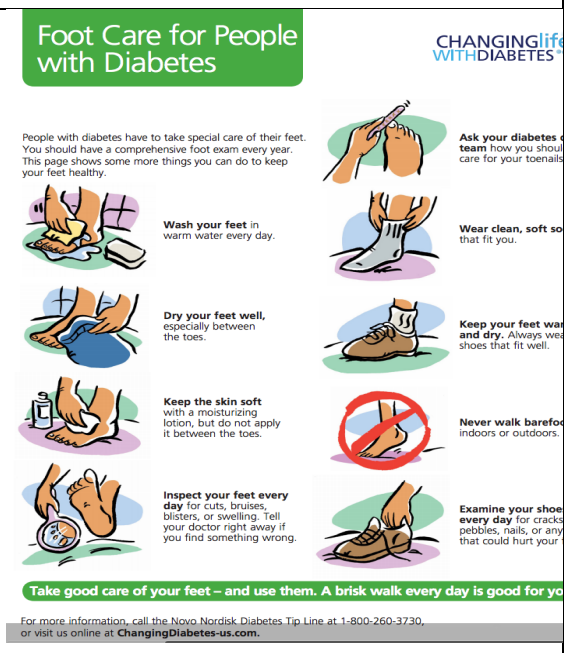
Note: If you type 2 diabetes is not managed, this what happen, it is sad, control your diabetes. Take charge

FLIP NO. 4 SYPTOM OF HYPOGLYCEMIA AND FOOT CARE PRINCIPLES

What do you see in figure below?



Take charge to avoid these symptoms through continue monitoring of your blood glucose



Care for your foot. It is key to type 2 diabetes management

FLIP CHART NO.5 IMPORTANCE OF FOOD VARIETY AND FOOD COMBINATION

What can you see in the diagram below?

RAW FOOD THAT CAN BE INCLUDED IN A SHOPING LIST (CEREALS, LEGUME)	INCLUDING DIFFERENT TYPE OF VARIETY OF VEGETABLES
	
DIFFERENT VARIETIES OF FOOD FROM FRUITS, VEGETABLES, NUTS AND MEAT GROUP	DIFFERENT VARIETIES OF FRUITS AND VEGETABLES
	
BOWL OF VEGETABLE SALAD: HAS A VARIETY OF VEGETABLES	PLATE OF FOOD VITH VARIETY OF FOODS :
	

FLIP CHART NO.6 CEREALS

What can you see in the diagram below?

Refined cereals **(avoid)**	Non refined cereals **(use: include in meals)**
   **Maize flour** **ugali**   **White rice** **White bread**	  **Wheat and wheat t Product (Whole meal bread)** **sorghum**   **Finger millet white millet**

ROOTS AND TUBERS	
  **Irish potatoes**   **Yams** **Cassavas**   **Arrow roots** **Sweet potatoes**	 **cooked Arrow roots** **Plantain**  **Green bananas**

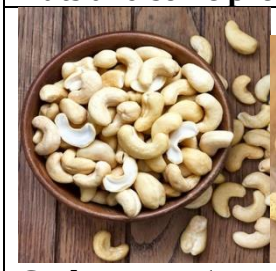
FLIP NO.7 LEGUMES

What can you see in the diagram below?

Legumes

Different types of legumes (pegeon peas, chick peas, split peas, different varrieties of beans

Nuts and some products



Cashew nuts (Roast) Peanuts (roast or fry)

Peanut butter Roasted nuts (can use for spread)

Seeds

Pumpkin seeds Chia seed (soak before use)

Sim sim seed (You can roast) **Sunflowere seedss**

FLIP NO. 8 VEGETABLES

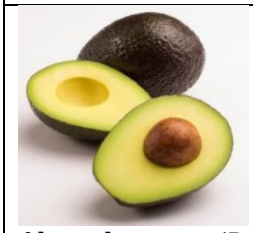
What do you see in the figure below?

<table>
<tr><td>Fresh vegetables</td><td></td></tr>
<tr><td> 
  </td><td> 
Fresh vegetables prepared to a salad
  
  </td></tr>
<tr><td>Carrots, cauliflower cabbage, brocolli, tomatoes, celery, capscum(red), Purple cabbage , onions</td><td>Green vegetables</td></tr>
</table>

FLIP NO.9 FRUITS

What can you see in the figure below?

You can use fruits like snacks and also can be taken in the morning

<table>
<tr>
<td> 
Apples (red and green)
 
 
Mangoes</td>
<td> 
Pomegranate (Puncia granatum
 
 
Pineapples</td>
<td> 
 
Passion fruits (yellow and purple varieties)
 
Watermelon (Citrullus lanatus)</td>
<td> 
 
Oranges
 
tree tomatoes (Solanum betaceum)</td>
</tr>
<tr>
<td> 
Alvacado (Persea americana)-</td>
<td> 
 
Ripe bananas(Musa acuminate (Strachy fruit-moderate)</td>
<td> 
Straw berries (Fragaria ananassa</td>
<td> 
 
Grapes</td>
</tr>
<tr>
<td colspan="4">Asorted fruits
 
  </td>
</tr>
</table>

FLIP CHART NO.10 FATS AND OILS

What do you see in the figure below?

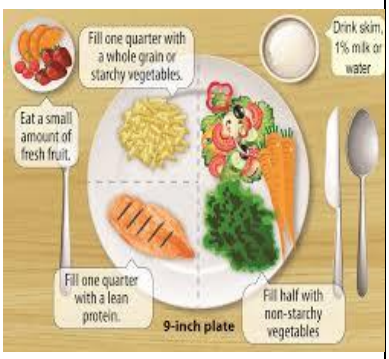
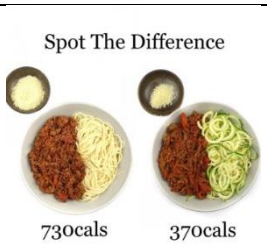
Palm oil and coconut oil from different companies	**Shortenings from different companies**

	
Corn oil, sunflower oil, olive oil, canola oil-BEST	**Margarines from different companies**
 **Corn oil sunflower oil canola oil**  **Olive oil (sun flower and palm oil)**	

NOTE: For food from this group choose sparingly

FLIP CHART NO.11 MEAL PLANNING TOOLS

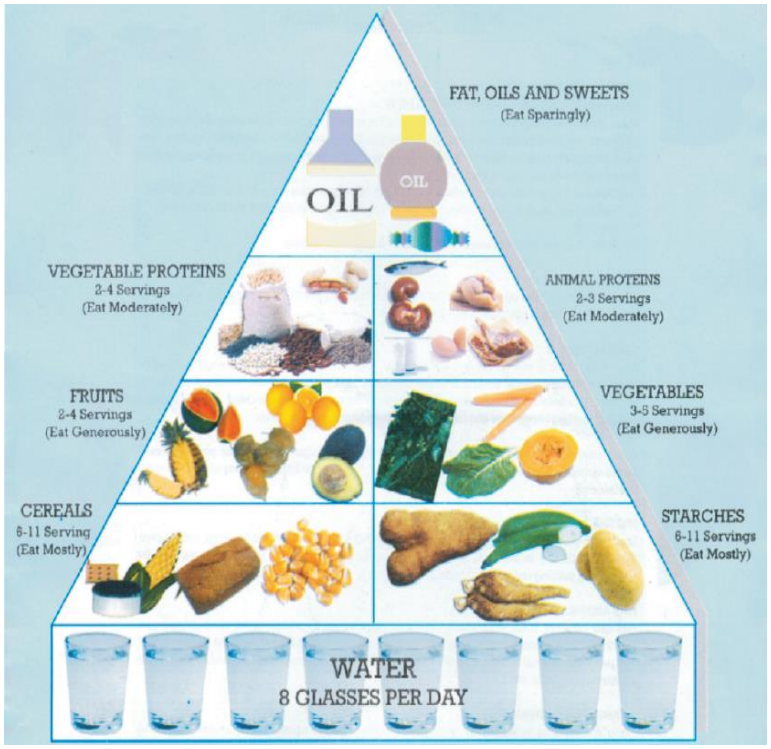
The hand plate model, the pyramid the signal system can be used
What can you see and learn from figure below?

Use of hand to estimate food portion	Using plate model in portion control
  	   **The plates show dif**  **ferent portion that can guide your planning**
	In all the diagrams Plate 2 better than plate 1

Choose a Rainbow of Colorful Food The more colorful the food, the more nutrients you're taking in. Choose some of our favorite colorful, healthy foods like

- **White — cauliflower, onions, garlic , fish** **Brown – legumes like beans, ground nuts**
- **Blue — blueberries, blackberries, eggplant** **Orange — carrots, sweet potatoes, apricots**
- **Green — broccoli, kale, spinach , kales** **Red— strawberries, raspberries, tomatoes, red peppers**

Flip chart No. 11 b: Food pyramid



1) Food guide for food pyramid(Maryniuk, 2006)

Food Guide for Food Pyramid

FOOD GROUP	NUMBER OF SERVINGS	EXAMPLES OF SERVINGS
Grains, bread and other starches	6-11	• 1 slice of bread • ½ cup of cooked rice/cereals • ¼ cup dry cereals • ½ cup pasta • 1 boiled/roasted green banana • A fist size of root tubers (arrow roots ,sweet potatoes, yams, cassava) • ½ cup boiled mashed Irish potatoes.
Vegetables	3-5	• ½ cup of cooked group B vegetables • 1 cup group A vegetables
Fruits	2-4	• 1 medium sized piece of fresh fruit. • 1 cup fresh fruit juice.
Milk and milk products	2-3	• 1 cup of skimmed/low fat milk. • ¾ cup plain yogurt.
Meat and meat substitutes	2-3	• 6-8 pieces of cooked meat (1 inch in size) • 1 drum stick or 1 chicken breast. • 1 egg • ½ cup of cooked pulses • ¼ cup of Omena
Fats and oils	Use sparingly	• 1 tea spoon margarine • 1 tea spoon oil or mayonnaise. • 1 table spoon peanut butter. • 1 tea spoon salad dressing

Signal system

Principles of Healthy Food Choices, Signal system			
Principles	**Green**	**Yellow**	**red**
Refined cereals and sugars	**Low**	**Moderate to high**	**High**
Saturated fat	**Low**	**Low**	**High**
Total fat	**Low**	**Moderate**	**High**

Glycemic index	**low**	**Moderate high**	**High GI**
Fiber	**High**	**Low**	**Negligible**
Cooking method	**Steaming, boiling, roasting, grilling, tandoor, dry heat, less fat in cooking**	**Pan fried, sautéed, stir fry; moderate amount of fat in cooking**	**Deep fried, extra butter, ghee added, rich sauce/dressing, rich in added sugar**
Processing	**Rich fiber, parboiled, hand pounded. Eat as permitted Moderate to high**	**Low fiber, refined, milled Moderation High**	**Low fiber processed, ready to eat Restrict**
How much to eat	**Eat as permitted**	**moderate**	**Restrict**

Key

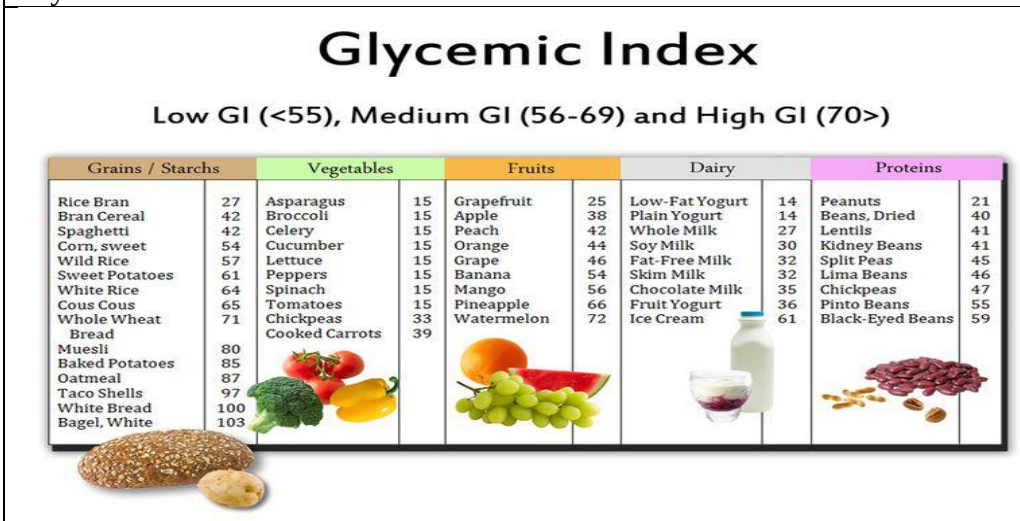
Green	Good signal you can use it "go for it'
Yellow	Moderate "Go slow"
Red	Restrict "Stop"

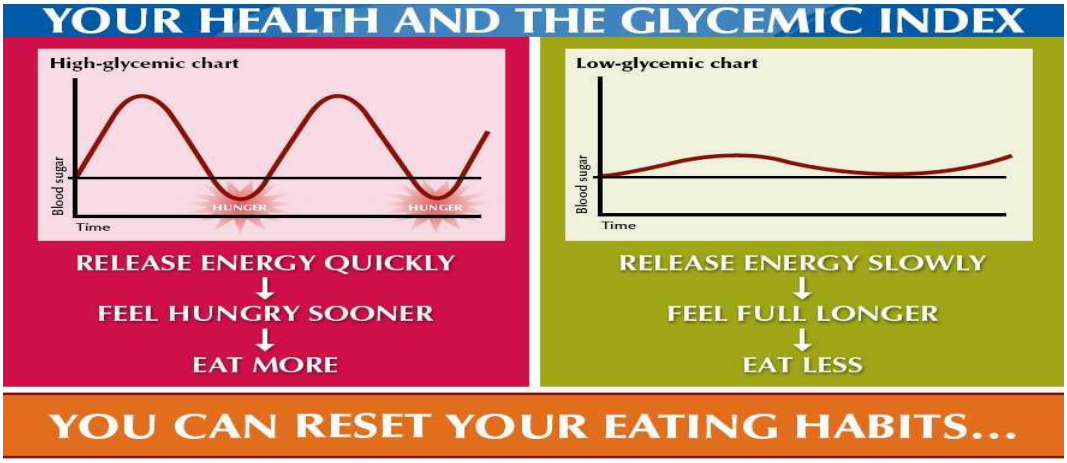
Figure below elaborate the signal system further

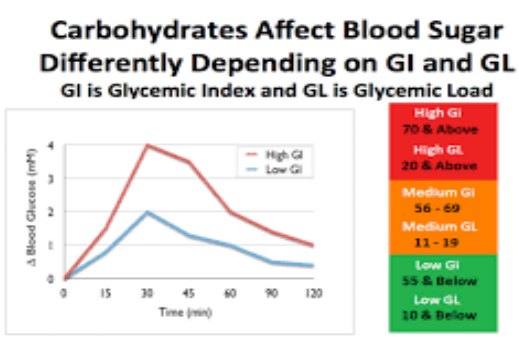
FLIP CHART 12: GLYCEMIC INDEX AND GLYCEMIC LOAD

What can you learn see and learn from the figure below?

Glycemic index of some food







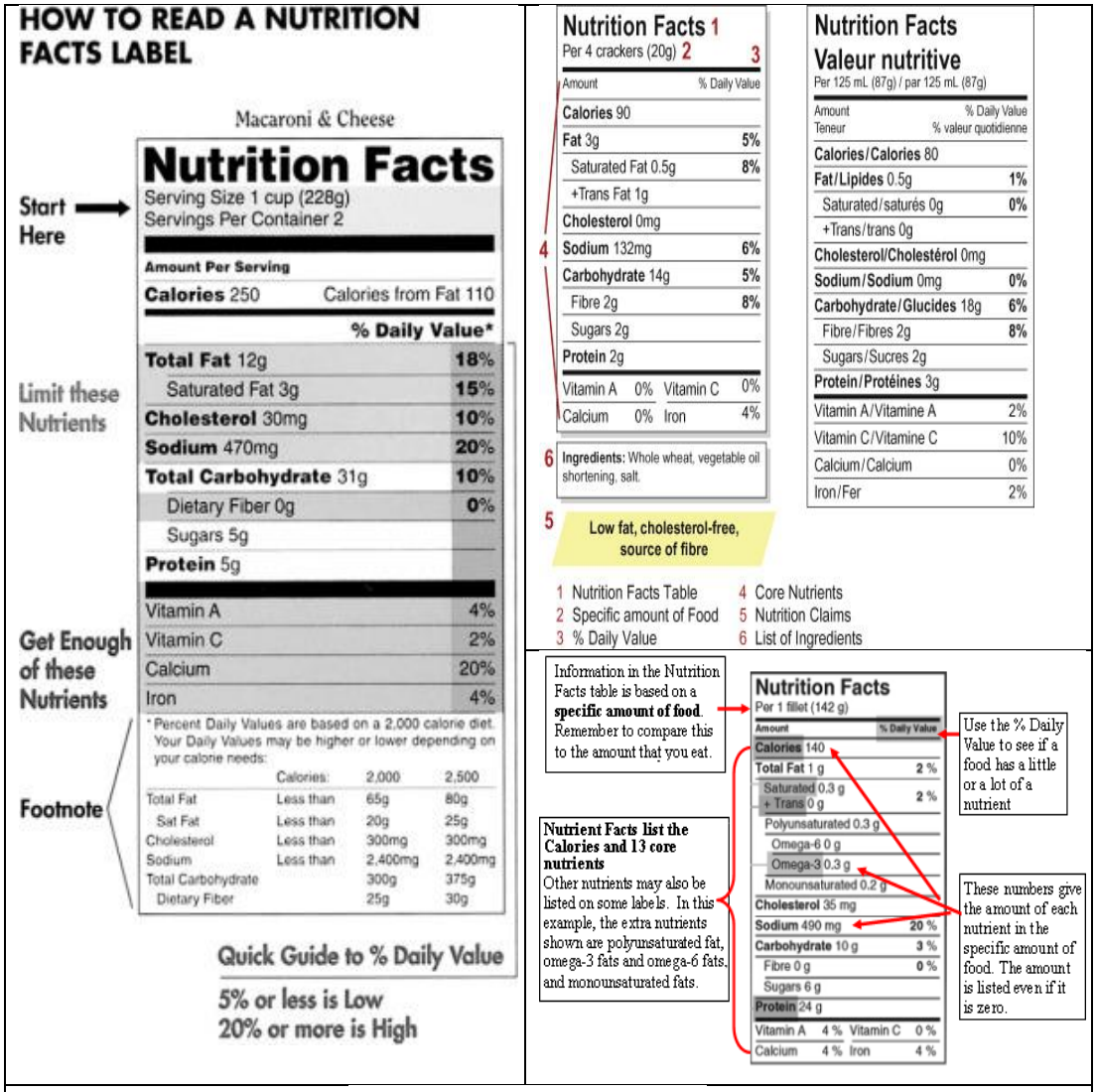
Glycemic load of different foods

LOW (GL 0-10)	MODERATE (GL 11-19)	HIGH (GL 20+)
Carrots (2)	Whole Wheat Pasta (13)	White Rice (27)
Apples (8)	Brown Rice (18)	White Pasta (23)
100% Bran Cereals (7)	Sweet Potato (12)	French Fries (22)
Lentils (5)	Rice Cakes (17)	Baked Potato (28)
Cashew Nuts (3)	Oatmeal (11)	Sweetened Fruit Juices (2

Note: choose food of low glycemic index and low glycemic load fo better blood glucose control

FLIP NO. 13: NUTRITION FACTS AND LABELS

How to interpret nutrition facts reading



Example foods in kenya with a nutrition label and facts

Note: Always read food labels in any food product you buy to know the nutrient contained in the food and energy. Tis will assist you in deciding the portion to include in your meal

FLIP CHART NO.14: PHYSICAL ACTIVITY

Stretching Exercise

Jogging

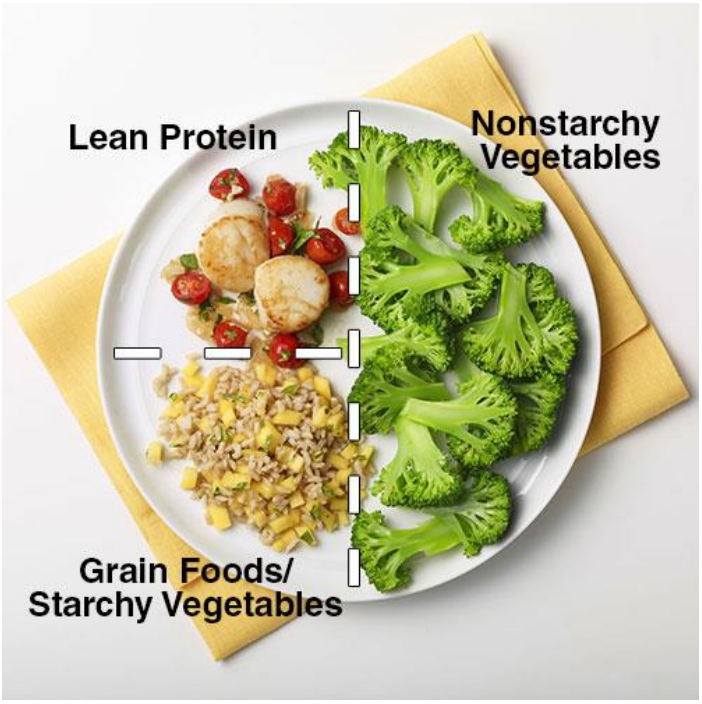
Hydrate your body well during Exercise

Aerobic exercise

FLIP CHART NO 15: COMMON KENYAN FOOD RECIPIES USED IN THE STUDY

 Mukimo (Irio; maize, pumpkin leaves ar mix) with beef stew and kachumabri (Tomatoes and Onions	 Chapati. Greem grams, dry beef stew wit tomatoes and kales
 Kales, rice and githeri (corn and beans)	 Pilau, fish and kachumbari(onions, tomatoes and capsicum)
 Ugali (African cornmeal mush), beef and vegetables (carrots and kales or Collard Greens)	 Githeri (Bean and corn)

Recommended plate and portion; adapted from ADA guidelines


Lean Protein
Nonstarchy Vegetables
Grain Foods/ Starchy Vegetables

Diabetes fliers given to the patients

What is diabetes

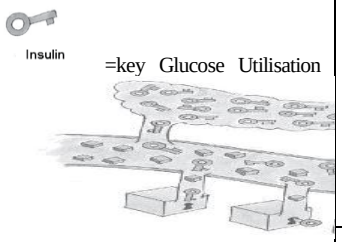
Diabetes is a disease in which your blood glucose in the blood is high (**hyperglycemia**) as a result of defects in insulin production, insulin action, or both

If **insulin** is not produced or after production it does not work properly, glucose level in blood increase and cannot get into the cell. This leads to diabetes

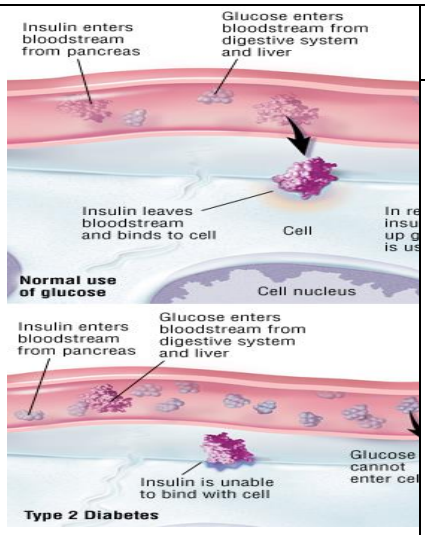
The glucose in the blood flows to the kidney and is excreted (removed) with urine and this makes you to feel thirsty

Glucose metabolism and Insulin action

- Glucose comes from food that we eat (Carbohydrates).
- Glucose is absorbed from the intestine to the blood.
- Insulin acts as a key (to help transport blood Glucose into the cells where it is used as energy by your body to perform its daily functions



=key Glucose Utilisation



What are symptoms of type 2 diabetes/hyperglycemia

- Feeling thirsty all the times
- Being extremely hungry
- Having an unexplained weight loss
- Increased fatigue - being tired all the time) Irritability -having unexplained anger)
- Blurred vision- not seeing well
- Slow healing of cuts and wounds
- Impotence-failure to sustain an erection Numbness, burning sensations ,pins and needles of the feet and hands

NB: a person can be living with diabetes without experiencing the symptoms, thus regular blood sugar testing is recommended

Types of diabetes (Two types)

Type 1 Diabetes

- In this type of diabetes the body does not produce insulin
- Insulin has to be provided
- Most found in children

Type 2 diabetes

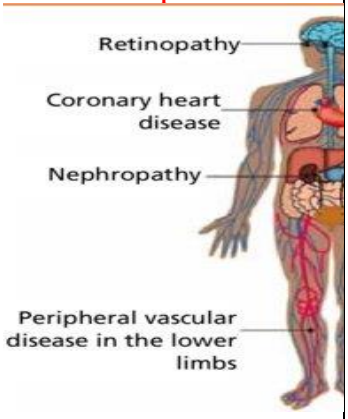
- In this type of diabetes produced insulin is not working properly **(insulin resistance)** or enough insulin is not produced or and or insulin is not produced at all.
- Drugs are given to improve on insulin function or insulin injection is used

Type 2 diabetes is associated with some risk factors like;

- Being overweight or obese- having extra weight
- Physical inactivty-failing to exercise or not being active
- Eating unhealth diet

Complications

If you don't manage your diabetes it will lead to other problem as shown.



Management for type 2 diabetes

Diabetes has no cure, but the **good news** is that it can be managed by

- Health Eating
- Physical Activity
- Drugs

Health eating

Healthy eating means;

Getting a wide variety of foods that are healthy each day to include in a meal. These foods includes, Vegetables, whole grains, fruits, nonfat dairy products, legumes ,lean meats, poultry, fish.

Principles of Healthy Food Choices, Signal system

Principles	Green	Yellow	red
Refined cereals and sugars	Low	Moderate to high	High
Saturated fat	Low	Low	High
Total fat	Low	Moderate	High
Glycemic index	low	Moderate high	High GI

- Spread/space your carbohydrates throughout the day; the amount of carbohydrate in your meals and snacks can make a big difference in your blood glucose level.
- You can use carbohydrate counting to monitor your carbohydrate intake in a day
- Carbohydrate counting helps you keep track of how much carbohydrate you are eating.
- The amount of carbohydrate to eat for each meal depends on things like how active you

Cereals legumes fruits vegetables milk meat and starch

Choose food high in fibre like fruits and vegetables and whole grains

- Eat meals and snacks at regular times every day; the timing of your meals can affect the level of sugar in your blood. If you wait too long to eat, your sugar level can be too low. If you eat meals too close together, or snack throughout the day, your sugar level can be too high.)
- Eat plenty of fruit and vegetables; include vegetables in your lunch and supper and eat fruit throughout the day;
  Note: You can eat a fruit in the morning or **use fruit as snack**

Fiber	High	Low	Negligible
Cooking method	Steaming, boiling, roasting, grilling, tandoor, dry heat, less fat in cooking	Pan fried, sautéed, stir fry; moderate amount of fat in cooking	Deep fried, extra butter, ghee added, rich sauce/dressing, rich in added sugar
Processing	Rich fiber, parboiled, hand pounded. Eat as permitted Moderate to high	Low fiber, refined, milled Moderation High	Low fiber processed, ready to eat Restrict
How much to eat	Eat as permitted	moderate	Restrict
Green	Good signal you can use it "go for it'		
Yellow	Moderate "Go slow"		
Red	Restrict "Stop"		

Healthy way of including food in a meal

- Use less added fat ; High-fat foods include: butter, cream, whole milk, cooking oil, coconut oil, and lard. If you have diabetes, any extra weight can put you at risk for heart disease, so limit fat by removing chiken skin, trimming of fat from meat and remove cream from milk
- Limit sugar, and salt.
- Eat about the same amount of food each day and watch your portion; The amount of food you eat will affect the level of sugar in your blood. Eat small amounts of food
- Do not skip meals.
- If you need to lose weight, cut down on your portion sizes

are and what medicines you takes

Food rich in carbohydrates

- Grains like rice, oatmeal, and barley
- Grain-based foods like bread, cereal, pasta, and crackers
- Starchy vegetables like potatoes, peas, and corn
- Fruit and juice
- Milk and yogurt
- Dried beans like pinto beans and soy products like veggie burgers

Sweets and snack foods like sodas, juice drinks, cake, cookies, candy, and chips – Avoid these completely

How much to Eat:

You can use a plate or your hand to estimate what to eat or use food pyramid

Use of hand to estimate portion size

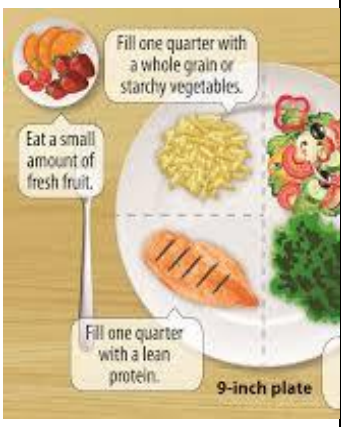
Palm = 1 portion of protein (meat/fish/poultry)
Closed fist = 1 portion of carbohydrates (grains & starches)
Thumb = 1 portion (tablespoon) of fat-heavy foods (peanut butter)
Cupped hands = 1 portion of fruit or vegetables

Plate model: using plate to estimate size

Food Pyramid: This is a guide you can use while selecting food and serving to include in a meal

Physical activity: being physically active

Did you know that exercise have unique benefits? One of the greatest benefits of exercise is that it can help prevent diabetes or it can help you manage diabetes

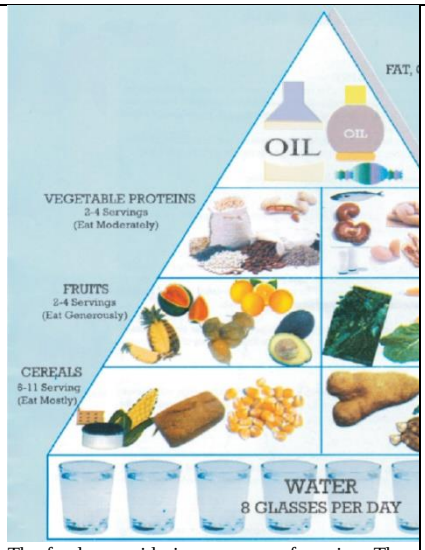


Vegetable can either be cooked or you can use raw vegetable in form of salad (bowl of salad)

Note: choosing food to include in your diet is not expensive

You can

- plant vegetables, fruits, cereals, root tubers and legumes in your garden
- use fruits and vegetable on season
- buy cereals and legumes during harvest time and store them well to prevent rodent and weevil attack
- mill your maize and wheat for flour
- Plan your meals for the week and make a grocery list. Only buy what you're sure you will use, and check out what you already have in your cupboards first.
- replace meat once or twice a week with beans and other legumes
- use whole grain cereals
- take plenty of water : at least eight glasses as shown in the pyramid

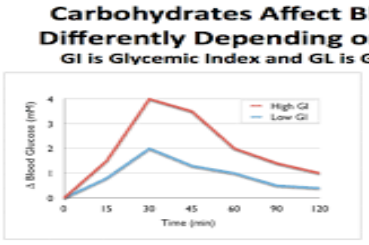


The food pyramid gives a range of serving. The exact number of serving depends in your diabetes goal and the calories and nutrient need your body requires.

NOTE: glycemic index (GI) and glycemic load (GL) of food is key to blood sugar control

GI is a measure of the effects of carbohydrates on blood glucose levels. Carbohydrates that break down during digestion releasing glucose rapidly into the blood stream have a high GI; carbohydrates that break down slowly, releasing glucose gradually into the bloodstream, have a low GI.

GL_{Food} = (GI_{Food} x amount (g) of available $carbohydrate_{Food}$ per serving)/100



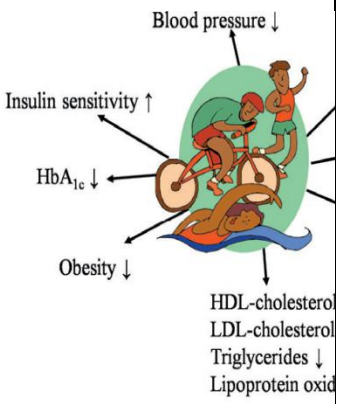
You can start by being more active every day. Get up and move as often as possible. Mix it up! Try walking, digging, dancing a bit, moving around the compound, cycling, jogging, watering plants or any variety of activities that you enjoy.

At least make sure you exercise for 15-30minutes continuous for at least 3-5days a week for overall benefit

Being active every day help

- keep your blood glucose under control
- to make insulin work properly
- lose weight
- lower cholesterol
- lower blood pressure

.

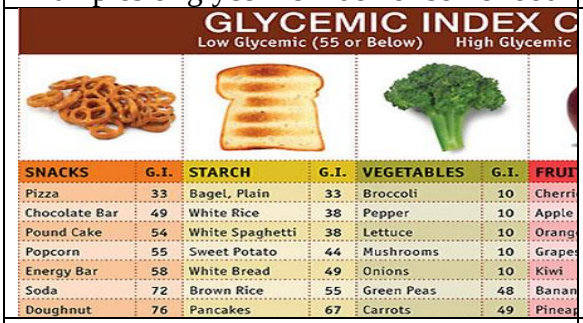


TAKE HOME MESSAGE

DIABETES IS MANAGEABLE, EAT HEALTH, BE ACTIVE
IF ON MEDICATION TAKE AS RECOMMENDED AND MONITOR YOUR BLOOD GLUCOSE REGURALY.

Additional fliers

Examples of glycemic index of some food



SNACKS	G.I.	STARCH	G.I.	VEGETABLES	G.I.	FRUI
Pizza	33	Bagel, Plain	33	Broccoli	10	Cherri
Chocolate Bar	49	White Rice	38	Pepper	10	Apple
Pound Cake	54	White Spaghetti	38	Lettuce	10	Orang
Popcorn	55	Sweet Potato	44	Mushrooms	10	Grapes
Energy Bar	58	White Bread	49	Onions	10	Kiwi
Soda	72	Brown Rice	55	Green Peas	48	Banan
Doughnut	76	Pancakes	67	Carrots	49	Pineap

Example of glycemic load of some food

LOW (GL 0-10)	MODERATE (GL 11-19)
Carrots (2)	Whole Wheat Pasta (13)
Apples (8)	Brown Rice (18)
100% Bran Cereals (7)	Sweet Potato (12)
Lentils (5)	Rice Cakes (17)
Cashew Nuts (3)	Oatmeal (11)

Symptoms of hypoglycemia(Low blood sugar levels): Dangerous avoid it

Foot care : Take care of your foot as elaborated below

Low blood sugar (Hypoglycemia)

Causes

You might get low blood sugar (also called hypoglycemia) if you:

- Take certain medicines and eat too few carbohydrates, or skip or delay a meal
- Take too much insulin or diabetes pills (ask your diabetes care team if this applies
- Are more active than usual

Signs and Symptoms

Here's what may happen when your blood sugar is low:

If low blood sugar is not treated, it can become severe and c
If low blood sugar is a problem for you, talk to your doctor o

Foot Care for People with Diabetes

People with diabetes have to take special care of their feet. You should have a comprehensive foot exam every year. This page shows some more things you can do to keep your feet healthy.

Wash your feet in warm water every day.

Dry your feet well, especially between the toes.

Keep the skin soft with a moisturizing lotion, but do not apply it between the toes.

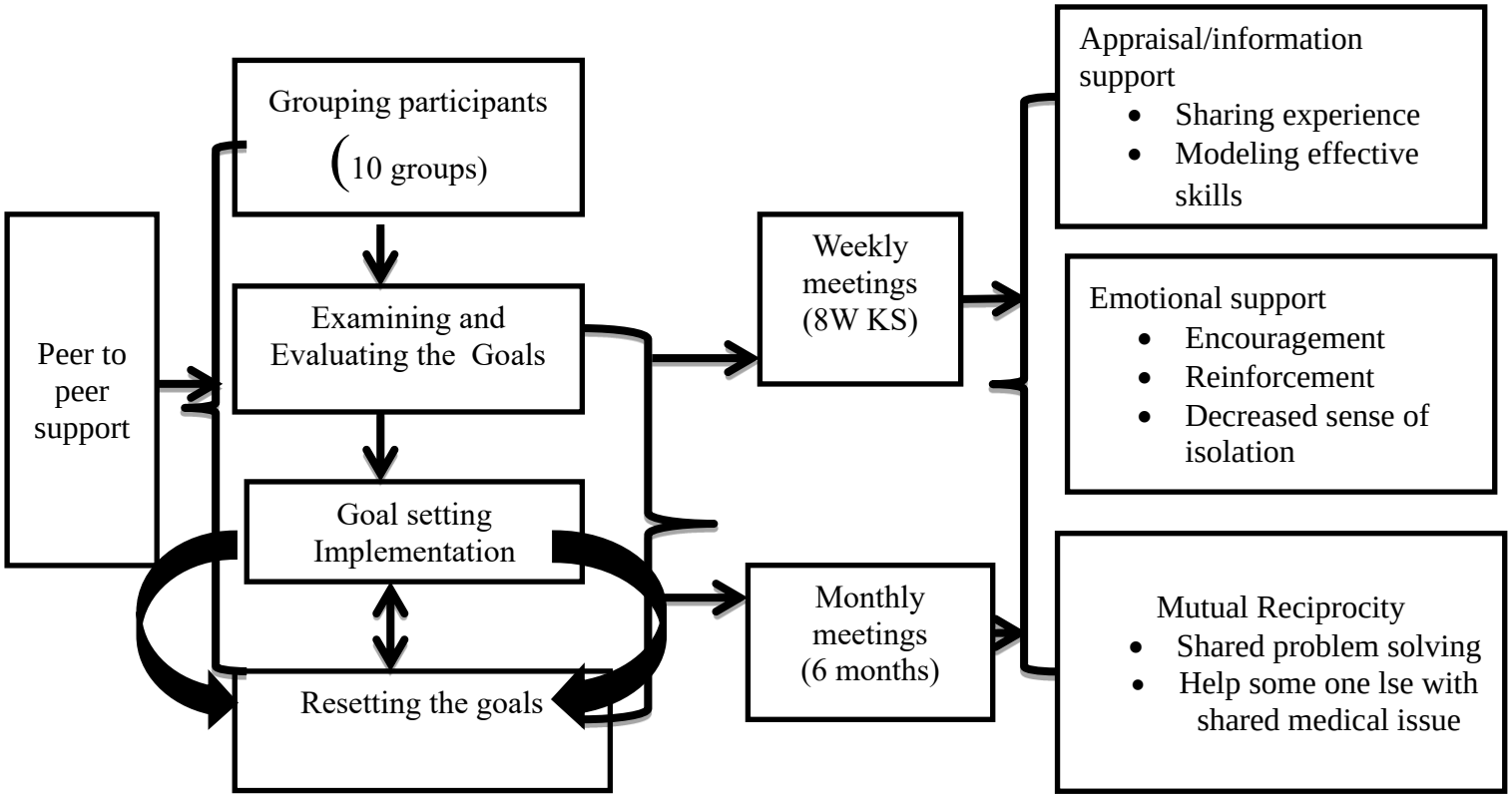
Inspect your feet every day for cuts, bruises, blisters, or swelling. Tell your doctor right away if you find something wrong.

Take good care of your feet – and use them. A brisk walk e

For more information, call the Novo Nordisk Diabetes Tip Line at 1-800-260-373
or visit us online at **ChangingDiabetes-us.com.**

Appendix XIII: Peer to Peer Support Model Used in the Study

Adapted from De- Vries (2014) and Heisler (2010).



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Heisler, M. (2010). Different models to mobilize peer support to improve diabetes self-management and clinical outcomes: evidence, logistics, evaluation considerations and needs for future research. *Family Practice*, *27 Suppl 1*(March 2009), 23–32. https://doi.org/10.1093/fampra/cmp003