UNIVERSITY OF GHANA

MEDITERRANEAN DIET SCORE AND GLYCAEMIC CONTROL OF PATIENTS WITH TYPE 2 DIABETES AT KORLE-BU TEACHING HOSPITAL

BY

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DECLARATION

I declare that this thesis is a result of an independent research undertaken by Cassandra Opoku Junior under the supervision of Dr. Rebecca Steele-Dadzie and Dr. Allen Steele-Dadzie towards the award of Master of Science Degree in Dietetics at the Department of Nutrition and Dietetics, School of Biomedical and Allied Health Sciences, College of Health Sciences, University of Ghana.

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ABSTRACT

Background: Over the past few decades, there has been an increase in the incidence of type 2 diabetes mellitus globally, with an increase in mortality. The most effective ways of controlling diabetes mellitus are through medication and lifestyle modifications primarily diet and physical activity. Evidence suggests that the Mediterranean diet is effective in the management of chronic diseases including diabetes mellitus. Some studies have investigated the adherence to this diet among diabetes patients and its effect on their glycaemic control with positive results. Most of these studies have, however, been conducted outside Ghana with scanty information on the adherence to the Mediterranean diet by diabetes patients in Ghana and its effect on their glycaemic control.

Aim: To determine the Mediterranean diet score and its effect on the glycaemic control among people with diabetes at the Korle-Bu Teaching Hospital.

Methods: The study design was cross sectional. A total of 100 type 2 diabetes patients were recruited from the National Diabetes Management and Research Centre (Diabetes Clinic) of the Korle-Bu Teaching Hospital. A validated structured questionnaire was used to obtain demographic and socioeconomic information of the participants. Anthropometric indices of participants were determined. Adherence to Mediterranean diet was estimated using the Mediterranean Diet Score Tool. Glycaemic control was determined using glycated hemoglobin (HbA1c). Descriptive statistics, means and standard deviation were used to analyze continuous variables (age, HbAIc, waist circumference, hip circumference, waist-to-hip circumference). Proportions were used to analyze adherence to Mediterranean diet. Association between Mediterranean diet score and HbA1c was determined using Pearson correlation. A p value ≤ 0.05 was considered statistically significant.

Results: Out of the 100 participants recruited for the study, seventy-three percent (73%) were females and 23 (23%) were males. The mean age of the participants was 58.4 ± 10.6 years. About 40% of the study participants were obese, 54% had low physical activity and 58% had moderate Mediterranean diet score. The mean HbA1c of study participants was 7.4 ± 1.7%. There was no significant differences in the mean nutrient intakes of study participant (p = 0.910, 0.164, 0.903, 0.140, 0.886, 0.246, 0.665 for energy, carbohydrate, protein, fat, fibre, magnesium and iron respectively). There was no significant relationship between Mediterranean diet score and glycaemic control (r2 = 0.139; p = 0.168).

Conclusions: Mediterranean diet score of type 2 diabetes patients was not found to be significantly associated with their glycaemic control in the study.

DEDICATION

I dedicate this work to God Almighty for His love and mercy and guiding me through this period of study. I also dedicate it to Mr. Edmund Opoku, Doris Nkrumah, Cynthia Opoku, Mercy Opoku, Michael Opoku and Cassandra Opoku Senior for their care, love, prayers and encouragement throughout my education.

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LIST OF ABBREVIATIONS

ABSI	A Body Shape Index
ADA	American Diabetes Association
BMI	Body Mass Index
CHO	Carbohydrate
EPIC	European Prospective Investigation into Cancer and Nutrition
HBAIc	Glycated Haemoglobin
HHS	Hyperglycemic Hyperosmolar State
IDF	International Diabetes Federation
MED	Mediterranean
NDMRC	National Diabetes Management and Research Centre
NCDCP	Non-communicable Disease Control Programme
OPD	Out-patient Department
WC	Waist Circumference
WHO	World Health Organization
WHR	Waist-to-Hip Ratio
WHtR	Waist-to-Height ratio

CHAPTER ONE

1.0 INTRODUCTION

1.1 BACKGROUND

Type 2 diabetes mellitus is a major global health issue and one of the major causes of morbidity and mortality. Diabetes mellitus is a chronic disease that occurs when the pancreas is no longer able to make insulin and when the body cannot make good use of the insulin it produces (International Diabetes Federation (IDF), 2018).

The World Health Organization stated that 9% of the world's population had diabetes in 2014 and over 90% of them were type 2 diabetes patients (World Health Organization, 2014). In 2017, IDF estimated 15.5 million of adults in sub-Saharan Africa (prevalence of 6%) lived with diabetes. In Ghana, there were 518,400 cases of diabetes in 2017, a prevalence rate of 3.6%, (IDF, 2017). Diabetes poses serious life-threatening health problems for people living with the disease which results in reduced quality of life, high cost of medical care and increased mortality.

The growing incidence of diabetes worldwide has been highly associated with the westernized dietary patterns, lack of physical activity, and increasing rates of obesity and metabolic syndrome (Sleiman, AI-Badri & Azar, 2015). Certain diets have however been associated with reduced incidence as well as improved outcomes of diabetes care (Satija, *et al.*, 2016). Among these is the Mediterranean diet.

The term Mediterranean diet was originally created by Ancel Keys in the 1960s (Keys, 1995). Mediterranean diet was created when Keys observed the dietary practices embraced by the population residing near the Mediterranean Sea and found among them a lower incidence of chronic diseases as well as higher life expectancy when compared to other regions of the

world (Keys, 1995). Mediterranean dietary pattern includes unprocessed plant foods (fruits, vegetables, legumes, nuts, whole cereals and olive oil) with moderate consumption of wine and fish and infrequent consumption of red meat, animal fats and processed foods.

In adhering to a Mediterranean diet, one has to take into account the geographical location, ethnicity, religious, cultural, and economic background of the population. Therefore, many indices were developed to describe the traditional Mediterranean diet. One of these indices was designed by Trichopoulo *et al*. (2003). In this scoring system, individuals were given points depending on their daily intake of the separate components of the Mediterranean diet with a score range of 0-9 (Trichopoulou *et al*., 2003). Also, there was another scoring system designed by Panagiotakos *et al*. (2005) which assessed the monthly intake of Mediterranean food rather than the daily one, with a score range of 0–55 (Panagiotakos *et al.,* 2005). Mediterranean diet score was determined by conformity to the diet. A higher score corresponds to higher conformity to the Mediterranean dietary pattern.

Over the past few years, there has been a great effort to study the relationship between dietary patterns and human health. Conformity to a healthy life style is strongly associated with reduction in the risk of chronic illnesses (Rim *et al.,* 2004). Conformity to Mediterranean diet was associated with a 52% reduction of diabetes mellitus incidence (Salas-Salvado *et al.,* 2011). Several studies suggest that Mediterranean diet contains antioxidant compounds, bioactive elements as well as anti-inflammatory effects and low glycaemic index which help to reduce the risk of chronic diseases such as cardiovascular disease, type 2 diabetes, cancers and obesity while meeting individual nutritional requirements and maintaining a healthy body weight (Estruch *et al*., 2016; Grosso *et al*., 2017; Toledo *et al.,* 2015).

Glycaemic control among type 2 diabetes patients is generally poor even among those treated in the hospitals. A study conducted by Titty (2010) at Tamale Teaching Hospital found that

majority (60%) of the patients had poor glycaemic control. According to Tengey (2012) in a study carried out at Atibie Government Hospital, poor glycaemic control was as a result of poor family support, low income level and high density lipoprotein and it was recommended that HbA1c assay equipment and reagents should be provided to measure glycaemic control among patients.

1.2 PROBLEM STATEMENT

The prevalence of type 2 diabetes in Ghana is high and increasing at an alarming rate (Danquah *et al.*, 2012). This increasing burden is associated with high morbidity and adverse socio-economic implications. The major complications of diabetes results from poorly controlled diabetes. Dietary practices contribute significantly to poor glycaemic control. Majority of Ghanaians over the years have shifted from traditional eating pattern to the westernized diets and this can have a negative effect on their glycaemic control. The Mediterranean diet has been documented to decrease the incidence of diabetes and it is also effective in glycaemic control among diabetes patients. Although most of the components of the Mediterranean diet are found in Ghanaian diets, there is limited information on how closely the Ghanaian diet conforms to the Mediterranean diet. In addition, the effect of a Ghanaian diet closely conforming to the Mediterranean diet on glycaemic control among diabetes patients in Ghana remains to be investigated. These gaps have necessitated this study.

1.3 JUSTIFICATION

The Mediterranean diet score if found useful in the Ghanaian context will provide a quick but effective way of assessing the diet of diabetes patients. Determining the Mediterranean diet score of people with diabetes will provide additional information about the dietary habits of these patients. Knowledge of any association between Mediterranean diet score and

glycaemic control obtained from this study may help in the counseling and planning of the diet of people with diabetes to optimize outcomes of management.

1.4 AIM

To determine the Mediterranean diet score and its association with their glycaemic control in people with diabetes at the National Diabetes Management and Research Centre, Korle-Bu.

1.5 SPECIFIC OBJECTIVES

The specific objectives are:

1. To determine the types and estimated amount of foods consumed in a week by patients using the quantitative food frequency questionnaire.
2. To estimate their Mediterranean diet score using the Mediterranean diet score tool.
3. To determine the glycaemic control of diabetes patients using HbA1c.
4. To determine the correlation between diabetes patients' Mediterranean diet score and their glycaemic control.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 THE BURDEN OF DIABETES MELLITUS

The prevalence of diabetes mellitus poses a major global health threat. Globally, the sum of people suffering from diabetes mellitus quadrupled between 1980 and 2014 (Worldwide trend in diabetes, 2016). The International Diabetes Federation (IDF) estimated that one in eleven adults aged 20–79 years (415 million adults) had diabetes mellitus in 2015 (IDF, 2015), but this estimate is projected to rise to 642 million by 2040, and the largest increases will come from the regions experiencing economic transitions from low-income to middle-income levels (IDF, 2015). Also between 2010 and 2030, it has been predicted that there will be a 20% increase in the number of adults with diabetes mellitus in developed countries and a 69% increase in developing countries (Shaw *et al.*, 2010). Despite scantiness of regional data in Africa, IDF estimated a regional prevalence of 2.1–6.7% in sub-Saharan Africa (IDF, 2015). Out-patient Department (OPD) of the Korle-Bu Teaching Hospital recorded that diabetes mellitus was among the top three non-communicable diseases with a frequency of three thousand, one hundred and seventy eight (3178) cases (Korle-Bu Annual report, 2016). The rising epidemic of diabetes mellitus is of multiple reasons. These reasons include; population ageing, economic development, urbanization, unhealthy eating habits and sedentary lifestyles. Over 90% of diabetes mellitus cases are type 2 (Schernthaner et al., 2017).

Diabetes mellitus is also associated with some economic cost. These include direct, indirect (unplanned) and intangible (immaterial) costs. The direct cost includes cost of treatment. Amon (2016) also stated that the direct cost is made up of two components, namely; medical and non-medical cost. The medical cost includes expenses on medical products and services

like consultation, drugs, hospitalization and other treatments whiles the non-medical cost includes cost of visits to the health facilities (e.g. transportation), diet and other survival expenses. Indirect costs include loss of wages due to diabetes and its associated complications. Patients living with diabetes, especially those with complications also suffer indirect costs in the form of output losses due to patient incapacity, sick leave and time family members' sacrifice by escorting patients when searching for care among others. Intangible costs include physical and psychological pains, stress, anxiety and reduced quality of life (Brown et al., 2014). The nature of life of people suffering from diabetes is reduced through pain and suffering they experience The global economic cost of diabetes in 2014 was estimated to be US$612 billion (IDF, 2016). Kumi-Ampofo (2015), reported that financial and non- financial household cost of diabetes mellitus in Ghana account for over two- thirds of household's income which is a serious issue.

2.2 PATHOPHYSIOLOGY OF DIABETES MELLITUS

Diabetes mellitus is a group of metabolic disorders whereby there is chronic high blood sugar levels (WHO, 2014). It is a common condition in which the metabolism of glucose in the body is impaired due to insulin deficiency and/or insulin resistance. Insulin is the hormone accountable for regulating up take of glucose from blood into certain body cells (muscle cells and adipose tissue). Insufficiency of insulin or insensitivity of insulin receptors underlies the pathogenesis of diabetes mellitus play important role in diabetes mellitus (ADA, 2014).

Glucose is obtained from the body from three main sources which are intestinal absorption of glucose, breakdown of glycogen and production of glucose from non-carbohydrate substrates. Insulin is secreted by beta cells of the islets of Langerhans found in the pancreas. If insulin secretion is insufficient or defective or insulin receptors are resistant or insensitive to insulin the glucose will not be absorbed by the cells and therefore cannot be stored in the liver and

muscles. This results in hyperglycaemia, hence diabetes mellitus. When glucose remains high in the blood for a long period, it causes the concentration of the glucose in the blood to be higher than that of the kidneys and therefore cause the kidneys to remove it into urine (glycosuria) (Bays, 2009). This increases the osmotic pressure of the urine and impedes reabsorption of water by the kidneys resulting in increased urine production (polyuria) and increased fluid loss. The volume of blood lost will be replaced osmotically from water held in blood cells and other body compartments causing dehydration and increased thirst (Shoback & Gardner, 2011).

Diabetes and its complications are associated with acute and long-term harm and destruction of various organ systems (Chawla *et al.,* 2016). Some of the acute complications include hypoglycaemia, hyperglycaemic crisis, diabetes ketoacidosis and hyperglycaemic hyperosmolar state. The long term complications include diabetic retinopathy which may lead to adult-onset blindness, diabetic nephropathy, diabetic neuropathy causing kidney failure, among others (Baynes, 2015).

According to Ahrens and Pigeot (2014), numerous risk factors other than overweight are associated with type 2 diabetes. These factors include how fat is distributed in the body, lifestyle-related factors and food or nutritional factors. McNaughton et al. (2008) found that eating pattern that is linked with insulin resistance can predispose an individual to type 2 diabetes after adjusting for a range of confounding variables. McNaughton et al. (2008) study therefore increases to the substantiation that dietary patterns are an important risk factor for type 2 diabetes. Recently, an analysis from the European Prospective Investigation into Cancer and Nutrition (EPIC)-Norfolk study revealed that larger total dietary multiplicity was linked with 30% lower risk of developing type 2 diabetes after comparing diets of the five major food groups which were dairy products, fruits, vegetables, grain/cereal products, and

protein (meat and alternatives) with three or fewer food groups (Conklin *et al*., 2016). Several studies have looked the usual food patterns in different populations (US, European and Asian populaces) and compared their relationship with the progression of diabetes mellitus (Esposito *et al*., 2010; Bauer *et al.,* 2013; Malik & Hu, 2012; Erber et al., 2010). Even though the dietary patterns identified in the various studies were inhabitants' specific there were important similarities between the studies. Majority of the studies identified a healthy dietary pattern which was described by a high intake of healthy foods such as complex carbohydrates (unrefined carbohydrate), fish, and poultry and was associated with a reduced risk of type 2 diabetes. Unhealthy patterns which were described by a high intake of foods such as refined, processed and fatty foods were related to a higher risk of type 2 diabetes.

This nutrition evolution is characterized by a change in disease problem from under-nutrition to over-nutrition associated with chronic diseases. The main factors of nutrition evolution include financial growth, urbanization and changes in dietary patterns from traditional diets which constituted complex carbohydrate and fibre to foods high in fat and sweeteners (Kearney, 2010). This factors together with increased sedentary lifestyle leads to obesity and associated chronic diseases (Ng & Popkin, 2012: Popkin, 1994).

2.3 GENERAL MANAGEMENT OF TYPE 2 DIABETES

Management of type 2 diabetes requires both pharmacotherapy and non-pharmacotherapy. Pharmacotherapy involves insulin and oral hypoglycaemic agents whiles non-pharmacotherapy involves diet and exercise. According to Asif (2014), the pharmacological treatment helps by lowering blood glucose whereas the non-pharmacological treatment (physical activity) helps by enabling glucose entry into the cells thereby lowering blood glucose levels. Schwingshackl *et al*. (2014) reported that different exercise trainings help

with glycaemic control in people with type 2 diabetes and combining both aerobic and resistance exercise was found to be the most beneficial.

Physical activity has been found to help people with diabetes attain a diversity of objectives. These include increased cardiorespiratory fitness, increased vigor, improved glycaemic control, decreased insulin resistance, improved lipid profile and blood pressure reduction and maintenance (Chudyk & Petrella, 2011; Colberg *et al.*, 2016; Wing et al., 2001). Umpierre *et al.* (2011) also found that exercise, with or without weight loss helped by improving the well-being of patients and also improved glycaemic control by lowering glycated hemoglobin (HbAIc) levels by 0.66%.

Diet also plays an important role in the management of diabetes (Kastorini & Panagiotakos, 2010). Asif (2014) stated that a diet regimen will help a diabetic patient to either reduce or maintain a healthy weight and therefore helps to improve insulin sensitivity thereby managing diabetes.

Diet plays a major role in the management of type 2 diabetes. According to American Diabetes Association (2010), dietary pattern really plays a role in glucose metabolism as well as reducing an individual's risk of developing type 2 diabetes. In Ghana, most of the diets consist of fruits, vegetables, legumes, nuts and whole grains and cereals. These are rich in vitamins, minerals, antioxidants, polyphenols and dietary fibres which help to prevent deficiencies and maintain normal health (De & De, 2019). Insoluble dietary fibre obtained from foods such as whole grains and legumes helps to delay glucose absorption from the small intestine and thus may help prevent the sudden rise in blood glucose levels that follow a meal (Estruch *et al.*, 2006). The main aim of managing diabetes is to achieve glycaemic control and it is globally accepted that the dietary determinant of blood glucose is dietary carbohydrate (ADA, 2006). Food intake is an important cause of blood glucose levels and in

order to achieve normal glucose levels it is vital to make dietary choices that result in normal postprandial glycaemic responses (Gallwitz, 2009).

Several studies have found that dietary carbohydrate restriction shows postprandial, overall glucose concentration as well as glycated haemoglobin (HbA1c) reduction (Rizza, 2010; Accurso *et al.*, 2008; Haussain *et al*., 2012). A study conducted by Hussain *et al.* (2012) to compare very low carbohydrate ketogenic diet and low-calorie diet in diabetic and non-diabetic groups found that after a 24 week period, blood glucose dropped in the group which was put on very low carbohydrate ketogenic diet than in those on the low-calorie diet. Also there was a significant drop in blood glucose in the patients with type 2 diabetes when placed on very low carbohydrate ketogenic diet. A meta-analysis conducted by Schwingshackl *et al.* (2015), showed that there was an inverse relationship between an individual's risk of type 2 diabetes and strongly adhering to a Mediterranean diet. Also, another study conducted by Huo *et al.* (2015) reported that there was an improvement in glycaemic control among people with type 2 diabetes who followed a Mediterranean diet when compared with a low fat diet. Some meta-analyses also reported low-carbohydrate, low-glycaemic index or load, high protein, vegetarian and Mediterranean dietary approaches as the effective dietary pattern in reducing glycated hemoglobin (Yokoyama *et al*., 2014; Ajala *et al*., 2013) though other meta-analyses found contradictory results (Schwingshackl *et al*., 2014; Carter *et al*., 2014; Emadian *et al.*, 2015). According to Dong *et al*. (2013), it was observed that high protein diet as compared with low protein diets showed improvements in glycated haemoglobin but not in fasting plasma glucose.

2.4 MEDITERRANEAN DIET

The Mediterranean diet is a scientific concept that reflects the traditional dietary pattern that reigned in the Mediterranean basin before the mid-1960s, that is, before globalization had its

influence on lifestyle, including diet (Trichopoulou *et al.*, 2014). Mediterranean diet include vegetables, bread, cereals, olive oil as the major source of fat, low to moderate amounts of fish, poultry and alcohol, and little red meat and fruits. These dietary factors have been outlined in the Mediterranean diet pyramid which forms the daily, weekly and occasional dietary guidelines for individuals. Several studies suggest that the Mediterranean diet contains antioxidant compounds, bioactive elements as well as anti-inflammatory effects and low glycaemic index which help to decrease the risk of chronic diseases such as cardiovascular disease, type 2 diabetes, cancers and obesity by meeting individual nutritional requirements and maintaining a healthy body weight (Estruch *et al.,* 2016; Grosso *et al.,* 2015; Toledo *et al.,* 2015). The anti-inflammatory and antioxidant compounds in the Mediterranean diet help to decrease the production of pro-inflammatory cytokines which act to make diseases worse while increasing that of an anti-inflammatory cytokines which help to reduce inflammation and in turn may improve insulin sensitivity (Esposito *et al.,* 2017). The fat obtained from the Mediterranean diet is predominantly unsaturated, mainly monounsaturated and polyunsaturated fatty acids. According to Gillingham *et al.* (2011), intake of monounsaturated fatty acids is associated with maintaining body weight and reducing central body fat.

According to Schwenk *et al.* (2010), the ability of the β cells to function effectively is influenced by the type of dietary fat. An increase in fat deposition in organs such as liver and muscle from diet high in saturated fat and lipogenic sugars are the cause of insulin resistance in type 2 diabetes (Samuel & Shulman, 2012). Therefore, the Mediterranean diet is low in refined sugars and saturated fats and helps prevent insulin resistance. Several studies have also reported that saturated and trans fatty acids which are low in the Mediterranean diet decrease insulin secretion and worsen insulin sensitivity but unsaturated fatty acids help to improve insulin secretion and sensitivity (Thompson *et al.,* 2011; Jafari *et al.,* 2013). It has

been reported that when saturated fatty acids are substituted with either monounsaturated or polyunsaturated fatty acids they improve insulin sensitivity and has a high tendency of reducing type 2 diabetes mellitus (Willett *et al.*, 2009). Olive oil which is the main source of fat in the Mediterranean diet consists of phytosterols (de la Mata-Espinosa, 2011) which are plant-derived compounds. According to Heggen *et al.* (2009), phytosterols help to improve serum lipids and reduce the risk of chronic diseases such as cardiovascular disease and diabetes. It was found in a study conducted by de Bock *et al.* (2013), that application of two phenols, oleuropein and hydroxytyrosol, which are abundant in olive oil as a supplement caused improved insulin secretion and sensitivity. The Mediterranean diet is made up of foods that contain vitamins, minerals and antioxidants which are low in glycaemic index. Foods that are low in glycaemic index help to keep the blood sugar levels in target range.

The Mediterranean diet is mainly made up of plant foods which are important sources of slow-release carbohydrate and dietary fibre. The role of soluble fibre in a diet is to slow down glucose absorption from the small intestine and thereby help to prevent a sudden rise in blood glucose levels and this help in the management of diabetes. According to Ley *et al*. (2014), an increased consumption of dietary fibre, mostly from cereals other than fruit and vegetables, is associated with a reduction in the incidence of type 2 diabetes. It has been found that minerals in the Mediterranean diet help to increase insulin sensitivity by participating in intracellular processes which are related to glucose homeostasis (Martini *et al*., 2010).

A study conducted by Esposito *et al*. (2014) using five randomized control trials in people with type 2 diabetes, found that improvement in glycaemic control and insulin sensitivity was greater in participants on a Mediterranean diet than other frequently used diets. Also, in a systematic review and meta-analysis conducted by Schwingshackl *et al*. (2013), it was found that conformity to a Mediterranean diet decreased an individual's risk of getting diabetes

hence it serves an important measure in preventing type 2 diabetes. A study that investigated people with type 2 diabetes who were assigned to a Mediterranean diet for 12 weeks found that there was a substantial drop of their glycated haemoglobin from 7.1- 6.8% (Itsiopoulos *et al.*, 2011).

2.5 MEDITERRANEAN DIET SCORE

Mediterranean diet score is a score indicating conformity to the Mediterranean diet. Assessing individuals adherence to the Mediterranean diet was not an easy work therefore indices were developed to define the conformity to the Mediterranean diet. In 1995, a researcher named Trichopoulos developed the Mediterranean diet score to assess people's adherence to the diet because of the numerous benefits of the Mediterranean diet (Trichopoulou *et al*., 1995). Since then, many studies have adopted the score or modified the score to suite a particular country or group of people. Francesco Sofi and his colleagues have so far published many cohort studies by summarizing systematic reviews and meta-analysis on the results obtained by applying the Mediterranean diet score (Sofi *et al.*,2010, 2014). Recently, Sofi and colleagues published an umbrella meta-analysis where summarized and evaluated results of 13 meta-analysis of observational studies were assessed and it was found that Mediterranean diet score was inversely associated with all-cause mortality and incidence of cardiovascular and neurodegenerative diseases (Dinu *et al*., 2018).

Intake of any of the components of the Mediterranean diet (diet rich in fruits, vegetables, legumes, whole grains, fish, olive oil, moderate read meat and alcohol) scores positive (1) whiles no intake scores zero (0). A higher score means a better adherence to the traditional Mediterranean diet. In a study conducted by Zaragoza-Marti *et al.* (2018) on the evaluation of Mediterranean diet adherence scores, it was concluded that the use of Mediterranean diet

scores to measure compliance to a traditional Mediterranean diet was a useful tool because it helps to identify the dietary patterns of a population.

2.6 TYPE 2 DIABETES AND GLYCAEMIC CONTROL

Glycaemic control is a way of ensuring and preserving blood glucose levels within the normal ranges to help in the management of diabetes. The main approaches used to achieve good glycaemic control are dietary and lifestyle modifications, appropriate pharmacological therapy and also regularly monitoring blood glucose level. The "Standards of Medical Care in Diabetes" (ADA, 2015) recommends self-monitoring of blood glucose with fasting blood glucose, random blood glucose and glycated haemoglobin (HbA1c) as the effective and safe ways in assessing an individual's glycaemic control.

HbA1c is used to determine average blood glucose over approximately a period of 3 months and it is used in predicting complications among diabetes patients (Albers *et al.*, 2010). The level of HbA1c of an individual is an indication of the total blood exposure which is obtained through fasting plasma glucose and postprandial plasma glucose. Therefore achieving good fasting plasma glucose and postprandial plasma glucose are important in achieving glycaemic control that can be maintained (ADA, 2015; Garber *et al.*, 2013).

Glycaemic control is used to determine a patient's predisposition to microvascular and macrovascular complications of diabetes. It was reported that nearly 50% of people living with diabetes were able to attain and sustain the suggested target of <7.0% for glycated haemoglobin (ADA, 2015). Ali *et al.* (2013) also reported that only 14.3% of people living with diabetes were at target goals for glycated haemoglobin, low-density lipoprotein cholesterol and non-smoking. According to ADA, Fasting Blood Sugar of 70-130 mg/dl, Random Blood Sugar of less than 180 mg/dl and HbA1c of less than 7% suggest good glycaemic control. But these targets should be individualized.

A study conducted by Patel *et al*. (2008) reported that intensive glycaemic control among newly diagnosed type 2 diabetes patients helped in reducing long term cardiovascular disease rates. Some randomized controlled trials also found that the main difference between intensive glycaemic control and less intensive glycaemic control is small reductions in risk for microvascular events (Hayward *et al*., 2015; Gerstein *et al*., 2011; Duckworth *et al*., 2009). According to Miller *et al*. (2013) self-monitoring of blood glucose helps diabetes patients to assess themselves to know how well they are responding to a particular treatment.

Again, self-monitoring of blood glucose results guide medical practitioners in selecting appropriate medical nutrition therapy, physical activity and medications to prevent hypoglycemia. It has been found that eating more high-quality foods such as fruits, vegetables, whole grains and olive oil which constitute a Mediterranean style-diet help to reduce inflammation and improve insulin sensitivity (Esposito *et al.*, 2017). According to Wing *et al.* (2013) and the Look AHEAD Research Group (2014), achieving weight loss and maintaining it over a period of time helps to reduce the medication needed to control blood glucose thereby improving glucose levels, blood pressure and lipids.

2.7 BODY COMPOSITION AND ANTHROPOMETRY IN DIABETES

Anthropometry affords the single most convenient, universally applicable, cheap and non-invasive technique for measuring the size, proportions and composition of the human body (Khanna *et al*., 2015). The most typically used measure is Quetelet's index or body mass index (BMI), defined as weight/height^2 with weight in kilograms and height in metres. Although it is clear that increased body weight is a risk factor for type 2 diabetes, the relationship between body weight and type 2 diabetes is more attributable to the quantity and distribution of body fat (Despres, 2012).

A Prospective epidemiological study showed increased abdominal fat accumulation to be an independent risk factor for type 2 diabetes (Schneider *et al*., 2007). According to Feller *et al*. (2010), the relationship between anthropometric measurements and type 2 diabetes risks differs across markers or parameters and thus increased body mass index (BMI) is not strongly associated with type 2 diabetes as compared to unfavorable body fat. Several studies have also been conducted to find out the strength of association between anthropometric measurements and the incidence type 2 diabetes. Meta-analyses conducted by Lee *et al*. (2008) and Kodama *et al.* (2012), found that waist-to-height ratio (WHtR) had the strongest association with type 2 diabetes as compared to waist circumference (WC), waist-to-hip ratio (WHR) and BMI whiles Hartwig *et al*. (2016) also found markers reflecting abdominal obesity, waist WC and WHR as the strongest associations with type 2 diabetes incidence with the exception of WHR. In Hartwig et al. (2016) study, it was also found that WC and WHR had the strongest associations with the incidence of type 2 diabetes in women whiles waist-to-hip ratio showed the strongest association with type 2 diabetes incidence in men. Nonetheless, Motamed *et al.* (2016) reported that in both men and women WHR ratio followed by WtHR had stronger associations with the incidence of type 2 diabetes whiles Paek and Chun (2010) also found that the predictive powers of WC and BMI for diabetes were stronger in Korean women than in men.

In a Chinese cohort study conducted by He and Chen (2013), it was found that waist circumference had the highest association for the incidence of type 2 diabetes mellitus followed by body mass index and a body shape index (ABSI) when participants were followed for 15 years. Rajpathak and Wylie-Rosett (2011) also found that among the Chinese immigrants, prevalence of diabetes and impaired glucose were found among those with bigger waist circumference even though they had normal body mass index. Salvotelli *et al.*

(2015) reported that body mass index is a contributing factor in the development of diabetic neuropathy.

Central obesity has been found to have a stronger association to diabetes than general obesity (Kamath *et al*., 2011). Unnikrishnan *et al.* (2014) also reported that although South Asians have low rate of obesity based on their body mass index but they have large waist circumference and waist-to hip ratio indicating a great degree of central body obesity this contributed to high prevalence of diabetes. It was found by Unnikrishnan et al. (2014) that the high degree of central body obesity was associated with high levels of insulin, higher degree of insulin insensitivity resulting in diabetes.

CHAPTER THREE

3.0 METHODOLOGY

3.1 STUDY DESIGN

A cross sectional design was used in the study.

3.2 STUDY SITE

The study was carried out at the National Diabetes Management and Research Centre (Diabetes Clinic) at the Korle-Bu Teaching Hospital. Korle-Bu Teaching Hospital is currently the largest referral facility in the West African Sub-Region. (Korle-Bu annual report, 2016). This facility of 200 beds has developed and expanded in both size and specialties into a capacity of over 2000 beds with several specialties and Centres of Excellence (Korle-Bu annual report, 2016). There are currently 17 clinical and diagnostic Departments/Units in the hospital (Korle-Bu annual report, 2016). The National Diabetes Management and Research Centre provides specialist service for diabetes patients and also conducts diabetes research. The Centre receives about 65 people with diabetes a day and the types of diabetes managed there are type 1, type 2 and gestational diabetes.

3.3 STUDY POPULATION

People with type 2 diabetes who sought routine care at the National Diabetes Management and Research Centre at Korle-Bu Teaching Hospital formed the study population.

3.3.1 INCLUSION CRITERIA

People with type 2 diabetes who had been receiving care at the National Diabetes Management and Research Centre for at least one year and who consented to participate in the study were considered eligible.

3.3.2 EXCLUSION CRITERIA

Patients with the following conditions which may affect glycaemic control were excluded:

1. Pregnant patients (Because during pregnancy hormones can cause insulin resistance and decreased glucose produced by the liver and therefore affect glycaemic control) (Johnson, 2008).
2. Patients with known chronic kidney disease (Because the disease is associated with rapid erythrocyte turnover (ADA, 2018).
3. Patients known to have anaemia (Low haemoglobin concentration less than 11g/dl) (Because they may not have sufficient haemoglobin for the test to be accurate) (ADA, 2018).

3.4 SAMPLING TECHNIQUE

Total enumeration, where all consecutive eligible patients present on each day of visit to the Centre were invited to participate in the study, was used to recruit the patients. With the help of the Records Units at the National Diabetes Management and Research Centre (NDMRC), eligible patients were identified. The principal investigator explained the objectives and relevance of the study, as detailed in the patient information sheet (Appendix I) to all eligible patients. Their expected role, voluntary participation, risk and confidentiality were also explained. Only patients, who consented to participate in the study by signing or thumb-printing the consent form, were recruited. All eligible patients were given unique identity numbers. Patient recruitment, interview and measurement at the NDMRC were done from Mondays to Fridays by the principal investigator assisted by research assistants from the Department of Nutrition and Dietetics. Repeated visits were paid to the Centre until the required number of patients needed was obtained.

3.5 SAMPLE SIZE DETERMINATION

Sample size for the study was determined using the equation;

$N = Z^2 (p*q)/E^2$ (Ford, Fox, & Jack, 2010)

N = sample size

Z = absolute value of confidence level at 95% (with a standard value of 1.96)

P = the proportion of population exhibiting what is being studied (p = 3.6%), (IDF, 2017)

q = the proportion of the population not exhibiting what is being studied (q = 96.4%)

E = the accepted margin of error (E = 0.04)

$N = 1.96^2* (0.036) (0.964)/0.03^2=83$

83 was rounded up to 100 to cater for a 10% drop out rate and a 10% non-response rate.

Therefore a total of 100 participants were needed for the study.

3.6 PROCEDURE FOR DATA COLLECTION

3.6.1 DEMOGRAPHIC AND SOCIO ECONOMIC INFORMATION

Demographic and socio-economic data were obtained by the administration of a validated structured questionnaire. Information obtained included age, gender, marital status, occupation, employment status and income in section of the questionnaire. All questionnaire were interviewer administered.

3.6.2 ANTHROPOMETRY

Weight was measured with the Seca scale (Seca 770, Hamburg, Germany) to the nearest 0.1 kg. Patients were made to stand barefooted on the platform of the scale in minimum clothing.

Height was measured with a Seca stadiometer (Model, 213, Germany) to the nearest 0.1 centimetre. Patients stood upright on a base plate without shoes, with their heads in Frankfurt's plane, their back straightened, feet together and heels touching the back of the plate. The head plate was lowered to touch the top of the head and height read. BMI was calculated as weight (kg)/ height (m^2). Range of values, defined as underweight (<18.5 kg/m^2), normal weight (18.5-24.9 kg/m^2), overweight (25-29.9 kg/m^2), class 1 obesity (30-34.9 kg/m^2), class II obesity (35-39.9 $kg/m^{2)}$ and class III obesity (≥40 kg/m^2) were used in the study based on WHO classification of obesity (WHO, 2016).

Waist and hip circumference were measured with a non-elastic plastic measuring tape to the nearest 0.1 cm to evaluate the body fat distribution at different locations. Waist measurement was taken by placing the tape mid-way between the lower border of the costal margin (bottom of the rib cage) and the top border of the iliac crest. The tape measure was positioned snugly, but not pinching the skin. The participants were allowed to breathe out normally with both hands placed loosely by their side before measurements were taken.

Hip circumference was measured by placing the tape measure around the hips (around the maximum circumference of the buttocks). Participants were asked to stand with their feet together, arms at their side with palms facing inwards and were allowed to breathe out gently as measurement was taken. Both waist circumference and hip circumference were taken in duplicate and the mean determined. Waist to hip ratio was calculated as waist circumference/hip circumference. WHO sex specific cut off points for waist circumference defined as 94 cm (men) and 80 cm (women) for increased risk, 102 cm (men) and 88 cm (women) for substantially increased risk and waist to hip ratio of ≥0.90 cm (men) and ≥0.85 cm (women) for substantially increased risk were used (WHO, 2008).

3.6.3 BODY COMPOSITION

Body composition measurements (visceral fat, total body fat and muscle mass) were measured using the Omron body composition analyzer (BC-418, Tokyo, Japan) with a maximum weighing capacity of 200 kg and a minimum weighing capacity of 2 kg. For measurements to be taken, the patients' age, gender and height were first entered. The patient was then made to stand barefooted and looking straight ahead with both arms held onto the hand sensor. The two arms were raised at 90 degrees to the body with elbows straightened while holding firmly to the grip electrodes of the display unit. Measurements were then recorded. The results of visceral fat were categorized as (1-9) normal, (10-14) high and (15-30) very high. The results of body fat and muscle mass were categorized as follows as shown under tables 3.1a and 3.1b.

Table 3.1a Gender specific percentage body fat classification
(Omron Healthcare Inc, 2018)

Gender	**Body Fat Classification (%)**				
	Age	**Low (-)**	**Normal (0)**	**High (+)**	**Very High (++)**
Female	18-39	< 21.0	21.0 – 32.9	33.0 – 38.9	≥ 39.0
	40-59	< 23.0	23.0 – 33.9	34.0 -39.0	≥ 40.0
	60-80	< 24.0	24.0 -35.9	36.0 – 41.9	≥ 42.0
Male	18-39	< 8.0	8.0 – 19.9	20.0 – 24.9	≥ 25.0
	40-59	<11.0	11.0 – 21.9	22.0 – 27.9	≥ 28.0
	60-80	<13.0	13.0 – 24.9	25.0 – 29.9	≥ 30.0

Table 3.1b Gender specific muscle mass classification
(Omron Healthcare Inc, 2018)

Gender	Muscle Mass Classification				
	Age	**Low (-)**	**Normal (0)**	**High (+)**	**Very High (++)**
Female	18 – 39	< 24.3	24.3 – 30.3	30.4 – 35.3	≥ 35.4
	40 – 59	< 24.1	24.1 – 30.1	30.2 – 35.1	≥ 35.2
	60 – 80	< 23.9	23.9 – 29.9	30.0 – 34.9	≥ 35.0
Male	18 – 39	< 33.3	33.3 – 39.3	39.4 – 44.0	≥ 44.1
	40 – 59	< 33.1	33.1 – 39.1	39.2 – 43.8	≥ 43.9
	60 – 80	< 32.9	32.9 – 38.9	39.0 – 43.6	≥ 43.7

3.6.4 PHYSICAL ACTIVITY ASSESSMENT

Patients' physical activity levels were assessed using the International Physical Activity Questionnaire (IPAQ). The IPAQ was used to measure participant's intensity, duration and frequency of physical activity. The type of activity, duration in minutes (per session) and the number of days these activities were carried out in a week were assessed. Activities were quantified into MET minutes based on IPAQ scoring. Vigorous intensity scored 8 MET, moderate intensity scored 4 MET and walking scored 3.3 MET. Patients' total physical activity per week in MET value was calculated by multiplying the type of activity, duration and frequency of physical activity. Those whose total physical activity score per week exceeded 3000 MET minutes were classified as highly physically active, those whose physical activity were above 600 but below 3000 MET minutes were classified as moderately active and those whose physical activity was below 600 MET minutes were classified as low level of physical activity (International Physical Activity Questionnaire, 2006).

3.6.5 DIETARY AND NUTRIENT INTAKE ASSESSMENT

Patients' usual dietary intake and nutrient intake were determined using a validated quantitative food frequency questionnaire. The questionnaire consisted of a list of foods (carbohydrate, protein, fruits and vegetables) categorized into seven groups based on similarities in nutrient profile. Patients were required to indicate the frequency of their intake of each food item in a typical week, and also with the help of handy measures (standard cups, plates, ladles and spoons) estimated the usual amount of food consumed at a sitting. Frequency of food intake was classified as never consumed for those not consumed. The foods consumed 1 – 2 times/ week were moderately frequently consumed and the ones consumed 3 or more times/week were categorized as high frequency. With the help of food models and the handy measures, patients also estimated actual quantities of each food item they consumed. The estimated amount of food consumed was converted into grams using the food weights and handy measures tables of the Dietetic Group of the Dreyfus Health Foundation, Ghana (1994). Weight of food consumed in grams were then converted into nutrient intake using Micro diet food composition data base version 3.0 developed by the International Network of Food Data Systems to obtain nutrient, energy and fiber intake. Nutrient intakes were compared to recommended daily requirements of the US department of health and Human Services and US Department of Agriculture, 2015-2020 (USDA, 2015).

Conformity to the Mediterranean diet score was estimated using the Mediterranean diet score tool (Martínez-González *et al.*, 2012). The Mediterranean diet score tool is a 14-unit dietary score. The 14-items listed are olive oil, vegetables, fruits, red meat, chicken, fish, seafood, nuts, legumes, sugar sweetened beverages, wine, natural spices, pastries and margarine. The Mediterranean diet tool enquires from patients if they consume particular amounts of each of the items listed in a week. A score of 1 was given for each component of the Mediterranean diet consumed whiles a score of 0 was given when the component was not consumed. A total

score of nine or higher indicated highest adherence or benefit, a score of four to eight indicated moderate conformity and a score less than four indicated lowest conformity or benefit to the Mediterranean dietary pattern.

3.6.6 BIOCHEMICAL ANALYSIS

Two millimeters of venous blood was obtained from patients in the morning using 2 ml syringes. Standard protocol for obtaining venous blood was followed using standard AOAC method (Prosky *et al*., 1980) to obtain the sample and it was carried out by a certified Phlebotomist. The blood sample was placed in a pre-labeled EDTA tube which contained sodium fluorid as anticoagulant. The whole blood was stored at 2-8^{O}C in a frozen gel packs and immediately transported to laboratory at Korle-Bu Polyclinic for analysis. Finecare laboratory reagent and a Biosystems Chemical Analyzer, model number BS 200E produced in India were used. HbA1c value of <7 was used as good glycemic control (ADA, 2015).

3.7 DATA ANALYSIS

Data was analyzed using the Statistical Package for Social Sciences (SPSS) version. Tables and figures were used to summarize the results obtained. Descriptive statistics (e.g. mean and standard deviation) were calculated for continuous variables (e.g. glycated haemoglobin, age, waist circumference, hip circumference, waist-to hip circumference and BMI) and proportions for categorical variable (Mediterranean diet score, gender, and educational level). Differences between means (e.g. anthropometric indicators and nutrient intake among males and females) were determined using independent sample T-test. Associations between categorical variables were determined using Pearson's Chi square while Pearson's Correlation was used to determine association between continuous variables. Binary logistics regression was used to determine the relationship between glycaemic control and the Mediterranean diet. Statistical significance was set at $p \leq 0.05$.

3.8 ETHICAL APPROVAL

Ethical approval was obtained from the Ethics and Protocol Review Committee of the School of Biomedical and Allied Health Sciences of the University of Ghana. In addition, ethical approval was sought from Institutional Review Board of Korle-Bu Teaching Hospital. After approvals, permission was sought from the National Diabetes Management and Research Centre of the Korle-Bu Teaching Hospital. An information sheet detailing the nature of the study, its benefits and harm was given to the patients. The study was explained in detail in the language each patient understood.

CHAPTER FOUR

4.0 RESULTS

4.1 SOCIO-DEMOGRAPHIC CHARACTERISTICS OF STUDY PARTICIPANTS

100 participants were recruited for the study. The mean age of the study participants was 58.4 ± 10.6 years with 61.2 ± 9.5 years been the mean age for males and 57.8 ± 10.8 years the mean age for females. Majority of the participants were females (77%) with males forming the minority of 23%. Table 4.1 reports the socio-demographic characteristics of participants. Majority of the participants were Akan (45%) whiles other tribes (4%) formed the minority. Seventy percent of the participants were married.

Over a third (41%) of the participants had senior high school as their highest level of education. More than half (54%) of the participants were employed. Majority (64%) of the participants earned incomes below GHC 500 monthly ($ 92.59). Fifty four percent of the participants had occupation. Out of the 54, forty were traders.

Table 4.1: Background characteristics of study participants.

Variable	Male *n* = 23	Female *n* = 77	Total *n* = 100	P – value
Ethnicity				
Akan	11 (47.8)	34 (44.2)	45 (45)	P = 0.547
Ewe	2 (8.7)	10 (13.0)	12 (12)	
Ga	9 (39.1)	21 (27.3)	30 (30)	
Northerner	1 (4.3)	8 (10.4)	9 (9)	
Other		4 (5.2)	4 (4)	
Total	**23 (100)**	**77 (100)**	**100 (100)**	
Marital status				
Married	23 (100)	47 (61)	70 (70)	P = 0.012*
Single	0 (0)	6 (7.8)	6 (6)	
Divorced	0 (0)	8 (10.4)	8 (8)	
Widow	0 (0)	14 (18.2)	14 (14)	
Separated	0 (0)	2 (2.6)	2 (2)	
Total	**23 (100)**	**77 (100)**	**100 (100)**	
Education				
No formal education	0 (0)	18 (23.4)	18 (18)	P = 0.057
Primary	1 (4.3)	4 (5.2)	5 (5)	
Junior high	3 (13.0)	13 (16.9)	16 (16)	
Secondary high	11 (47.8)	30 (39.0)	41 (41)	
Tertiary	8 (34.8)	12 (15.6)	20 (20)	
Total	**23 (100)**	**77 (100)**	**100 (100)**	
Employment				
Yes	10 (43.5)	44 (57.1)	54 (54)	P = 0.249
No	13 (56.5)	33 (42.9)	46 (46)	
Total	**23 (100)**	**77 (100)**	**100 (100)**	
Occupation				
Administrative staff	5 (21.8)	5 (6.5)	10 (10.0)	P = 0.001*
Traders	3 (13.1)	37 (48.0)	40 (40.0)	
Seamstress	0 (0)	2 (2.6)	2 (2.0)	
Carpenters	1 (4.3)	0 (0)	1 (1.0)	
Electricians	1 (4.3)	0 (0)	1 (1.0)	
Total	**10 (43.5)**	**44 (57.1)**	**54 (54)**	
Monthly income				
< GHC 500	7 (35.0)	41 (75.9)	48 (64.9)	P = 0.009*
GHC 500 – 1000	8 (40.0)	10 (18.5)	18 (24.3)	
GHC 1001 – 2000	3 (15.0)	2 (3.7)	5 (6.8)	
≥ GHC 2000	2 (10.0)	1 (1.9)	3 (4.1)	
Total	**20 (100)**	**54 (100)**	**74 (100)**	

Significant at $p \leq 0.05$: Pearson's Chi square
SD: Standard Deviation

4.2 PHYSICAL ACTIVITY LEVELS OF STUDY PARTICIPANTS

Majority (54%) of the study participants were involved in low physical activity with a p - value = 0.144 as shown in Table 4.2. This was especially true for females (58.4%) compared to males (39.1%). Most males (56%) were involved in moderate physical activity.

Table 4.2: Physical activity levels of study participants.

Variable	Male *n* = 23	Female *n* = 77	Total *n* = 100	P – value
Physical activity				
Low activity	9 (39.1)	45 (58.4)	54 (54)	P = 0.144
Moderate activity	11 (56.5)	26 (33.8)	39 (39)	
High activity	1 (4.3)	6 (7.8)	7 (7)	
Total	**23 (100)**	**77 (100)**	**100 (100)**	

Significant at p ≤ 0.05: Pearson's Chi square

4.3 MEDICATION TAKEN BY STUDY PARTICIPANTS

Participants' medication intake ranged from oral glucose lowering drugs to insulin injecting as well as a combination of the two. Majority (36%) of the participants were on both Metformin as well as a combination of Insulin and Metformin as shown in Table 4.3.

Table 4.3: Medication taken by study participants.

Variable	Male *n* = 23	Female *n* = 77	Total *n* = 100	P – value
Medication				
Metformin	7 (30.4)	29 (37.7)	36 (36)	P = 0.765
Insulin	2 (8.7)	4 (5.2)	6 (6)	
Insulin & Metformin	10 (43.5)	26 (33.8)	36 (36)	
Glimepiride	0 (0)	4 (5.2)	4 (4)	
Metformin & Glimepiride	4 (17.4)	13 (16.9)	17 (17)	
Metformin & Glimepiride & Insulin	0 (0)	1 (1.3)	1 (1)	
Total	**23 (100)**	**77 (100)**	**100 (100)**	

Significant at p ≤ 0.05: Pearson's Chi square

4.4 ANTHROPOMETRY AND BODY COMPOSITION OF STUDY PARTICIPANTS

Table 4.4 shows the mean anthropometry and body composition indices of study participants. Body mass index of male and female participants was comparable. Total body fat was however significantly higher ($p < 0.001$) among females compared to males. Conversely, visceral fat and muscle mass were also significantly higher among males ($p < 0.001$; $p < 0.001$) compared to females. Waist – to – hip ratio was significantly the same for males and females ($p = 0.905$).

Table 4.4: Anthropometry and body composition of study participants.

Variable	**Male** ***n*** **= 23** **Mean ± SD**	**Female** ***n*** **= 77** **Mean±SD**	**Total** ***n*** **= 100** **Mean ± SD**	**P – value**
Body mass index (kg/m^2)	28.7 ± 4.4	29.3 ± 5.3	29.1 ± 5.1	P = 0.644
Total body fat (%)	27.9 ± 8.9	40.7 ± 6.4	37.7 ± 8.8	P < 0.001
Visceral fat	14.5 ± 6.9	9.5 ± 2.7	10.6 ± 4.5	P < 0.001
Muscle mass	31.2 ± 5.8	25.0 ± 2.6	26.4 ± 4.4	P < 0.001
Waist-to-hip ratio (cm)	0.9 ± 0.1	0.9 ± 0.1	0.9 ± 0.1	P = 0.905

Significant at $p \leq 0.05$: Independent Sample Test

4.4.1 ANTHROPOMETRIC MEASUREMENTS OF STUDY PARTICIPANTS

Fig 1 shows BMI classification of study participants. None of the study participants was underweight. Majority (36%) of the study participants were obese, especially among females compared to males, though not statistically significant.

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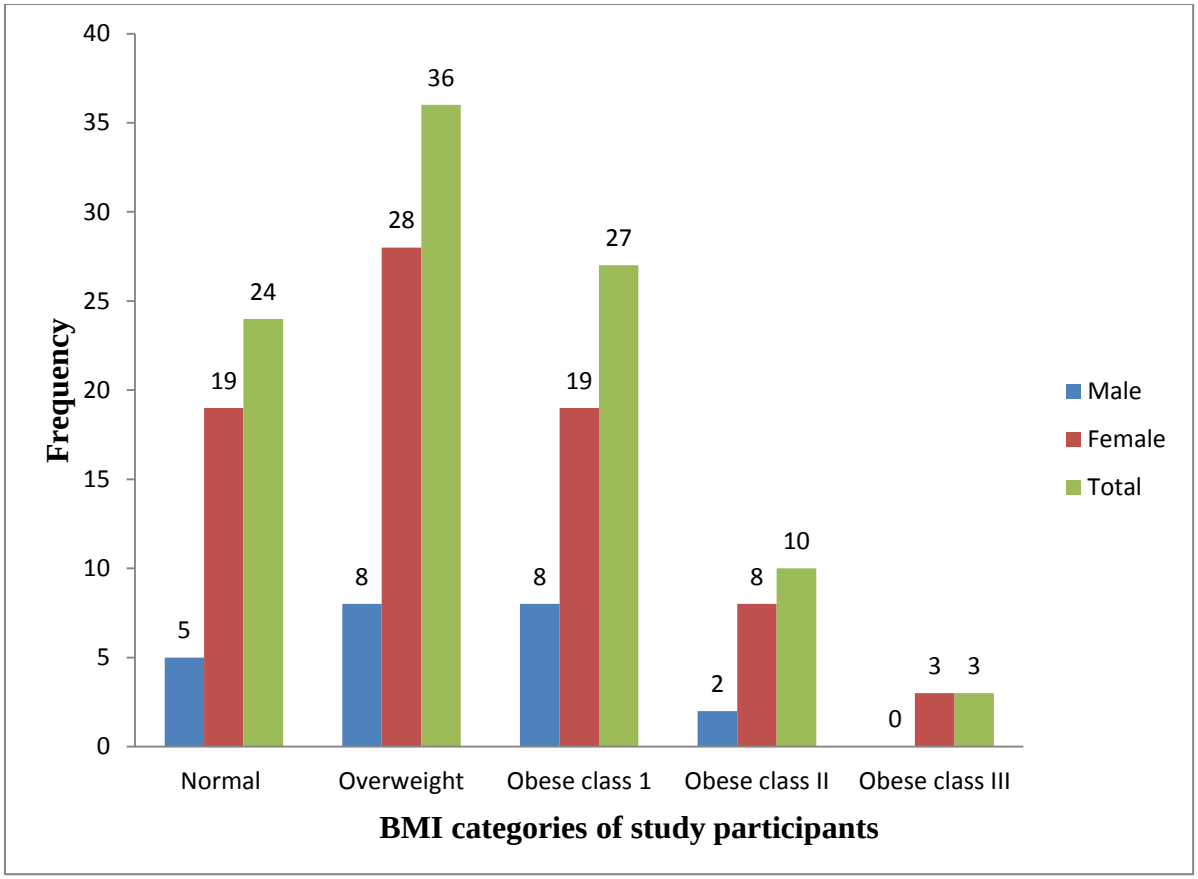

Fig 1: BMI classification of study participants.

4.5 NUTRIENT INTAKE OF STUDY PARTICIPANTS COMPARED WITH THEIR RECOMMENDED DAILY ALLOWANCE (RDA)

Table 4.5 shows nutrient intake of study participants compared with their RDA's. Mean energy, protein and magnesium intake of most male participants fell below their RDA's whiles they had their mean carbohydrate, fat and iron exceeding their RDA's. Among the female participants most of their nutrient intakes like carbohydrate, fibre, protein and iron exceeded recommended intakes. There were no significant differences in the mean nutrient intakes of males and female participants (p = 0.910, 0.164, 0.903, 0.140, 0.886, 0.246, 0.665).

Table 4.5: Nutrient intake of study participants compared with their RDA

Variable	Male *n* = 23 Mean ± SD	RDA	Female *n* = 77 Mean ± SD	RDA	Total *n* = 100 Mean ± SD	P –value
Energy (Kcal)	1535.7 ± 417.8 (847 – 2359)	2000	1547.4 ± 441.8 (794- 2500)	1600	1544.7 ± 434.4 (794 – 2500)	0.910
Carbohydrate (g)	238.9 ± 78.6 (102 – 406)	130	280.7 ± 135.9 (85 – 845)	130	271.1 ± 126.0 (85 – 845)	0.164
Protein (g)	48.8 ± 26.6 (23 – 127)	56	49.6 ± 26.4 (14 – 137)	46	49.4 ± 26.3 (14 – 137)	0.903
Fat (g)	49.4 ± 47.8 (9 – 233)	20	37.9 ± 26.8 (6 – 109)	20	40.5 ± 32.9 (6 – 233)	0.140
Fibre (g)	29.3 ± 13.9 (5 – 59)	30	29.8 ± 14.7 (5 – 63)	21	29.7 ± 14.5 (5 – 63)	0.886
Magnesium (mg)	158.8 ± 109.9 (10 – 422)	235	131.3 ± 96.2 (10 – 559)	205	137.6 ± 99.6 (10 – 559)	0.246
Iron (mg)	18.1 ± 13.0 (7 – 62)	8	17.0 ± 10.2 (5 – 63)	8	17.2 ± 10.9 (5 – 63)	0.665

Significant at $p \leq 0.05$: Independent Sample Test
RDA (recommended dietary allowance, 2002)

4.6 FREQUENCY OF FOOD INTAKE

Table 4.6 shows foods frequently consumed by participants. The most frequently consumed carbohydrates (3x/week) were bread (51%), plantain (49%), banku (35%), rice (33%), kenkey (25%) and whiles the least consumed carbohydrates were apapransa (0), kaffer (1%), kokonte (1%) and cocoyam (1%). Over 25% of participants consumed them three or more times in a week. Fish (91%) and milk (26%) were the most frequently consumed protein food with beans (12%) being the most frequently consumed legume. Most frequently consumed vegetables were onion (96%), tomatoes (91%), garden eggs (52%) and kontomire (37%). Over 37% of participants ate them at least 3 times in a week. Other green leafy vegetables like dandelion, aleefu, moringa and gboma were never consumed by over 76% of participants. Over 28% consumed fruits like grapes, watermelon, coconut, orange, apple, banana, pawpaw and mango between once and twice/week. Sweetened drinks and snacks were not frequently consumed by majority (>76%) and (78%) participants, respectively. All

the participants (100%) never consumed bake beans, mayonnaise, soy sauce and salad dressing.

Table 4.6: Frequency of intake of foods within a week by study participants

FOOD	NEVER	1 – 2x/WEEK	≥ 3x/WEEK
CARBOHYDRATE			
Sugar	91 (91)	3 (3)	6 (6)
Banku	34 (34)	31 (31)	35 (35)
Rice	40 (40)	27 (27)	33 (33)
Yam	46 (46)	37 (37)	17 (17)
Plantain	34 (34)	17 (17)	49 (49)
Fufu	38 (38)	43 (43)	19 (19)
Tuozaafi	85 (85)	7 (7)	8 (8)
Kokonte	85 (85)	14 (14)	1 (1)
Cocoyam	90 (90)	9 (9)	1 (1)
Gari	81 (81)	15 (15)	4 (4)
Wheat	62 (62)	26 (26)	12 (12)
Oats	48 (48)	41 (41)	11 (11)
Tombrown	42 (42)	47 (47)	11 (11)
Hausa koko	59 (59)	22 (22)	19 (19)
Corn porridge	37 (37)	44 (44)	19 (19)
Rice porridge	93 (93)	5 (5)	2 (2)
Milo	76 (76)	9 (9)	15 (15)
Bread	40 (40)	9 (9)	51 (51)
Tea	67 (67)	8 (8)	25 (25)
Kenkey	41 (41)	34 (34)	25 (25)
Apapransa	100 (100)	0 (0)	0 (0)
Kaffer	97 (97)	2 (2)	1 (1)
PROTEINS			
Goat meat	73 (73)	21 (21)	6 (6)
Cow meat	84 (84)	11 (11)	5 (5)
Fish	4 (4)	5 (5)	91 (91)
Crabs	92 (92)	5 (5)	3 (3)
Shrimps	98 (98)	1 (1)	1 (1)
Octopus	99 (99)	0 (0)	1 (1)
Bush meat	96 (96)	3 (3)	1 (1)
Offals	94 (94)	6 (6)	0 (0)
Chicken	57 (57)	30 (30)	13 (13)
Snail	94 (94)	5 (5)	1 (1)
Mushrooms	99 (99)	1 (1)	0 (0)
Eggs	51 (51)	33 (33)	16 (16)
Milk	65 (65)	9 (9)	26 (26)
Beans	46 (46)	42 (42)	12 (12)
Cheese	100 (100)	0 (0)	[0 (0)
VEGETABLES			
Okro	42 (42)	31 (31)	27 (27)
Carrots	65 (65)	21 (21)	14 (14)
Cabbage	40 (40)	41 (41)	19 (19)
Green beans	93 (93)	5 (5)	2 (2)
Broccoli	98 (98)	1 (1)	1 (1)
Lettuce	65 (65)	22 (22)	13 (13)
Green pepper	68 (68)	19 (19)	13 (13)

FOOD	NEVER	1-2x/WEEK	≥ 3x/WEEK
Kontomire	26 (26)	37 (37)	37 (37)
Garden eggs	18 (18)	30 (30)	52 (52)
Tomatoes	0 (0)	9 (9)	91 (91)
Onions	0 (0)	4 (4)	96 (96)
Dandelion	76 (76)	6 (6)	15 (15)
Moringa	95 (95)	1 (1)	4 (4)
Aleefu	92 (92)	2 (2)	6 (6)
Gboma	97 (97)	2 (2)	1 (1)
FRUITS			
Orange	50 (50)	31 (31)	19 (19)
Pineapple	75 (75)	20 (20)	5 (5)
Banana	43 (43)	42 (42)	15 (15)
Apple	58 (58)	34 (34)	8 (8)
Mango	43 (43)	44 (44)	13 (13)
Guava	93 (93)	6 (6)	1 (1)
Coconut	66 (66)	28 (28)	6 (6)
Pawpaw	46 (46)	46 (46)	8 (8)
Watermelon	39 (39)	47 (47)	14 (14)
Grapes	93 (93)	6 (6)	1 (6)
Sugar cane	99 (99)	1 (1)	0 (0)
DRINKS			
Alcohol	93 (93)	7 (7)	0 (0)
Fizzy drinks	76 (76)	21 (21)	3 (3)
Brukina	98 (98)	2 (2)	0 (0)
Asana	99 (99)	1 (1)	0 (0)
Kalyppo	100 (100)	0 (0)	0 (0)
SNACKS			
Meat pie	80 (80)	19 (19)	1 (1)
Spring rolls	92 (92)	8 (8)	0 (0)
Rock buns	97 (97)	3 (3)	0 (0)
Chips	98 (98)	2 (2)	0 (0)
Groundnuts	84 (84)	11 (11)	5 (5)
Tiger nuts	96 (96)	3 (3)	1 (1)
OTHERS			
Tuna flakes	94 (94)	4 (4)	2 (2)
Corned beef	91 (91)	7 (7)	2 (2)
Sardine	71 (71)	28 (28)	1 (1)
Bake beans	100 (100)	0 (0)	0 (0)
Mackerel	93 (93)	6 (6)	1 (1)
Mayonnaise	100 (100)	0 (0)	0 (0)
Salad cream	99 (99)	1 (1)	0 (0)
Ketchup	97 (97)	3 (3)	0 (0)
Soy sauce	100 (100)	0 (0)	0 (0)
Margarine	94 (4)	4 (4)	2 (2)
Salad dressing	100 (100)	0 (0)	0 (0)

4.7 MEDITERRANEAN DIET SCORE CATEGORIES OF STUDY PARTICIPANTS

For most participants, the Mediterranean diet score was moderate (4 – 8). This was especially higher among females than males. Over 50% of males reported high Mediterranean diet scores (≥ 9), Table 4.7

Table 4.7: Mediterranean diet score of study participants

Variable	Male *n* = 23	Female *n* = 77	Total *n* = 100	P – value
Med diet score				
Low score (> 4)	0 (0)	3 (3.9)	3 (3)	0.252
Moderate score (4-8)	11 (47.8)	47 (61.0)	58 (58)	
High score (≥ 9)	12 (52.2)	27 (35.1)	39 (39)	
Total	**23 (100)**	**77 (100)**	**100 (100)**	

Significant at p ≤ 0.05: Pearson's Chi square

4.8 GLYCAEMIC CONTROL OF STUDY PARTICIPANTS.

Blood glucose of majority (55%) of study participants was well controlled based on HbA1c (≥ 7). This was higher among females (59.7%) than males (39.1) although not statistically significant (p = 0.081).

Table 4.8: Glycaemic control of study participants

HbA1c	Male *n* = 23	Female *n* = 77	Total *n* = 100	P – value
Well controlled (< 7%)	9 (39.1)	46 (59.7)	55 (55)	0.081
Poorly controlled(≥ 7%)	14 (60.9)	31 (40.3)	45 (45)	
Total	**23 (100)**	**77 (100)**	**100 (100)**	

Significant at p ≤ 0.05: Pearson's Chi square

4.9 MEAN MEDITERRANEAN DIET SCORE AND HbA1c OF STUDY PARTICIPANTS

The mean HbA1c of study participants was 7.4 ± 1.7% ranging from 4.0 – 13.2%. The mean Mediterranean diet score of study participants was 7.7 ± 1.9 with a minimum score of 3 and a maximum score of 12. For both variables, males had higher means though not statistically significant (p = 0.081, p = 0.252), Table 4.7.

Table 4.9: Mean HbA1c and Mediterranean diet score of study participants.

Variable	Male *n* = 23	Female *n* = 77	Total *n* = 100	P – value
HbA1c	7.6 ± 1.6 (4.9 – 11.0)	7.3 ± 1.8 (4.0 – 13.2)	7.4 ± 1.7 (4.0 – 13.2)	0.081
Med diet score	7.7 ± 1.9 (3 – 12)	7.5 ± 1.9 (3 -12)	7.7 ± 1.9 (3 – 12)	0.252

Significant at p ≤ 0.05: Pearson's Chi square

4.10 CORRELATION BETWEEN HbA1c, MEDITERRANEAN DIET SCORE AND NUTRIENT INTAKE.

Table 4.10 shows the correlation between HbA1c, Mediterranean diet score and nutrient intake of study participants. There was no significant association between Mediterranean diet score and HbA1c (r^2 = 0.139; p = 0.168). However dietary fiber and carbohydrate intakes correlated significantly and positively with Mediterranean diet score (r^2 = 0.197; p = 0.050) and (r^2 = 0.228; p = 0.022) respectively.

Table 4.10: Correlation between HbA1c, Mediterranean diet score and nutrient intake of study participants.

	HbA1c	M diet score	Energy	CHO	Protein	Fat	Fiber	BMI
HbA1c	1							
M diet score	.139 .168	1						
Energy	.061 .548	.111 .271	1					
CHO	.076 .455	.228 .022	.539* .000	1				
Protein	.061 .545	.172 .087	.390* .000	.534* .000	1			
Fat	-.077 .446	.079 .437	.402* .000	.280* .005	.537* .000	1		
Fiber	.036 .723	.197* .050	.208* .038	.502 .000	.252* .011	.135 .182	1	
BMI	-.145 .151	.097 .335	.101 .319	.087 .389	.050 .619	.013 .900	.134 .182	1

Significant at $p \leq 0.05$: Pearson's Correlation
M diet score = Mediterranean diet score
CHO = Carbohydrate
BMI = Body Mass Index

Table 4.11a: Association between Mediterranean diet score and glycaemic control among participants.

From Table 4.11a, there was no significant association between Mediterranean diet score and glycaemic control among study participants.

Glycaemic control		**Mediterranean diet score**			**Total**	**P – value**
		Low	**Moderate**	**High**		
HbA1c	Well controlled	2	30	23	55	P = 0.717
	Poorly controlled	1	28	16	45	
Total		**3**	**58**	**39**	**100**	

Pearson's Chi square Analysis: Significant at $p \leq 0.05$

CHAPTER FIVE

5.0 DISCUSSION AND CONCLUSION

5.1 SOCIO-DEMOGRAPHIC CHARACTERISTICS OF PARTICIPANTS

A total number of 100 participants were recruited for the study. Seventy-seven percent were females and 23% were males. This distribution is in contrast with a study carried by Ibu *et al.* (2012). They found that overall diabetes prevalence was higher in men than in women. The overall mean age of these study participants was 58.4 ± 10.6 years. According to a report by the Ghana Living Survey, people 50 years and above are among the age groups most vulnerable to diseases (Ghana Statistical Service, 2008). Dillin *et al.* (2014) and Niccoli & Patridge (2012) reported that aging is among the greatest known risk factors for most human diseases. This finding is consistent with the observation reported by other researchers. A study by Amoah (2002) in urban Ghana found that type 2 diabetes affects at least 6% of the adults and is associated with age. Another study conducted in Kenya by Ayah *et al.* (2013) found that the prevalence of diabetes varied in different age groups with the older population being at a higher risk as compared to the younger generation.

More than half (54%) of the participants were employed and had attained their secondary education. Education level is an important aspect when it comes to the management of diabetes because it helps patients to understand their glycaemic control (Heisler *et al*.,2005). A study by Hu *et al*. (2007) suggested that patients with higher education level were more likely to take actions to better manage their diabetes which is consistent with this study finding. Majority (40.0%) of the employed participants was traders and received a monthly income of less than GHC 500 ($ 92.59) which is low. It is well documented in the literature that there are significant costs involved in the care and management of diabetes for the individual patients. In a population-based cross-sectional study by Branfield et al. (2019), it was found that people with diabetes with lower incomes had significantly worse glycaemic

control compared with their counterparts on higher incomes. Majority of the participants (70%) were married. Being unmarried was significantly associated with unacceptable diabetic control. This is because a stable life partner could potentially provide a strong social and emotional support for a patient with chronic disease like diabetes to help the patient in maintaining a healthy lifestyle and compliance to treatment (Kavouras *et al*., 2007).

5.2 PHYSICAL ACTIVITY OF STUDY PARTICIPANTS

The results of the study showed that more than half (54%) of the study participants were involved in low physical activity. This showed that most of the participants did not meet the public health recommendation of a minimum of 150 minutes of moderate to vigorous physical activity or 75 minutes vigorous physical activity a week to maintain general health (Garber *et al.,* 2011), even though it has been well established that physical inactivity is a risk factor for diabetes and thus management of the disease includes regular physical activity (Jeon *et al.,* 2007). This finding is consistent with that of Hallal *et al*. (2012), who reported that about one third of adults worldwide do not meet the recommended weekly physical activity. In a study conducted by Snowling & Hopkins (2006), regular physical activity was found to cause a reduction in glycated haemoglobin, triglycerides, blood pressure and insulin resistance. Another study conducted among adults living with diabetes found that people living with diabetes engaged in less physical activities when compared with people with prediabetes and those who had normal glucose levels (Steeves *et al*., 2005).

5.3 DIETARY INTAKE OF STUDY PARTICIPANTS

Nutrition therapy is one of the most important and efficient aspects of diabetes management (Evert *et al.,* 2014). The intake of energy and carbohydrate were higher in women when compared to the men in this study. This could be that most of the men were conscious of the quality of their diet in order to manage the disease and prevent complications. The RDA's for

the participants were compared with their dietary intake and gaps in the macronutrient and micronutrient intake were observed. This study found that participant's intakes of carbohydrate and fat intake were higher than the recommended dietary allowance with the exception of fibre. Food intake of participants from the food frequency data showed that their carbohydrate intakes were high and that they were mostly from high-fibre (unrefined) carbohydrate. The most frequently consumed carbohydrate were banku and kenkey which are made from fermented whole grains and could therefore be high in fibre. Also rice was frequently consumed which is mostly refined and could be high in calories. Also fruit and vegetable intake among participants were not frequent as expected and this can poorly affect their glycaemic control. In a study by Gross et al. (2004), they reported that increasing intakes of refined carbohydrate related with decreasing intakes of fibre paralleled the rising in the trend in the prevalence of type 2 diabetes and this can result in long term complications such as diabetic retinopathy which may lead to adult-onset blindness, diabetic nephropathy, diabetic neuropathy causing kidney failure, among others (Baynes, 2015).

The quality of dietary fats and carbohydrates consumed has been found to be more important than the quantity (Ley et al., 2014) when it comes to management of diseases. A considerable body of evidence from prospective studies supports the importance of individual nutrients, foods and dietary patterns in the prevention and management of type 2 diabetes (de Koning *et al.,* 2011; Rossi *et al.,* 2013). Carbohydrate intake is a major factor of glycaemic control because of its immediate effect on postprandial glucose levels (Franz *et al*., 2010). An observational study reported that a moderately higher carbohydrate intake compared to a lower carbohydrate was associated with better glycaemic control (Xu *et al.,* 2007) which is consistent with this study.

5.4 ANTHROPOMETRY AND BODY COMPOSITION OF STUDY PARTICIPANTS

More than half (76%) of the participants were overweight and obese. This finding is consistent with a study conducted by Amoah (2002) which found that type 2 diabetes was associated with obesity. Another study conducted by Dankwah *et al.* (2012) identified obesity as an independent risk factor of diabetes in Ghana. In the Framingham Heart Study, it was found that increased risk of diabetes was most pronounced in those with high body mass index (BMI) (Fox *et al.*, 2006). A meta-analysis of prospective cohort studies conducted to examine the relative risk of developing type 2 diabetes among overweight and obese populations found that obesity was a major risk factor for developing type 2 diabetes (Abdullah *et al.*, 2010). Abdullah et al. (2010) finding is consistent with conclusions from European elderly and Asian population studies. They showed that overweight Asian people were more susceptible to type 2 diabetes (Olafsdottire *et al.*, 2009; Noale *et al.*, 2006; Nagay a *et al.*, 2005). These studies found significant differences in 3 body composition parameters (total body fat, visceral fat and muscle mass) between male and female study participants. This is consistent with studies conducted by Von Eyben *et al*. (2003) and Chandra *et al.* (2014). These studies found that central obesity or visceral fat was a stronger risk factor for type 2 diabetes when compared with body mass index. This is because visceral fat was found to be a stronger risk factor for glucose intolerance, insulin resistance and hyperinsuliemia when compared with body mass index.

5.5 MEDICATION

Medication plays a role in glycaemic control. All the participants were on medication. The participants were put on either one, two or three types of medication in order to achieve good glycaemic control. Thirty-six (36%) of the participants were on metformin only. This finding is consistent with a study by Tahrani *et al.* (2016) that observed that Metformin was the first-line pharmacotherapy for patients with type 2 diabetes. In Tahrani et al. (2016) study, it was

found that two or three medications were required as the disease advances and also insulin was required when other medications were not able to achieve adequate glycaemic control.

In a randomized control trial, it was found that Dapagliflozin added to glimepiride in patients with type 2 diabetes significantly improved HbA1c and reduced weight (Strojek *et al.*, 2011). This finding is also consistent with a randomized clinical trial that found that among patients with type 2 diabetes, oral semaglutide resulted in better glycaemic control than placebo over a period of 26 weeks (Davies *et al.*, 2017).

5.6 GLYCAEMIC CONTROL OF STUDY PARTICIPANTS

The study found out that more than half (55%) of the study participants had a good glyacemic control. This can be attributed to the fact that about 58% of the participants recorded moderate Mediterranean diet scores. The most frequently consumed carbohydrates were fufu, bread, banku, kenkey and rice. These form part of the main staples in the Ghanaian diet. These sources of carbohydrates contain an amount of fiber that is good for health and glycaemic control. Beans was moderately consumed by participants. This is because most of the participants knew that beans contain a good amount of carbohydrate, protein and fiber which will help in the management of the disease. The role of soluble fibre in a diet is to slow down glucose absorption from small intestine and thereby help to prevent a sudden rise in blood glucose levels and this help in the management of diabetes.

Onions, tomatoes, garden eggs and kontomire were the most consumed vegetables. Most Ghanaian meals are prepared with tomatoes and onion and this could account for the reason why 91% and 96% of participants consumed it more than 3 times in a week, respectively. According to Ley et al. (2014) and Salas-Salvadó (2011), diets rich in whole grains, fruits, vegetables, nuts and legumes have been shown to be associated with lower risk of diabetes. According to Evert et al. (2014), carbohydrate intake from vegetables, fruits, whole grains

and legumes were found to be better than carbohydrate sources that contain added fats, sugars and sodium in the management of diseases.

Majority (55%) of the study participants had good glycaemic control even though majority (54%) was involved in low physical activity. This can be due to the fact that majority of the employed participants were traders who might not have had enough time to exercise as part of their job schedule. A research carried out by Davila *et al.* (2011) found that suboptimal glycaemic control was achieved in adult with type 2 diabetes who worked 40 hour/week and this occurred in agricultural workers other than white collar jobs. Majority of the participants scored moderate Mediterranean scores because of their frequent intakes of banku, kenkey, porridges which are all made from whole grains and contain good amount of fibre and also low consumption of drinks and snacks. It was found that participants intake of other green leafy vegetables and most fruits which are component of the Mediterranean diet were not very frequent and this could account for the fact why their glycaemic control did not correlate with Mediterranean diet score.

There was no significant association between Mediterranean diet score and glycaemic control even though it correlated positively in this study. This finding is consistent with the PREDIMED trial which found that there was an inverse association between adherence to Mediterranean diet and glycaemic control even though it did not reach statistical significance.

5.7 LIMITATION

The study encountered some limitations as follows,

Microdiet software version 3.0 which was used to convert usual food intake in grams into nutrients which did not contain some of the Ghanaian food items and therefore food items had to be substituted with similar ones listed on the software. This may have affected the nutrients generated.

The sample size (100) was small which cannot be generalized.

5.8 CONCLUSION

Findings from the study showed majority (58%) of the participants had moderate Mediterranean diet score and 55% had good glycaemic control. There was no significant relationship between Mediterranean diet score and glycaemic control even though it correlated positively. This implies that dieticians can use Mediterranean diet in counseling and planning diet for diabetes patients to ensure optimal outcome.

CONTRIBUTION TO KNOWLEDGE

The study has provided information on how diets of diabetes patients at the National Diabetes Management and Research Centre conform to the Mediterranean diet.

The study has shown the proportion of diabetes patients at the Centre with well controlled blood sugars.

The study has shown that Mediterranean diet did not correlate significantly with glycaemic control among study participants.

5.9 RECOMMENDATION

- Nutrition education should be incorporated into the routine management of diabetes at National Diabetes Management and Research Centre.
- Dieticians should use the Mediterranean diet in the counseling and planning of diet for diabetes patients to optimize outcomes of management.
- Further research in this area is recommended which shall investigate the number of diabetes patients who have seen dietician.
- Further studies using larger sample size is recommended.

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APPENDIX I

DEPARTMENT OF NUTRITION AND DIETETICS, SCHOOL OF BIOMEDICAL AND ALLIED HEALTH SCIENCES

INFORMATION SHEET

Title: Mediterranean Diet Score and Glycaemic Control of Patients with Type 2 Diabetes at Korle-Bu Teaching Hospital

Participant Name: …… Participant ID ……

Over the past few years, there has been a worldwide increase in the incidence of type 2 diabetes mellitus with associated increase in mortality. Dietary intake is a major component of lifestyle modifications which has been shown to be effective in the prevention and management of type 2 diabetes. In particular research has shown that conforming to the Mediterranean style of eating, significantly reduces the incident of type 2 diabetes, and also effectively manages it. Most of these studies have, however, been done outside Ghana. We are therefore carrying out a study to determine the Mediterranean diet score of people with diabetes in Ghana and how it affects their glycaemic control.

You are hereby being invited to participate in the study. When you agree to take part in the research, you will spend a few minutes answering questions about yourself and your dietary and medical information. We will also measure your blood pressure, height, weight, waist circumference, hip circumference and body composition. Height will be measured using Seca Stadiometer. You will be required to stand on the platform for your height to be measured in centimetre. Your weight, percentage body fat, visceral and muscle mass will be measured using Omron body composition monitor. You will be required to stand with bare feet on the equipment for your measurement to be taken. The information we ask about yourself may

make you feel uncomfortable. This risk is, however, not more than you will normally be exposed to when you report to the clinic for check-up.

In addition, 2 mls, the equivalent of half a teaspoon of blood, will be drawn to measure your glycated haemoglobin. This will not affect your health negatively in any way, besides, a similar amount of blood is what the laboratories normally demand when you report for such medical check-up. Please understand that taking part in the research is entirely voluntary. You are further to note that you may refuse to take part or withdraw from the study at any time without anyone objecting or refusing you care at the clinic.

Please be assured that all information you give us in this research will be kept confidential and secure. The information will only be available to the researchers conducting this study. You are further assured that if a report of this study is prepared for the scientific and medical community you will not be identified by name.

Please note that there may be no personal benefit to you. However, your taking part in the study will help us identify the closeness of our Ghanaian diet to the Mediterranean diet and how it affects glycaemic control. It will enhance dietary counselling of people with diabetes in our hospitals and improve dietetic care in Ghana.

Do you have any questions or concerns about this study?'' Should you later wish to have any matter or question relating to this research clarified, please contact Miss Cassandra Opoku Junior of Department of Nutrition and Dietetics, School of Biomedical and Allied Health Sciences, University of Ghana on 0550239470. Thank you.

APPENDIX II

CONSENT FORM

I have fully explained to …… ……..... the nature and purpose of the research and risks that are involved in its performance. I have answered and will answer to the best of my ability, all questions he or she might have relating to the study.

……. …… ……..

Signature Name of Research Team Member Date

I ……..... have read (or have had it read to me in a language that I fully understand) the proposed research and that I have understood what is going to be done. Also, any questions/concerns I have, have fully been explained to me by …….. My signature or thumbprint below indicates that I have understood what is going to be done and that I agree to take part in the study voluntarily.

…… Date: …….

(Signature/thumbprint of Study Participant)

……. Date: ……

(Signature: Witness)

APPENDIX III

QUESTIONNAIRE

Patient ID…… Date……

SECTION1: Demographic and Socioeconomic Information

1. Gender [ ] Male [ ] Female
2. Age……..
3. Residence……..
4. Ethnicity [ ] Akan [ ] Ga [ ] Ewe [ ] Northerner [ ] Other
5. Marital Status [ ] Married [ ] Single [ ] Divorced [ ] Widowed [ ] Separated [ ] Other……
6. Educational Background [ ] None [ ] Primary [ ] JHS [ ] SHS [ ] Tertiary
7. Employment status ……
8. Occupation ……
9. Monthly income [ ] GHC<500 [ ]GHC 500-1000 [ ]GHC 1,001-2,000 [ ] ≥ GHC2,000

SECTION 2: Clinical Information

10. Year you were first told you had diabetes …….
11. How many years have you lived with diabetes? ……..
12. How often do you visit the hospital for diabetes review (check-up)?

    ……. Year ……. Month …… Weeks

13. a) Are you on medication [1] Yes [11] No
13. b) If yes please indicate which option

    [I] Oral hypoglycaemic medication [II] Insulin [III] Both oral hypoglycaemic medication and insulin

13. c) Please tell us the names of your current diabetes medications

Name of medication	Dosage

SECTION 3: PHYSICAL ACTIVITY LEVEL

14. During the last 7 days, on how many days did you do vigorous physical activities like heavy lifting, digging, aerobics or fast bicycling for at least 15 minutes?

    …… days per week

    [ ] No vigorous physical activities

15. During the last 7 days how much time did you spend doing vigorous physical activities?

    -------- hours per day

    --------- minutes per day

    [ ] Don't know/Not sure

16. During the last 7 days, on how many days did you do moderate physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis for at least 30 minutes? Do not include walking.

    --------- days per week

    [ ] No moderate physical activities

17. During the last 7 days how much time did you spend doing moderate physical activities?

    -------- hours per day

    --------- minutes per day

    [ ] Don't know/Not sure

18. During the last 7 days, on how many days did you walk briskly for at least 30 minutes at a time?

    --------- days per week

    [ ] No brisk walking

19. During the last 7 days, how much time did you spend walking briskly?

-------- hours per day

--------- minutes per day

[ ] Don't know/Not sure

20. During the last 7 days, how much time did you spend sitting on a week day?

    -------- hours per day

    --------- minutes per day

    [ ] Don't know/Not sure

SECTION 4: ANTHROPOMETRY

a. Height (cm) …….
b. Weight (kg) …….
c. BMI (kg/m^2) ……
d. Percentage (%) body fat ……..
e. Visceral fat …….
f. Muscle mass ……

	1st reading	2nd reading
Waist circumference		
Hip circumference		

g. Waist-to-Hip Ratio ……

SECTION 5: QUANTITATIVE FOOD FREQUENCY

Please indicate how frequently you consume the following foods

Food	Number of times consumed/week	Portion size consumed
CARBOHYDRATE		
Sugar		
Banku		
Rice		
Yam		
Plantain		

Patients will be assisted to estimate portion sizes of the various foods consumed using food handy measures (example; standard cups, plates, ladles, spoons).

Food	Number of times consumed/week	Portion size consumed
Fufu		
Tuo Zaafi		
Kokonte		
Cocoyam		
Gari		
Wheat		
Oats		
Tombrown		
Hausa Kooko		
Corn Porridge		
Milo		
Bread		
Tea		
Kenkey		
Apapransa		
Kaffer		
PROTEINS		
Goat Meat		

Patients will be assisted to estimate portion sizes of the various foods consumed using food handy measures (example; standard cups, plates, ladles, spoons).

Food	Number of times consumed/week	Portion size consumed
Cow Meat		
Fish		
Crabs		
Shrimps		
Octopus		
Bush Meat		
Offals		
Chicken		
Snail		
Mushooms		
Egg		
Beans		
Milk		
Cheese		
VEGETABLES		
Okro		
Carrots		
Cabbage		

Patients will be assisted to estimate portion sizes of the various foods consumed using food handy measures (example; standard cups, plates, ladles, spoons).

Food	Number of times consumed/week	Portion size consumed
Green Beans		
Broccoli		
Lettuce		
Green Pepper		
Kontomire		
Garden Eggs		
Tomatoes		
Onion		
Dandelion		
Moringa		
Aleefu		
Gboma		
FRUITS		
Orange		
Pineapple		
Banana		
Apple		
Mango		

Patients will be assisted to estimate portion sizes of the various foods consumed using food handy measures (example; standard cups, plates, ladles, spoons).

Food	Number of times consumed/week	Portion size consumed
Guava		
Coconut		
Pawpaw		
Watermelon		
Grapes		
Sugar Cane		
Tiger Nuts		
DRINKS		
Alcoholic Drink		
Fizzy Drinks		
Brukina		
Asana		
Kalyppo/Juvita		
SNACKS		
Meat Pie		
Spring Rolls		
Rock Buns		

Patients will be assisted to estimate portion sizes of the various foods consumed using food handy measures (example; standard cups, plates, ladles, spoons).

Food	Number of times consumed/week	Portion size consumed
Chips		
Nuts		
OTHERS		
Tuna Flakes		
Corned Beef		
Sardine		
Bake Beans		
Mackerel		
Mayonnaise		
Salad Cream		
Ketchup		
Soy Sauce		
Margarine		
Salad dressing		

Patients will be assisted to estimate portion sizes of the various foods consumed using food handy measures (example; standard cups, plates, ladles, spoons).

SECTION 6: MEDITERRANEAN DIET SCORE

	Question	Yes	No	Nutritional issue to discuss in response
1.	Is olive oil the main culinary fat used?			**Choosing Healthier Fats** Olive oil is high in monounsaturated fat. Using unsaturated fats instead of saturated fats in cooking and preparing food is advisable.
2.	Are ≥ 4 tablespoons of olive oil used each day?			**Healthy fats are better than very low fat** Med diet is more beneficial than a very low fat diet in prevention of CVD. So replacing saturated with unsaturated fat is better than replacing it with carbohydrates or protein.
3.	Are ≥ 2 servings (of 200g/3 soup ladles each) of vegetables eaten each day?			**Eat plenty of fruits and vegetables** Eating a wide variety of fruit and vegetables every day helps ensure adequate
4.	Are ≥ 3 servings of fruit (80g =1 serving)e.g 1/4 watermelon, small size apple, 1 finger of banana, ½ medium size orange, I small size tangerine, 1/7 of a big mango, ¼ pear, ½ medium pawpaw, ½ small cup fruit salad eaten each day? (3 times each of these)			intake of many vitamins, minerals, phytochemicals and fibre. Studies have shown that eating plenty of these foods is protective for CVD and cancer.
5.	Is < 1 serving (100-150g or 3 match box sizes) of red meat/ hamburgers/other meat products eaten each day?			**Choose lean meats and consider cooking methods** Red and processed meats are high in saturated fat, can be high in salt and are best replaced with white meat or fish or vegetarian sources of protein. Grill or roast without fat, casserole or stir fry.
6.	Is < 1 serving (12g or 1 dessertspoonful/ tablespoon) of butter, margarine or cream eaten each day?			**Keep saturated fat low** These foods are high in saturated fat which can increase your blood cholesterol level. Choose plant-based or reduced-fat alternatives.
7.	Is < 1 serving (330ml or 1 bottle) of sweet or sugar sweetened carbonated			Excessive consumption of sugar-sweetened beverages can worsen many risk factors for CVD: keep consumption to < 1/day.

	beverages consumed each day?			
8.	Are≥ 3 glasses (of 125ml or 1 small wine glass) of wine consumed each week?			**Moderate alcohol intake with meals** While this does have some protective effect but there is no evidence that non-drinkers should take up drinking alcohol.
9.	Are ≥3 servings (of 150g or 1 cup) of legumes consumed each week?			**Include soluble fiber** These foods are high in soluble fiber and other useful nutrients. Regular consumption is advisable for raised cholesterol.
10.	Are ≥ 3 servings of fish (100-150g or 5 middle portions of fish) or seafood (200g or 8 medium sizes of snail, 5 big sizes of crab) eaten each week?			**Eat more oily and white fish** Oily fish is an excellent source of essential omega 3-fats. White fish is very low in saturated fat.
11.	Is a < 3 serving of commercial sweets/pastries (e.g. 9 pieces of doughnut, 3 spring rolls, 3 pieces of digestive biscuit)eaten each week?			**Eat more oily and white fish** Oily fish is an excellent source of essential omega 3-fats. White fish is very low in saturated fat.
12.	Is > 1 serving (30g or 1 dessertspoon or 12 pieces of small size) of nuts consumed each week?			**Snack on modest servings of unsalted nuts** Nuts are rich in unsaturated fat, phytosterols, fiber, vitamin E and iron, e.g. walnuts, almonds, hazelnuts
13.	Is chicken, turkey or rabbit routinely eaten instead of veal, pork, hamburger or sausage?			"White meat" choices are lower in saturated fat. Remove the skin and consider your cooking method.
14.	Are pasta, vegetable or rice dishes flavoured with garlic, tomato, leek or onion eaten > twice a week?			Using a tomato and garlic or onion or leek-based sauce regularly is a key feature of the Med diet.

TOTAL SCORE (total no. of "yes" answers)

APPENDIX 1V

PRINCIPLE AND DETERMINATION OF HbA1c ON THE MINDRAY BS 200E FULLY AUTOMATED CHEMISTRY ANALYZER

Quantitative determination of Haemoglobin A1c (HbA1c) in human blood was performed using the Mindray BS-200 analyzer. The principle of this method was based on the interaction of antigen and antibody to directly determine the HbA1c in the whole blood. Total haemoglobin and HbA1c have the same unspecific absorption rate to specific latex particles. When mouse antihuman HbA1c monoclonal antibody is added (R20), latex-HbA1c-mouse antihuman HbA1c antibody complex is formed. Agglutination is formed when goat anti-mouse IgG polyclonal antibody interacts with the monoclonal antibody. The amount of agglutination is proportional to the amount of HbA1c absorbed on to the surface of latex particles. The amount of agglutination is measured as absorbance. The HbA1c value was then obtained from a calibration curve. A Haemoglobin A1C calibrator set with catalog number H7541-CAL was employed and Haemoglobin/Glyco haemoglobin standards with catalog numbers H 7506 STD and G7540-STD were employed in each batch of run.

Exactly 2 ml of patient's whole blood was centrifuged at 5000 rpm for 5 minutes and 25 microlitres of concentrated red blood cells was pipetted into a test tube. About 50 microlitres of lying reagent was added to haemolyse the concentrated red cells for 15 minutes. The resultant haemolysate was placed into the BS 200 analyzer for subsequent reactions with antihuman HbA1c monoclonal antibody labeled (R20), and latex-HbA1c-mouse anti human, resulting in the formation of the HbA1c antibody complex which was read at an absorbance of 540 nanometres and the concentration of HbA1c obtained from a calibration curve.

APPENDIX V

Appendix XX: Contribution of Mediterranean diet score to glycaemic control in a binary logistic regression model after adjusting for gender.

	B	P – value	Odds ratio	95% C. I. for odds ratio		Nagelkerke R^2
				Lower	Upper	
Mediterranean diet score	-0.291	.451	.747	.350	1.595	.047
Gender	-.902	.069	.406	.153	1.073	
Constant	2.082	.136	8.017			

Appendix XY: Contribution of body composition indicators to glycaemic control in a linear regression analysis.

Model	Unstandardized Coefficients		Standardized Coefficients	T	Sig.	95.0% Confidence Interval for B	
	B	Std. Error	Beta			Lower Bound	Upper Bound
(Constant)	11.002	4.193		2.624	.010	2.676	19.327
BMI	.025	.072	.071	.343	.732	-.118	.167
Total body fat	-.059	.058	-.290	-1.020	.310	-.173	.056
Visceral fat	-.093	.062	-.239	-.1.515	.133	-.216	.029
Muscle mass	-.089	.088	-.221	-1.005	.317	-.265	.087
Waist-to-hip ratio	1.377	2.559	0.55	.538	.592	-3.705	6.458

*: Linear regression analysis: significant at $p \leq 0.05$. ($p = 0.461$; $R2 = 4.7\%$)

Body composition parameters did not significantly account for HbA1c among study participants.

Appendix XZ: Contribution of macronutrients and dietary fibre to glycaemic control in a linear regression analysis.

Model	Unstandardized Coefficients		Standardized Coefficients	T	Sig.	95.0% Confidence Interval for B	
	B	Std. Error	Beta			Lower Bound	Upper Bound
(Constant)	6.859	.731		9.379	.000	5.407	8.311
Energy	.000	.001	.074	.582	.562	-.001	.001
Carbohydrate	.000	.002	.021	.143	.886	.409	-.011
Protein	.008	.009	.114	.829	.409	-.011	.026
Fat	-.009	.007	-.175	-1.389	.168	-.023	.004
Fibre	.001	.015	.005	.039	.969	-.028	.029

*: Linear regression analysis: significant at $p \leq 0.05$. ($p = 0.763$; $R^2 = 2.7\%$)

Micronutrients, energy and dietary fibre did not significantly account for HbA1c among study participants.