An-Najah National University
Faculty of Graduate Studies

The Effect of Whole Food, Plant-Based Diet and Low Fat Content on The Glycaemic Control and Quality of Life in a Group of Type 2 Diabetes Patients: A Pilot Study

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This Thesis was Defended Successfully on 29/5/2018 and approved by

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3. Dr Ahmad Eid / Internal Examiner	**.....**

Dedication

People are alike in their feelings and emotions. All people get rid of tiredness of morning or evening to live better.

I dedicate this study to all people, hoping long life without diseases, problems or obstacles.

Acknowledgement

I would like to present my thanks and gratitude for my supervisor Dr Mohammad Altamimi for his support, patience, and motivation.

Moreover; deepest thanks to my wife, family, and to all people who took part in making this thesis real.

I would like first to thank the person who inspired me to write my thesis Dr. Munjed Amin the family doctor, and my study colleague. I would like to express my sincere gratitude to my friend and also my study colleague the engineer Zuhair Dwaikat who supported me a lot during my long journey in searching for knowledge. I also would like to thank my friend Dr. Fahd Abuzant.

I'm also grateful to all people who supported me and provided me with power and energy to accomplish my research and spread knowledge to everyone.

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Finally, I would like to acknowledge the work of Dr. Barnard Neal, and I'm gratefully indebted to his valuable ideas that I have pointed in this study.

الإقرار

أنا الموقع أدناه، مقدم الرسالة التي تحمل العنوان:

The Effect of Whole Food, Plant-Based Diet and Low Fat Content on The Glycaemic Control and Quality of Life in a Group of Type 2 Diabetes Patients: A Pilot Study

تأثير الغذاء المرتكز على النباتات بمجموعها والقليل المحتوى من الدهون على السيطرة على تحلون الدم وجوده الحياه في مجموعة من مرضى السكري النوع الثاني : دراسة استطلاعية

أقر بأن ما اشتملت عليه هذه الرسالة إنما هو نتاج جهدي الخاص، باستثناء ما تمت الإشارة إليه، حيث ان هذه الرسالة كاملة، أو أي جزء منها لم يقدم من قبل لنيل أي درجة أو لقب علمي أو بحث لدى أي مؤسسة تعليمية أو بحثية أخرى.

Declaration

The work provided in this thesis, unless otherwise referenced, is the researcher's own work, and has not been submitted elsewhere for any other degree or qualification.

Student's name: **اسم الطالب:**

Signature: **التوقيع:**

Date: **التاريخ:**

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The Effect of Whole Food, Plant-Based Diet and Low Fat Content on The Glycaemic Control and Quality of Life in a Group of Type 2 Diabetes Patients: A Pilot Study

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Abstract

Background: Chronic diseases including diabetes are of high concern in the Palestinian community as they became the major cause of death. Life style such as diet is a modifiable risk factor that may play a major role to alleviate diabetes' mortality and morbidity.

Material and Methods:

First study: Fifteen diabetic patients aged 50.9 ± 6.5 years who were diagnosed with diabetes at least 5.0 months ago participated in a pilot study for 12 weeks to assess the effect of whole-food, plant-based diet on their diabetes features. Participants were 2 females and 13 males with the following baseline measurements (means±SD); 30.2 ±5.2 kg/m^2, 189.2 ± 77.2mg/dL and 9.4 ± 2.5% for body mass index [BMI], fasting blood glucose [FBG] and HbA1c respectively. There was no restriction on the energy and protein intake came from plant sources however, processed and refined food items were restricted.

Second study: Two matching groups of DM patients were recruited to assess their quality of life. The first one is the intervention group (IG) from the first study, included 15 patients, was assigned to whole-grain food plant

based diet for 12 weeks with no medication to DM. The second one was a control matching group (CG), of 15 patients, was assigned to conventional diet and medications to DM. At the end of follow up period both groups filled WHO Qol-bref questionnaire which contained 4 domains; Physical, psychological, social and environmental.

Results: First study: Participant's adherence to the dietary programme on a scale of 0 -10 was 8 ± 1.5. Their endpoint BMI, FBG and HbA1c were 28.7 ± 4.3 kg/m^2, 102.9 ± 19.6 mg/dL and 6.15 ± 0.8 %, respectively.

Weight loss was significantly correlated with baseline body weight, baseline BMI and time since diagnosis with diabetes. While Baseline FBG was correlated with baseline and endpoint HbA1c [$p<0.01$], However, it was not significantly correlated with endpoint body weight [$p<0.08$] and BMI [$p<0.018$].

Second study: The results of WHO qol-bref for the intervention group have shown improvements in all 4 domains of the questionnaire regarding quality of life in comparison to the control group of patients with diabetes and taking regular medications. Physical domain average scores were 57.7 point (±11.9) and 65.6 point (±5.4) for control and intervention groups respectively. Psychological domain average scores were 42.9 point (±17.2) and 64.8 point (±6.6) for control and intervention groups respectively. Social domain average scores were 39.8 point (±17.4) and 72.6 point (±14.4) for control and intervention groups respectively and environmental domain average scores were 52.3 point (±12.9) and 60.5 point (±7.5) for

control and intervention groups respectively. All domains' results were significantly different ($p<0.01$ for domain 2 and 0.05 for domains 1, 3 and 4).

Conclusion: This study has shown that management of anthropometric parameters (weight and BMI) through diet, such as whole-food, plant-based diet, has resulted in a significant reduction in diabetes parameters such as FBG and HbA1c. In addition to improvement in patient's quality of life.

1. INTRODUCTION

Modern life style is characterised by a plethora of pros and cons started with the easiness and convenience to get food and high reliance on technology in almost everything. As a result, physical inactivity and obesity have become predominant. Chronic diseases such as cardiovascular diseases, cancer and diabetes, which are another face of modern life, are affecting every house in the developed society.

In Palestine, chronic diseases became the major cause of death largely due to a shift in life style from traditional to western type of life. The traditional way of life in Palestine was very close to the healthy life style known as the Mediterranean diet, however, due to urbanisation and deterioration of agricultural land [constituting 15.5% of the total area of Palestine [1]. Palestinians became more reliable on convenient (ready to eat or easy to prepare) foods from shops and markets. Palestinians are spending more than a third of their income on food items which in averages as JD 58.8 out of JD 165.0 per month per capita [1]. Major spending is on bread products and cereals and meat (red meat and poultry). Such a shift from traditional life style in Palestine may have consequences on health. It was reported that prevalence of Diabetes mellitus in Palestine was 9.7% in 2000, increasing to 15.3% by 2010 with a forecast to reach 20.8% for 2020 and 23.4% for 2030 [2].

With limited resources, the burden of diabetes care is huge on both individual and national levels. Moreover, the quality of life of a person

having diabetes is affected, as most of complications are serious and are ending up with disabilities. The primary care of diabetics is based on medically agreed protocols starting with glucose regulators followed by doses of insulin and in most cases medications of blood pressure are prescribed.

The main aim of such a protocol is to establish a glucose homeostasis, however, reversing the ability of tissues to be insulin sensitive never happened [3]. It is very often that physicians flout the potential values of good nutrition and promptly prescribe medications instead of giving patients a chance to modify their disease through healthy eating and active living [4].

Changes in life style of diabetics including type of diet is more effective than medications alone not only to establish healthy glucose homeostasis but also to reverse diabetes [2].

Therefore, the main aim of this study is to:

Investigate the effect of plant based diet on glycaemic features of type 2 diabetic patients.

Objectives of the study:

1. To apply plant based diet on a group of type 2 patients.
2. To study the adherence of patients to the diet and its correlations with diabetes.

3. To report body weight changes and its correlation with diabetes.

4. Compare the quality of life of 2 groups of type 2-diabetics where control group consumed conventional diet and interventional group consumed plant-based diet.

2. LITERATURE REVIEW

2.1 Diabetes Types, prevalence and consequences

Diabetes mellitus (DM) can be defined as a systemic metabolic disease with both disturbances in carbohydrate, fat and protein metabolism and chronic hyperglycaemia which result from a trouble in insulin secretion or action or both [5].

There are two main types of diabetes; Type 1 diabetes is caused by autoimmune destruction of pancreatic cells which in turn leads to less insulin production. It usually takes place in young individuals with full dependence on insulin injections. Type 2 diabetes is characterised by insulin secretion with resistance to its actions. It affects mainly the middle-aged and elderly people (although it is largely being observed in obese young individuals).

Type 2 diabetes accounts for 90-95% of diabetics [6]. In known cases, abnormal insulin response to hyperglycaemia caused by β-cell dysfunction coexist usually with insulin resistance. It is not obvious which is the primary abnormality [5]. Its frequency varies in different racial/ethnic subgroups and it is often associated with a strong genetic predisposition [6]. In type 2 DM, symptoms gradually develop and are not noticeable even with hyperglycaemia and insulin levels normal or elevated. Having hyperglycaemia with hyperinsulinemia and β-cell function normally results in the amount of insulin is not enough to cause insulin-

resistance level. Hyperglycaemia primarily results from increased production of glucose by the liver and the less removal of glucose from blood which in turn causes glycosuria.

Other life threatening conditions of uncontrolled diabetes are ketoacidosis especially with type 1 diabetes, non-ketotic hyperglycaemia or lactic acidosis [5]. Serious complications caused by chronic hyperglycaemia affect and damage different organs particularly the eyes, kidneys, nerves, heart and blood vessels. Symptoms of such complications include polyuria, polydipsia, blurred vision and weight loss that sometimes accompanied with polyphagia [6].

2.2 Diagnosis

Random blood glucose level can be useful in patients with symptoms and extreme hyperglycaemia but it is not always diagnostic. Fasting blood glucose (FBG) can be measured after at least 8 h over-night fasting and it is considered the preferred method. Other methods include oral glucose tolerance test which is considered more sensitive and modestly more specific than FBG for diagnosis. However, it is not used routinely for diagnosis except in pregnancy. On the other hand, glycosylated haemoglobin (HbA1c) is very useful tool for monitoring glycaemic control over a period of time, however, it has some disadvantages such as the lower sensitivity of A1C at the designated cut point, greater cost, limited availability of A1C testing in certain regions of the developing world, and the imperfect correlation between A1C and average glucose in certain

individual [7 ,8]. Therefore, it is important to recognize that A1C is an indirect measure of average blood glucose levels, such levels may be affected by health status, age and race of the individuals.

Table 1summerises the criteria used for diagnosis of diabetes according to the American Diabetes Association 2017 [8].

2.3 Diabetes Aetiology and risk factors

Environmental factors are implicated in the incidence of diabetes; many patients are reported to be obese especially with visceral (intra-abdominal) obesity, in addition to decreased physical activity amongst diabetic patients [5]. However, specific aetiology for DM is not known [6]. There is a wide range of risk factors including non-modifiable factors such as ethnicity, race, familial aggregation, genetic susceptibility, age and gender.

Table (1). Criteria for the diagnosis of diabetes according to ADA (2017)

FBG ≥126 mg/dL (7.0 mmol/L). Fasting is defined as no caloric intake for at least 8.
Or
2-h BG ≥200 mg/dL (11.1 mmol/L) during an Oral Glucose Tolerant Test. The test should be performed as described by the WHO, using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water.
Or
HbA1C ≥6.5% (48 mmol/mol). The test should be performed in a laboratory.
Or
In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose ≥200 mg/dL (11.1 mmol/L).

Adapted from [7]

Whereas, modifiable factors include obesity, percentage of body fat and its distribution, lack of physical activity, diet, smoking, alcohol abuse, changing life style (urbanization), gestational diabetes and low birth weight [9 -10].

In this section we are going to shed the light on some of the modifiable factors as they are part of the life style one can change to decrease both the diabetes incidence and its impact.

2.3.1 Obesity, Weight gain and Fat Distribution

Obesity, overall obesity and factors related to obesity are associated with increased incidence of type 2 diabetes [11]. Abdominal obesity, total fat and distribution of fat are associated with high risk for diabetes [12 and 13]. Also abdominal obesity (visceral fat) with low BMI are associated with DM. High calorie intake is related to obesity and diabetes [14]. Prevalence of obesity in USA adults has increased dramatically and it is associated with several health risks and diseases including diabetes regardless to gender, educational level, race, age, and smoking levels [15]. Comorbidities associated with obesity are well documented and prevention of obesity has eliminated a great risk for type 2 diabetes [16]. In a cohort study, an increase of 1kg in body weight increased the risk of having diabetes by 4.5% [17]. While a prospective study, for 13 years involving more than a million participants, has shown that intentional weight loss has eliminated risk of type 2 diabetes [18]. Another prospective study considered studying annual changes in weight over 10 years had shown

that an increased risk of diabetes in overweight adults and that any weight loss has reduced the risk [19]. Unplanned fasting and elevated postprandial glucose results accompanied with obesity and sedentary life style also were associated with high risk of diabetes [20]. Reducing weight, total fat and saturated fat, increasing fibre intake and physical activity in patients with diabetes for 3.2 years have remarkably improved their diabetes markers measured by glucose-tolerance test orally [21]. High BMI is associated with high risk for type 2 diabetes, however, it differs between black and white Americans due to fat distribution. In this context, high visceral fat was the main player affecting incidence of diabetes regardless to BMI of an individual [22 - 24]. Furthermore, incidence of diabetes related to fat distribution shows that central obesity related to type 2 diabetes in females is more frequent than men [25]. Other factors related to obesity such as early obesity, adulthood obesity and abdominal obesity are also considered risk factors [26 and 27]. In the nurses' health study central obesity was associated with insulin resistance and type 2 diabetes [28].

2.3.2 Diet

It was reported by many studies that diet is a major risk factor in developing diabetes qualitatively and quantitatively. Sugar-sweetened beverages increase obesity and further may be associated with diabetes [29]. Consuming fructose-sweetened beverages will increase visceral adiposity leading to a decrease in insulin sensitivity and high blood glucose levels [30]. Increased animal fat intake, edible oil, added sweetener such as

fructose corn syrup, increased intake of foods of animal sources are factors related to obesity and increased risk for type 2 diabetes [31]. High-Glycaemic Index (GI) diet such as refined grain products, polished white rice [32] and in general low fibre food with high GI and Glycaemic load (GL) increases the risk [33]. A study conducted in China has indicated that high GI and GL foods, in particular consumption of rice, increased the risk for diabetes [34]. In the USA consumption of brown rice instead of white rice was found to decrease the risk in women and men [35]. Trans-fat, vegetable and animal ghee intake was shown to increase the risk of diabetes [10]. In a follow-up study saturated and total fat in food have been associated with high risk [35]. Total and saturated fat intake have been associated with a higher risk values such as fasting insulin concentration compared to starch and fibre intake in a prospective study [36]. Also, high fat low carb diets are considered as risk factors [37]. Consumption of red meat and processed red meat was considered as a risk factor for the development of type 2 diabetes [38]. Many evidence showed that processed meat has increased the risk of diabetes [39-41]. For example, in a meta-analysis of cohort studies found that high intake of red meat and processed meat was associated with diabetes [38]. Moreover, the women's health study, prospectively, showed that high intake of red and processed meat are risk factors for developing diabetes type 2 [42 and 43]. On the other hand, it was reported that iron from meat is a high risk factor [44]. In a cohort study high haem-iron intake, came mainly from animal source, has increased the risk of type 2 diabetes [45]. Haem-iron, which is provided

largely by animal sources, is associated with such a high risk while non-haem dietary iron (from plant sources) is not a risk factor. Interestingly, blood donation decrease ferritin level and improve insulin sensitivity [43]. It is worth to say that meat consumption, which was related to obesity in men and women, was found to be associated with developing type 2 diabetes [46 and 47]. Studies on nutrients intake and its association with type 2 diabetes are summarised in Fig 1 and Fig 2. These two figures clearly show that some food items or nutrients are associated with the risk of incidence of type 2 diabetes (relative risk more than 1.0) while other food items or nutrients (relative risk less than 1.0) are considered protective against type 2 diabetes.

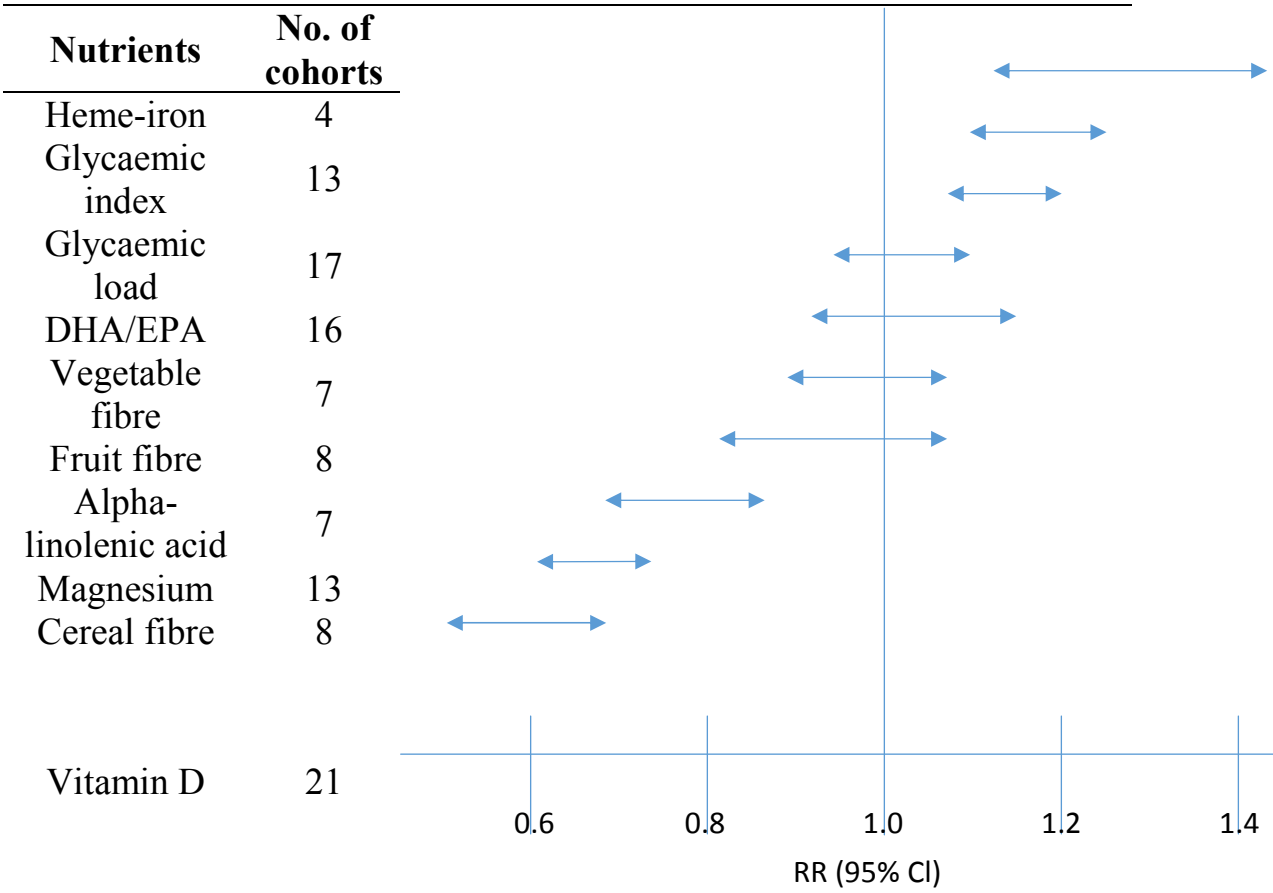

Fig. (1) Summary of meta-analysis of prospective cohort studies on nutrient intake and type 2 diabetes relative risk.

Where: DHA is docosahexaenoic acid; EPA is eicosapentaenoic acid and Relative risks [RR]. All nutrients were assessed from food intake except vitamin D blood 25-hydroxyvitamin D values were used. Adapted from [14]

Foods	Number of cohort
Processed meat	9
Unprocessed red meat	9
Fish /seafood	13
White rice	7
Green leafy	4
Green leafy European	5
Sugar-sweetened beverages	8
Sugar-sweetened beverages European	8
Coffee	28

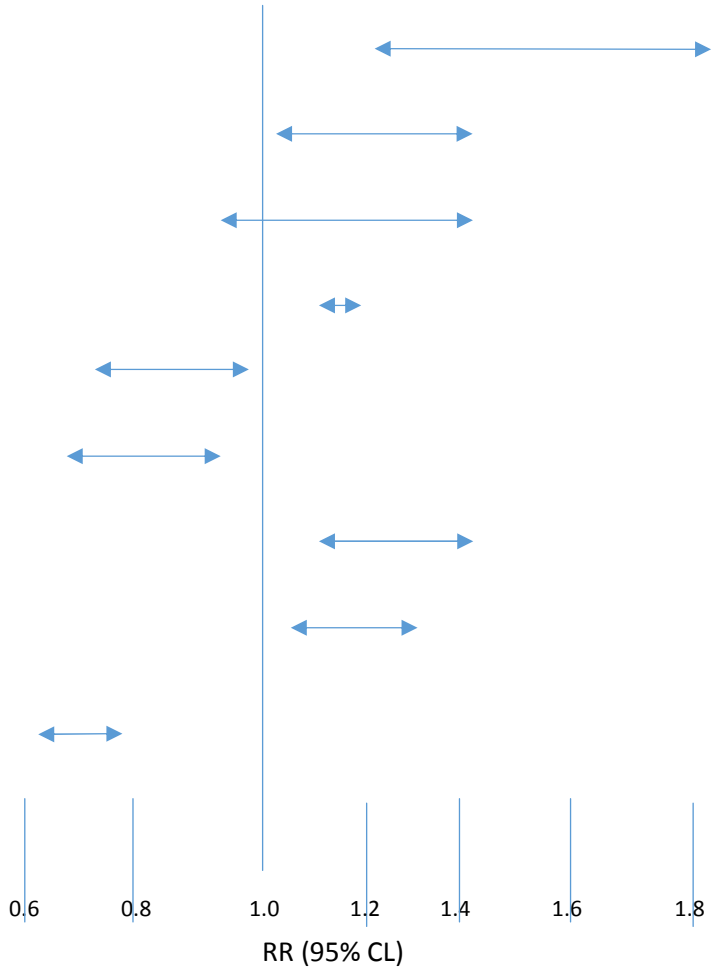

Fig. (2) Summary of meta-analyses of prospective cohort studies on food and beverage intake and type 2 diabetes relative risk.

Relative risks (RR) are comparison of extreme categories, except for processed meat (per 50 g/d increase), unprocessed red meat and fish/sea food (per 100g/d), white rice (150g per each serving/d), whole grains (per 3 servings/d), sugar-sweetened beverages in European cohorts (per 336g/d), adapted from [14]

2.3.3 Physical activity

There are loads of evidence confirming that sedentary lifestyle, spending hours watching screens (TV, mobile phones, electronic games etc.), reduced energy expenditure, increased snacking will lead to obesity. Moreover, type of profession, ways of transportation, use of technology can affect level of obesity [10]. In a systematic review of the effect of exercise training on HbA1c, it was found that aerobic exercise was associated with improvement of HbA1c, with >150 min per week having better results than <150 min [48]. Physical activity and exercise in general have led to a better insulin sensitivity, an improvement in pre-diabetes and gestational diabetes [49]. Diabetes complications also could be reduced by improvement in HbA1c accompanied by exercise [50]. Although some studies indicated that different forms of exercise have small benefits control of glucose [51], a meta-analysis has indicated that there was a significant improvement by exercise in controlling diabetes with reduced visceral adipose tissue [52]. In addition, a randomized trial of individuals aged from 39-70 years has been conducted. A sedentary control group and 3 exercising groups that performed a task 3 times a week for 22 weeks (aerobic training, resistance training and a combination of both). It was found that the best improvement has been achieved by a combination of resistance and aerobic exercise than aerobic exercise alone [53 and 54]. Stair climbing, walking, sports, physical activity in general were reported to act in preventing type 2 diabetes in most high risk individuals [55].

Moderate intensity physical activity for at least 30 min was reported to reduce the risk of type 2 diabetes [56].

2.3.4 Smoking

In a prospective study addressing the risk of smoking in developing diabetes, there was a positive association between smoking and insulin resistance on the short and long terms [56]. Another systematic review and meta-analysis study with 25 prospective cohort studies with 1.2 million participants. Follow up period ranged from 5 to 30 years. Association of increased risk of diabetes was found in active smoking (heavy) ≥ 20 cigarettes/day more than lighter and/or former smokers [57]. Abdominal obesity also was found to be associated with smoking and have dose dependent relation [58]. Another cohort study for 8 years involved 2312 individuals who received questionnaires by post, has indicated that there was an increased risk amongst individuals started smoking in younger age [59]. In addition to that study, in Japan it was found that amongst 1266 Japanese workers, 35-59 years of age, the number of cigarettes and years of exposure have positive relation to developing type 2 diabetes [60]. The adverse health effects of smoking are evident and smoking cessation may lead to reduced prevalence of diabetes [61 and 62]. Moreover, risk of diabetes may be increased in offspring of smoking mothers [63]. A Finnish prospective study in women and men found that risk of smoking for developing diabetes is independent to obesity level and/or physical activity. Furthermore, cessation of smoking has been found to reduce the such a risk

[64]. In the Coronary Artery Risk Development in Young Adults (CARDIA) study that included current smokers, previous smokers, never been smokers but exposed to second hand smoke, and never been smokers or exposed to second hand smoke, all participants were followed up for 15 years. The results showed that current smoking and exposure to smoke have increased the risk of diabetes. Also there was a dose response effect of smoking while exposure to smoke had an intermediate risk [65]. Smoking is not a risk factor to insulin resistance but also it is a contributing factor in developing metabolic syndrome and impaired glucose tolerance [66-67].

2.3.5 Gestational diabetes (GDM)

Women who experienced GDM or showed an insulin resistance and/or impaired insulin secretion are at high risk for developing type 2 diabetes if the same life style is maintained [68]. Women with GDM have higher risk for developing diabetes type 2 than women having impaired glucose test and no past history of GDM [69]. A follow up study for pre-gestational diabetes indicated that GDM has made an increased risk for developing DM type 2 [70]. On the other hand, a systematic review has examined the risk of developing type 2 diabetes in women with history of GDM. After delivery testing for glucose was required to monitor the risk of developing the disease. Although ethnicity may vary in the risk, mothers who were exposed to GDM were at higher risk of developing diabetes type 2 later in their lives provided that life style was kept the same [71].

2.3.6 Low-birth weight

The relation between low birth weight and developing the disease later in life was studied. During pregnancy poor nutrition to the foetus may be related to impaired β-cell function, however, low insulin is needed at that time. Later on as the infant grows, more food is ingested and more insulin is needed hence, the risk for developing diabetes increases [72]. It was also documented that decrease in birth weight was related to an increase in insulin resistance [73]. The risk of developing the disease was reported for both low and high birth weight infants [74]. Other study has indicated that in low-birth weight, developing insulin resistance later in life seems to be the risk for developing the disease rather than β-cells dysfunction and there is an interaction of obesity in the adulthood [75]. In Pima Indians population, low-birth weight infants were more insulin resistant than normal birth weight infants, and those with high birth weight had less insulin resistance but were more obese [76]. Poor nutrition during critical times of pregnancy was linked to the development of impaired glucose tolerance in adulthood, also it was linked with increased obesity as indicate by a study on individuals lived a famine experience [77].

2.3.7 Breastfeeding

Breastfeeding is associated inversely with developing type 2 diabetes [78]. In native Canadian children reduction in the risk of type 2 diabetes was observed due to breast-feeding and adoption of breastfeeding policy has reduced the incidence of the disease on the population level (79]

2.4 Diabetes management and diet

According to American diabetes association [ADA, 80], the main goals for a nutritional programme that addresses diabetes are:

- To promote and support healthy eating patterns with wide range of food categories and proper size portion.
- To address individual nutritional needs based on personal and cultural preferences.
- To maintain the pleasure of eating by providing positive messages about food choices while limiting food choices only when indicated by scientific evidence.
- To provide the individual with diabetes with practical tools for day-to-day meal planning rather than focusing on individual macronutrients, micronutrients, or single food [81].

Acceptance of any diet related to nutritional therapy for adults with diabetes emerges from achieving the goals that the American diabetes association has approved. One of the healthful eating pattern is plant based diets [81]. The current position of the American Dietetic Association is that appropriately planned vegetarian diets, including total vegetarian or vegan diets, are healthful, nutritionally adequate, and may provide health benefits in the prevention and treatment of certain diseases. Moreover, well-planned vegetarian diets are appropriate for individuals during all stages of the lifecycle, including pregnancy, lactation, infancy, childhood, and

adolescence, and for athletes [81 and 82] Improvement in chronic diseases by adopting plant-based diets is emerging with many supportive evidence. For instance, lowering HbA1c, loss of weight, improved insulin sensitivity, in addition to reduction in the need for medication for hypertension and CHD [81]. Vegan and vegetarian diets are nutritionally adequate by appropriate planning to manage type 2 diabetes [81]. Dietary patterns must be considered together with all food consumed rather than a single food item [83]. HbA1c levels can be reduced by vegetarian diet [84]. And incidence reduction in diabetes was also obtained by adopting plant-based diet [85]. A low fat plant-based diet improves body weight and plasma lipids in addition to glucose sensitivity [86] during fasting without exercise [87]. Improvement of CHD seen in adopting vegetarian diets also may prevent diabetes partly due the active ingredients the diet contains which protect from inflammation and oxidation [88]. Improvement was also reported on weight and insulin sensitivity [89], low LDL and total cholesterol concentration [90] improvement in lipids and glycaemic results [91]. High-carbohydrate, high-fibre diet lowers insulin doses and improve glucose results [92]. Vegan diets protect from CVD, and also protect beta-cells [93]. Adopting plant-based diets may improve diabetes markers reduce risk factors that promote the onset of diabetes [94]. Vegetarian diets affect the quality of life by decreasing the feel of hunger, improving mental health and mood and physical performance [95]. Decreased insulin resistance and improved oxidative stress markers were also reported [96]. On the other hand, vegan diet improves the quality of life and individual's

productivity in a low cost manner [97]. A low fat-plant-based diets consisting of whole grains, vegetables, legumes and fruits without restriction of amounts or messages about choices, in addition to minimizing oil and preference to low GI foods, leads to health effects on weight, lipids and glucose in diabetics [98 and 99].

2.4.1 Dietary patterns

According to what has been illustrated above about diet as a risk factor for developing type 2 diabetes, it is certain that diet is a modifiable risk factor and changing of diet may help in preventing or even treating the disease and achieving the nutritional goals of the American diabetic association [100]. Dietary patterns including low carbohydrate, Mediterranean diet, Alternative healthy eating index (AHEI), Dietary Approaches to Stop Hypertension (DASH), low fat dairy products, low GI, high protein diets may help [101 and 102]. Moreover, in a meta-analysis of randomised-control trials (RCTs) it was shown that dietary patterns including the aforementioned diets were effective in controlling diabetes [101]. In a systematic review related to type 2 diabetes control and prevention found that patients adopting Mediterranean diet improved glycaemia and lowered the risk of developing diabetes type 2 in a clear association between adherence and level of improvement [103]. Alternate healthy eating index [AHEI) may reduce the risk of chronic diseases such as diabetes type 2 [104]. For low-fat dairy pattern the risk of developing diabetes type 2 may also be lower [105]. DASH eating pattern contains

fruits, low fat dairy products, vegetables, nuts, seeds, whole grains, limited amount of meat, poultry, eggs, fats and oils may prevent diabetes type 2 if adherence to the diet was tangible [106]. Vegetarian diets, from vegan to lacto-ovo-vegetarian, lacto-vegetarian, pseco-vegetarian to semi-vegetarian have protection effect against diabetes with vegan and lacto-vegetarian being the most effective in protection and controlling diabetes than other patterns [107].

For the purpose of this study the following sections will be focused on; vegetarian, Mediterranean and low-fat diets as they are very relevant to the scope of this study.

2.4.1.1 Definition of vegetarian diets

Vegetarian dietary patterns have some variations and versions. Diets that exclude meat, poultry, fish, dairy, eggs and all food products that have any animal origin is known as vegan. While diets that avoid meat, poultry, fish and allow grains, legumes, vegetables, nuts, seeds, dairy, eggs are known as lacto-ovo-vegetarian [108].

2.4.1.2 Definition of Mediterranean diet

Mediterranean diet (MD) is a description of the life style and related food items presented in the Mediterranean region. Such a region is heterogeneous of its geographical, racial, habits and traditions, plantations and socioeconomic components, however, traditional MD common components are high intake of olive oil (as a major source of fat),

vegetables, fruits, whole grains, legumes, moderate intake of dairy products and low intake of red and processed meat. Some variations of MD were reported in each individual country depending on the staple food of that particular area; for example, coastal regions were more dependent on sea foods and fish [109].

2.4.1.3 Definition of low fat plant based diet

Whole-foods, plant-based, low-fat diet is the diet that encourages plant foods in their whole form, such as vegetables, fruits, legumes, and seeds and nuts (in smaller amounts). For maximal health benefits this diet limits animal products in all forms with more restriction on processed red meat. Total fat such as pressed and purified vegetable oils (e.g. sunflower, soy and canola oils) are also restricted [110].

It was reported since 1935 that high-carbohydrate low fat diet had decreased insulin need by 57% at the end of 5-year treatment period and sugar levels were better than lower carbohydrate diet and higher fat content diet, in addition clinically patients looked and felt well, digestive tract disorders were improved, increased vitality. There was a decrease in diabetic coma, a decrease in acetonuria from 9% to 2%. Therefore, high-carbohydrate low-fat diet has a potential effect in controlling diabetes [111].

A list of some dietary approaches and their outcomes regarding diabetes are summarised in Table 2.

Table (2) Summary of main dietary approaches targeting Type 2 diabetes and main outcomes. Adapted from [109].

	Main components	Diabetes prevention	Diabetes management
Mediterranean diet	High consumption of minimally processed plant food, olive oil as principal fat. Low consumption of red meat	Associated with lower risk of Type 2 diabetes in many studies.	Compared with convectional diet improved glycaemic control and insulin sensitivity.
DASH diet	Rich in vegetables and fruits, low fat dairy products, whole-grain, poultry . low in saturated fat meat, sweets and sugars and salts.	Associated with lower risk of Type 2 diabetes	Restriction of salt to 2400mg/d has effect on glycaemic control and risk from CVD.
Vegetarian and vegan	Devoid all animal products.	Associated with lower risk of Type 2 diabetes	Improve glycaemic control, inconsistent for CVD and calorie restriction was difficult to be isolated

3. MATERIALS AND METHODS

3.1 Dietary programme design

This pilot study represents a trial of using plant-based diet as nutritional management for diabetes. Whole grains, vegetables, legumes and fruits are the main components of the diet, while animal products, meat, poultry, fish, dairy products and eggs are avoided. Moreover, oils are minimised to less than 3g per day and eating low GI foods was encouraged [99]. Low-fat plant-based diets as planned by clinical trials usually contain 10% of energy from fat, 15% protein and 75% carbohydrate which include vegetables, fruit, grains, and legumes and avoidance of meat, dairy products and eggs, added oils, fried products, avocadoes, nuts and seeds [112]. Another trial design for vegetarian diet include (25% fat, 15% protein and 60% carbohydrates) come from vegetables, legumes, fruits and nuts. Animal- containing food should be limited to a maximum of 1 portion of low-fat yogurt a day [113]. Another version of this diet is as follows; eating until satiety without counting calories of whole grains, legumes, vegetables and fruits while avoiding refined oils, meat, fish, eggs and dairy products, processed foods nuts, avocadoes, sugar, salt, and caffeinated beverages in addition, to providing individual with B12 supplements (50 micrograms daily). This will provide 7-15% of total energy from fat [114] and can be achieved by complete avoidance of refined oils, animal products, eating whole wheat flour, rice, corn, oats, barely, quinoa, potatoes, sweet potatoes, beans, peas, and lentils, fresh fruits, non- starchy

green, leafy vegetables, orange and yellow vegetables. More diet designs were experimented; these contain 7% fat, 12% protein and 81% carbohydrates with no restriction on quantities [115]. Vegan diet containing brown rice and eating low glycaemic index food with no restriction on portion and energy consumed while avoiding polished rice, processed food made from rice-flour, or wheat flour and animal food products is another design to conduct similar experiment [115]. This dietary programme will be used in this study to assess its effect on diabetes.

3.2 Subjects recruitment and ethical approval

This study took place in the city of Nablus, Palestine during the period of April 2017 to February 2018. For the first study all patients were recruited after referral from their physicians then enrolled in a 12-week dietary programme to assess the effect of plant-based diet on their diabetes parameters. Dietary programme and the study procedures were approved by the Institutional Review Board (IRB), An-Najah National University number IRB (10 Feb-2017). All patients were interviewed for at least 1 hour and given detailed explanation about the dietary programme, then they signed a written consent before the commencement of the study.

3.2.1 Subjects

All patients were confirmed to be diabetic by their physicians accompanied by recent results of their blood analysis. Inclusion criteria were; age 30-70 years, with diabetes for less than 1 year, and hyperglycaemic with HbA1c above 6.2. Exclusion criteria were:

pregnancy, having medication for diabetes or its complications or following a diet plan for any reason (i.e. weight loss plan). None of the patients has received any kind of incentive for their participation. Fifteen patients were eligible and have been recruited in this open randomised pilot study. Participants who were eligible to enrol the study were from both genders.

3.3 Measurements

Anthropometric measurements of all patients were taken and body mass index (BMI = person's weight in kilograms (kg) divided by his or her height in meters squared) was calculated at the beginning of the study and at the end using Centre for disease and control prevention (CDC) calculator, (2015)[116]. https://www.cdc.gov/healthyweight/assessing /bmi/adult _bmi/metric_bmi_calculator/bmi_calculator.html. BMI was categorised according to the international classification of BMI (kg/m^2) in adults suggested by WHO as "underweight" (<18.5), "normal weight" (18.5-24.9), "overweight" (25.0-29.9) and "obese class I-III" (30.0-34.9, 35.0-39.9 and ≥40, respectively) [117]

The recent baseline fasting blood glucose and HbA1c were either taken from patients' files or were analysed in a private laboratory. Similar measurements were taken after 12 weeks.

3.4 Food frequency questionnaire (FFQ)

A food frequency questionnaire containing 10 questions (Appendix 1) was filled by all patients prior to the start of the trial. Such a

questionnaire was comprised of 3 parts; part 1 included personal information, part 2 included health history and part 3 included food items frequently consumed in the last 3 months. Food categories mentioned in the questionnaire were based on modified Mediterranean diet (MMD) [118 and 119] as a reference and contained the following food items: fruits, vegetables, legumes, red meat, white meat, dairy products, fish, cereals and refined cereal products, processed meat, canned vegetables, nuts, soft drinks, juices and sweetened beverages, tea, coffee, traditional sweet and other sweet.

Frequency of food intake ranged from more than once a day to none within 3 months. Quantities of each food items were not recorded and FFQ was based on qualitative frequency, i.e. the number of intakes of any food item. Scoring of patient's food intake was based on closeness to MMD (Table 3) [119].

3.5 Dietary programme

All participants were interviewed using a face-to-face counselling method. Dietary programme was explained by the researcher. Then a list of allowed food items and not-allowed food items was given to each patients (Table 4). All participants were given no restriction to eat from the allowed list (*ad libtum*), hence, daily energy intake and other nutrients requirements were not calculated. The participants were advised to maintain their life style as before the trial with no extra physical activity or unusual change to their habits.

3.6 Programme compliance and follow up

During the period of the trial all patients were followed up and a weekly phone call was made for further counselling and to assess their adherence to the dietary programme .A scoring system was placed to assess such an adherence with scores from 0-10. If the participant fully adhered to the programme for a week, a 10-score adherence level was given. For any intake of the not-allowed list one point was taken out of 10. For example, if the patient ate red meat once a week and had cheese twice a week this will add up to 3 points then the patient's score will be 10-3= 7, for the corresponding week. The average of 12 scores representing the 12 weeks for each patients was calculated. During the follow up period, patients were also advised not to take any additional supplements or unusual herbal infusion (such as cinnamon, ginger tea etc.) that may interfere with glucose metabolism.

After the assigned period all participants were asked a question about their willingness to carry on the programme by their own.

3.7 Quality of life assessment

For the second study and in order to assess the changes of quality of life of intervention group who followed the dietary programme, their quality of life level was compared with a matching patients group (control) admitted the ministry of health (MOH) clinic in Nablus. This group was randomly recruited in parallel with the interventional group. Control group has the following criteria; they were on conventional diet (diet used by

none diabetic people), aged between 30-70, diagnosed with diabetes for at least 1 year, had their fasting blood glucose and HbA1c recorded after diagnosis for 3 consecutive periods and were taking medications for diabetes according to the MOH protocols. All patients' details were extracted from the patients file kept at the clinic.

Fifteen patients were eligible and met the inclusion criteria. Demographic, socioeconomic and health parameters are listed in Table 8. All patients of control group were interviewed face-to-face by the researcher. During the interview they filled a questionnaire about their quality of life during the last 3 months. The Quality of life Questionnaire, used here, was validated in 15 countries with different languages and life standards, and approved by the World Health Organisation (WHOqol-bref, 1996) [120] in its both Arabic and English versions.

Whoqol-bref questionnaire is composed of 26 items spread over 4 domains: physical, psychological, social relationships and environment. Each question has its score from 1-5 scale, where 1 represents very poor and 5 represents very good. Each domain has its scoring level then these scores are transformed into a scale of 0-100. Higher scores were representing better quality of life. Whoqol-bref questionnaire and scoring method is found in Appendix 2.

3.8 Statistical analysis

The main endpoints that were determined by this study were Fasting blood glucose and HbA1c of the tested group and their correlation with

diet. Therefore, different correlations were conducted to 1) determine if there were correlation between baseline and endpoint levels with dietary programme. 2) determine if adherence to the dietary program was associated with the changes in the endpoints. Another outcome was to evaluate the changes in BMI as a secondary endpoint and if changes in BMI is related to dietary programme. Finally, means differences and analysis of variance in all domains for two groups of patients were analysed to determine the quality of life using SPSS ™ programme.

Table (3) Scoring methodology of frequently food intake by the participants. Scoring was based on closeness to MMD [118 and 119].

Food item	> once a day	1-3 a week	Once every 2 weeks	Once a month	Once every 3 months	Not at all
Vegetables	1	0	-1	-1	-1	-1
Fruits	1	0	-1	-1	-1	-1
Legumes	1	0	-1	-1	-1	-1
Red meat	-1		1	1	1	1
White meat	-1		1	1	1	1
Fish	1		0	-1	-1	-1
Dairy products	-1	0	1	-1	-1	-1
Refined Wheat products, rice, maize etc.	-1	0	1	-1	-1	-1
Processed meat	-1			0	1	1
Canned veg.	-1		0	1	1	1
Nuts	1		0	-1	-1	-1
Soft drinks	-1		0	1	1	1
Juices	-1		0	1	1	1
Tea with sugar	-1		0	1	1	1
Coffee with sugar	-1		0	1	1	1
Sweets (any variety)	-1		0	1	1	1

Table (4) List of food categories that are allowed and that are prohibited in the plant based diet [110 and 111].

Allowed food list	Prohibited food list
Dried legumes , beans, peas, chickpeas etc.	Meat (beef, lamb, poultry etc.) Fish.
	Dairy products (milk, butter, cheese etc.)
Nuts	Extracted vegetable oil (olive, soy, corn oils) and margarine from plant, ghee from animal source)
Green leaves, lettuce, spinach, rockets, radish, onions, garlic etc. Fresh vegetables, carrots, cucumber , cauliflower etc.	Processed foods such as canned, highly refined products.
Skinned potatoes and sweet potatoes. Whole grains, oat, barley, brown rice etc Whole wheat products or fragments	White flour pastries, White bread. Short grain rice.
Fresh fruits or their fresh unsweetened juices.	Sugary and sweetened drinks (soft and juices)
Any mixture of above-mentioned items	Any mixture of above-mentioned items

4. RESULTS

4.1. Demographic, physical and clinical criteria of participants

In the first study Participants were from both genders, with male representing 86.7% of the total number (Table 5). The average age of the participant was 50.9 (±6.5) years with a range from 41 to 66 years. The average of BMI of all participants was 30.2 (±5.2) with a range from 23.4 to 38.2, however, only 3 out of 15 patients (20%) had normal body weight while 5 out of 15 (33 %) had overweight and the rest 47% were obese. All patients were diagnosed with diabetes for 1 year or less with an average of 5 months (±3.8) and a range of 1 -12 months. Their mean initial fasting blood glucose was 189.2 mg/dL (±77.0 mg/dL) with a range from 95 to 340 mg/dL. They were distributed as follows: 6% < 110, 26.7 % from 110-120 and 66.7 % > 120. Similarly, measurements of HbA1c showed that the average of this group was 9.4 % (±2.5%) with a range from 6.4% to 13.5%.

Other clinical parameters showed that 3 out of 15 (20%) of the patients have had other illness in addition to diabetes with only 2 (13.3%) of them on medication (not related to diabetes) for these diseases.

Moreover, 9 out 15 (60%) of the patients have declared that a first degree relative (parents and parents' brothers and sisters or the patients' brothers or sisters) has diabetes.

4.2 Qualitative Food Frequency

Data collected from food frequency questionnaire, before the beginning of the study, showed that all participants have negative scores.

The average score on MMD for this group was - 6.4 (±2.17) with a range between -1 to -10. Only 2 and 4 out of 15 participants have scored positive intake on a daily basis for vegetables and fruits respectively,

Table (5) Demographic, physical and clinical status of participants at the beginning of the 12-week trial.

	Gender	Age	Weight (kg)	Height (cm)	BMI	Time since diagnosed (m)	Diabetic Relative	Other disease	On medication	FBG mg/dl	HbA1c %
1	M	50	104	165	38.2	3	Yes	No	No	140	10.6
2	F	50	76	164	28.2	10	No	No	No	280	13.5
3	M	40	112	173	37.4	6	Yes	Yes	Yes	115	6.7
4	M	41	85	185	24.8	3	Yes	No	No	270	12
5	F	50	93	161	35.9	1	No	No	No	95	7
6	M	56	78	178	24.6	3	No	No	No	250	11
7	M	49	80	176	25.8	1	Yes	No	No	118	7
8	M	66	76	174	25.1	1	No	No	No	157	7.2
9	M	51	95	175	31.0	3	Yes	Yes	Yes	235	12.4
10	M	56	88	165	32.3	6	No	No	No	208	9.3
11	M	45	75	165	27.6	1	Yes	Yes	No	155	7
12	M	53	95	173	31.7	7	Yes	No	No	110	6.4
13	M	58	70	173	23.4	6	Yes	No	No	250	10.8
14	M	49	110	170	38.1	12	Yes	No	No	115	7.2
15	M	49	91	176	29.4	12	No	No	No	340	12.3

while none of participants has consumed any type of legumes on a daily basis. On the other hand, the main negative scoring contributors in their food intake, which showed common trends in all participants, were meat (red and white) 13 out of 15, dairy products 14 out of 15, white bread 11 out of 15, soft drinks 12 out of 15, while juices, tea and coffee (with sugar) and sweets were 13, 15 and 9 out 15 respectively. These food items were taken on regular basis and sometime more than once a day. It worth to

be mentioned that participants showed positive scores in 2 food items; processed meat and canned food with 5 out of 15 and 1 out of 15, respectively had consumed it on regular basis (Fig 3).

4.3 Compliance with dietary programme

The results of participant's adherence to the dietary programme on a scale of 0—10 are shown in Fig 4. The average score of participants was 8 (±1.5) with a range between 5-10.

4.4 Effect of the dietary programme on the diabetes parameters

Participants' fasting blood glucose, HbA1c and body mass index at the end of the trial are shown in Table 6. All participants have completed the 12 week-dietary programme and none of them has any adverse health issues due to being involved in such a programme.

4.4.1 Fasting blood glucose

Measurements of baseline and endpoint fasting blood glucose are shown in Fig 5. The average FBG at baseline was 189.2 mg/dL (±77.0) while endpoint average FBG was 102.9 mg/dL (±19.7). The total average reduction was 84.6 mg/dL which corresponds to 45.6% reduction in blood glucose from the baseline.

4.4.2 HbA1c %

Measurements of baseline and endpoint HbA1c are shown in Fig 6. The average value for the group at baseline was 9.4 % (±2.5) while at the

endpoint was 6.15 % (±0.84). this means a total reduction in averaged HbA1c equals to 3.25 points which corresponds to 35%.

4.5 Effect of dietary programme on anthropometric measurements

4.5.1 Body weight

The baseline of individual body weight and at the endpoint are shown in Fig 7. All participants have shown a reduction in body weight with an average of 4.6 kg (±3.9), however the range was between 1 to 14 kg.

4.5.2 Body mass index (BMI)

The formula for BMI is universal, meaning that BMI is calculated the same way for all people, regardless of gender, age, ethnicity or even body composition. The baseline and endpoint body mass index of all participants are shown in Fig 8. There was a reduction in BMI for all participants and the group averaged 28.7 (±4.3) with a range between 23.1 to 34.9. The total reduction in BMI was 1.5. Moreover, percentage of normal body weight category has increased from 20% to 33% and all overweight, obesity and sever obesity values have been shifted down to some extent.

4.6 Correlations between baseline and endpoint variables

Sixteen variables (in both baseline and endpoint) were measured and analysed statistically by finding Pearson square and 2-tailed significant

differences (Table 7). Significant differences on 2 levels of p (< 0.01 and 0.05) were denoted with** and * respectively.

Baseline body weight was correlated to baseline BMI, while it was also correlated with endpoint weight, endpoint BMI and weight loss. Baseline BMI was significantly correlated with baseline fasting blood glucose ($p<0.05$) and significantly correlated with endpoint body weight, weight loss and BMI. Duration that patient has been with diabetes was correlated only with weight loss ($p<0.05$). Baseline fasting blood glucose was correlated with baseline and endpoint HbA1c ($p<0.01$), it was not significantly correlated with endpoint body weight ($p<0.08$) and BMI ($p<0.018$). Baseline HbA1c was correlated with endpoint HbA1c ($p<0.01$). Total score of qualitative food frequency and compliance were not significantly correlated with any of the 16 variables. Endpoint fasting blood glucose was significantly correlated with baseline fasting blood glucose ($p<0.01$) and endpoint HbA1c ($p<0.001$). Endpoint body weight was significantly correlated with baseline body weight ($p<0.001$), baseline BMI ($p<0.001$), endpoint BMI ($p<0.001$) and weight loss ($p<0.009$). Endpoint BMI was significantly correlated with baseline weight ($p<0.001$), baseline BMI ($p<0.001$), endpoint body weight ($p<0.001$) and endpoint weight loss ($p<0.022$). Weight loss was significantly correlated with baseline body weight, baseline BMI and period with diabetes.

It was found that gender and age were not correlated with any of the 16 variables.

Table (6) Changes in participants' diabetic parameters and anthropometric measurement after 12-week dietary programme of plant based diet.

No.	Gender	Endpoint FBG mg/dL	Reduction mg /dL on FBG	Endpoint HbA1c %	Reduction on HBA1c %	Endpoint BMI	Reduction Points on BMI
1	M	90	50	6.3	4.3	34.9	3.3
2	F	100	180	6.3	7.2	26.2	2.0
3	M	80	35	5.2	1.5	32.7	4.7
4	M	100	170	6	6	24	0.8
5	F	95	0	6	1	34.7	1.2
6	M	100	150	6.4	4.6	23.7	0.9
7	M	100	18	6.4	0.6	25.5	0.3
8	M	146	11	6.5	0.7	24.8	0.3
9	M	115	120	8.3	4.1	30.7	0.3
10	M	118	90	6.6	2.7	30.9	1.4
11	M	95	60	5.1	1.9	26.8	0.7
12	M	75	35	5.3	1.1	30.1	0.6
13	M	140	90	7.1	3.7	23.1	0.3
14	M	90	25	5.2	2	34.9	3.3
15	M	100	240	5.6	7.7	27.1	2.3

Fig (3) Accumulative scores of frequent food consumed by participants over a 12-week period before the beginning of the trial.

Based on Table 3 positive scores represent healthier life style either by consuming good food items or avoiding bad food items. While negative scores represent non-healthy life style by eating bad food items or avoiding good food items

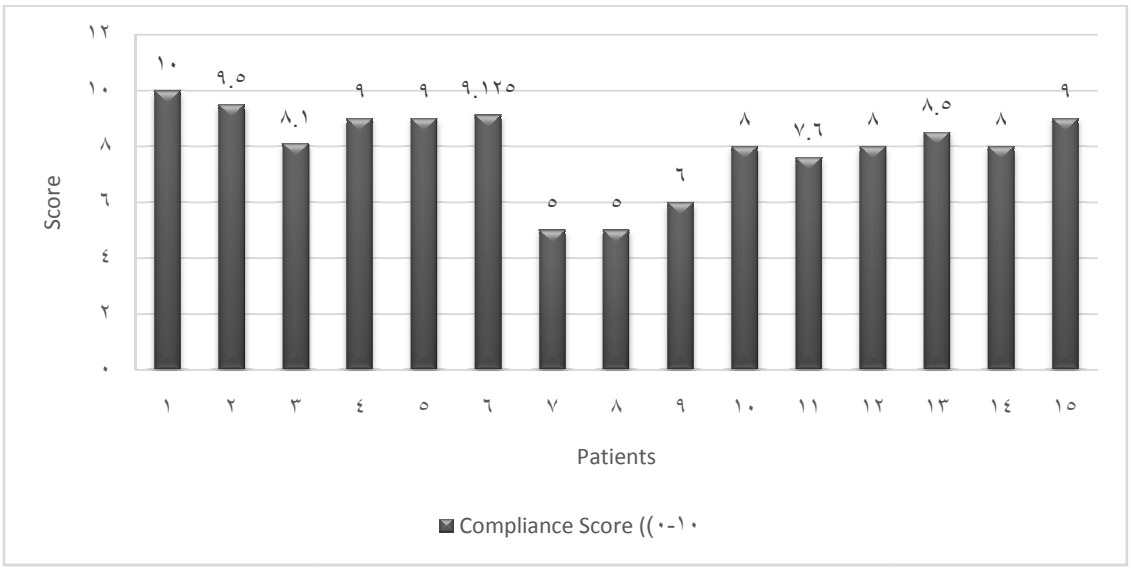

Fig (4) Adherence score to the dietary programme by participants over a 3-month period.

Each column represents the average of 12 weeks of a weekly recorded score on a scale 0-10.

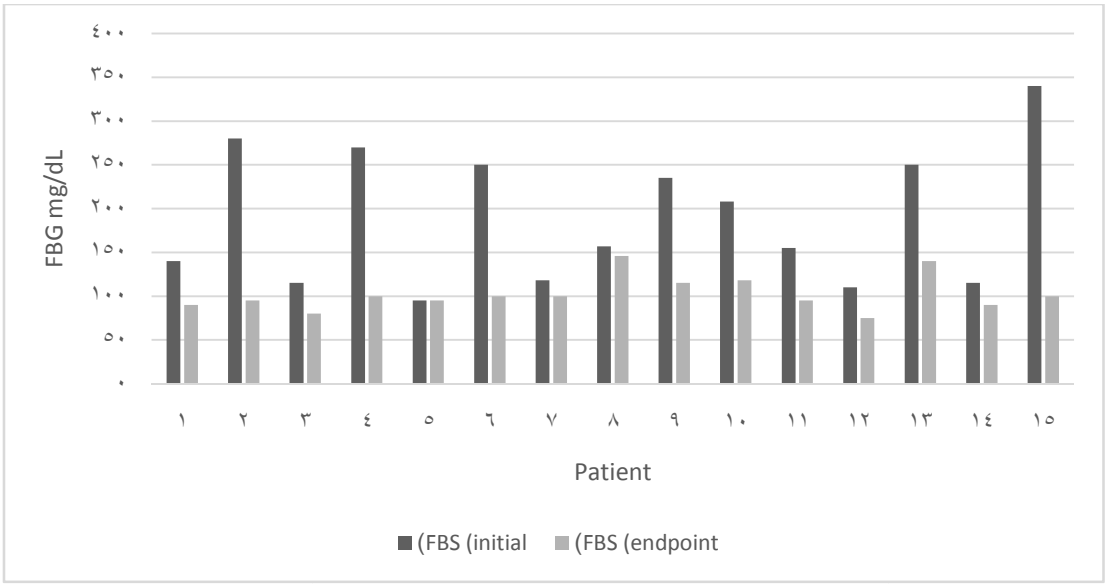

Fig (5) Baseline fasting blood glucose(mg/dL) and fasting blood glucose at the end of the trial.

Each column represents a participant, who enrolled a 12-week dietary programme.

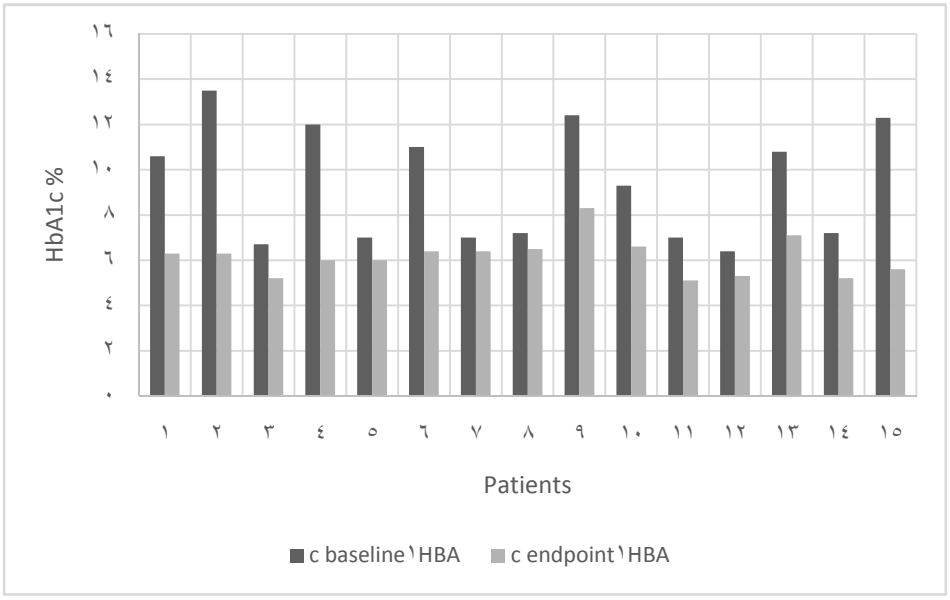

Fig (6) Baseline HbA1c (%) and HbA1c at the end of the trial.

Each column represents a participant who enrolled a 12-week dietary programme.

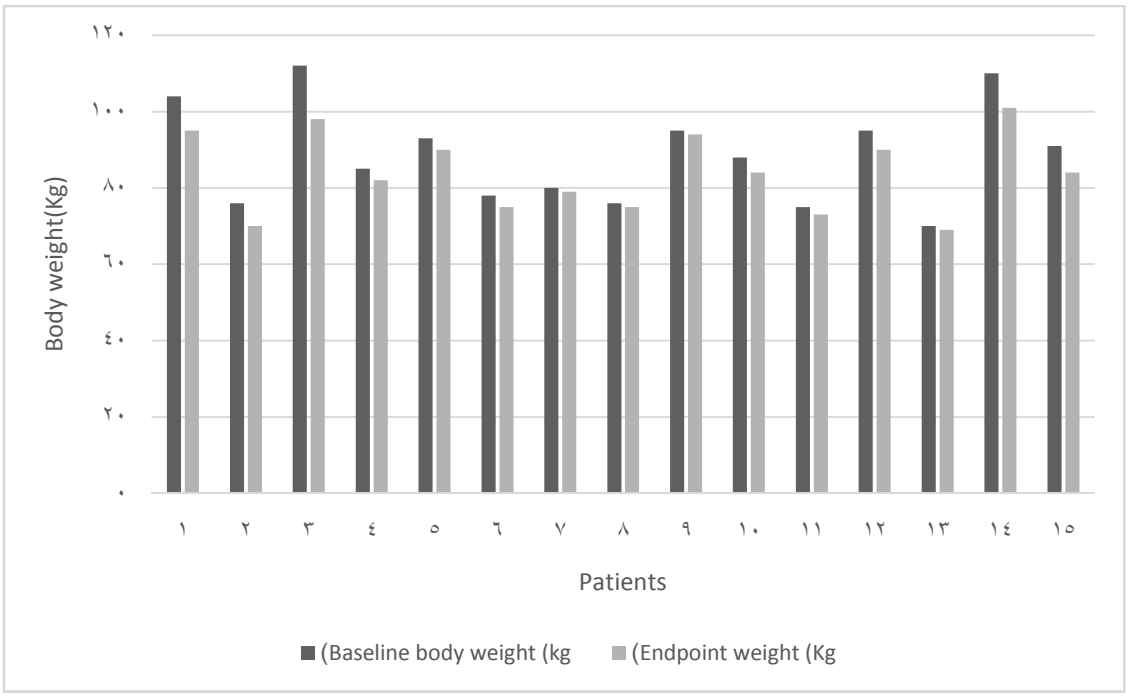

Fig (7) Distribution of baseline and endpoint body weight (kg) of participants.

Each column represents a participant who enrolled a 12-week dietary programme.

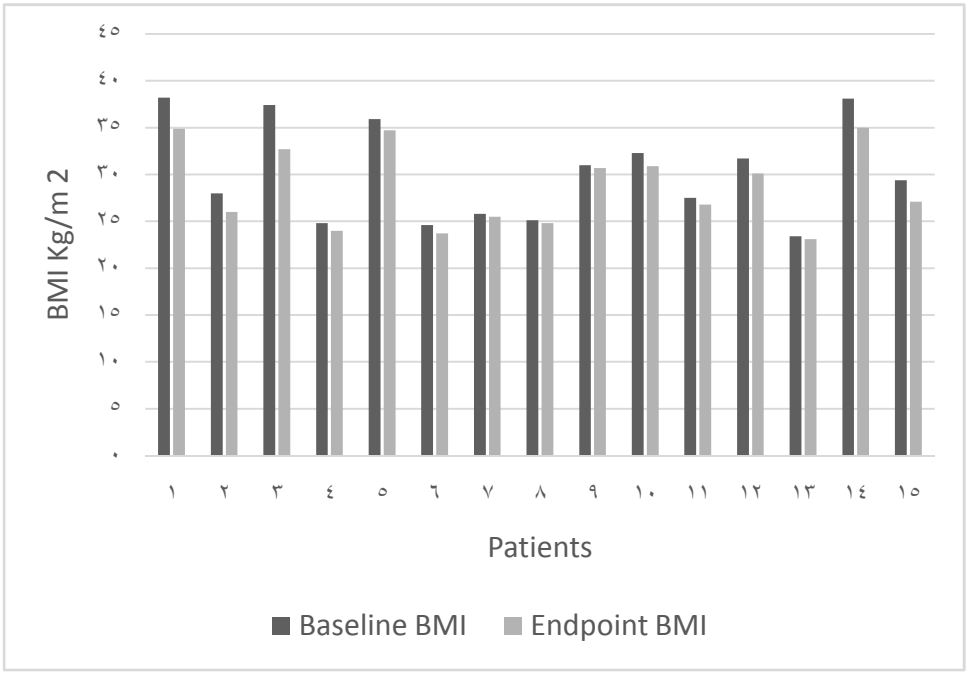

Fig (8) Distribution of baseline and endpoint Body Mass Index (BMI, kg/m^2) of participants.

Each column represents a participant who enrolled a 12-week dietary programme.

Table (7) Correlations between baseline and endpoints of blood and body parameters with lifestyle (total score before trial and compliance to the dietary programme) of intervention group who enrolled a 12-week plant based diet.

		Baseline wt.	Baseline BMI	Interval on diabetes (M)	baseline fast blood sugar	Baseline HbA1c	Total Score	Compliance	Endpoint FBS	Endpoint HbA1c	Endpoint wt.	Endpoint BMI	Wt. loss	sex	age
baseline wt.	Pearson Correlation	1	.921**	0.337	-0.430	-0.270	0.346	0.180	-0.155	-0.204	.976**	.869**	.799**	-0.138	-0.185
	Sig. (2-tailed)		0.000	0.219	0.110	0.330	0.207	0.520	0.581	0.466	0.000	0.000	0.000	0.624	0.510
baseline BMI	Pearson Correlation	.921**	1	0.226	-.568*	-0.377	0.280	0.231	-0.218	-0.275	.905**	.983**	.718**	0.033	-0.109
	Sig. (2-tailed)	0.000		0.419	0.027	0.166	0.313	0.407	0.435	0.321	0.000	0.000	0.003	0.906	0.699
interval on diabetes (M)	Pearson Correlation	0.337	0.226	1	0.335	0.266	-0.152	0.380	0.404	0.160	0.236	0.141	.527*	0.007	-0.264
	Sig. (2-tailed)	0.219	0.419		0.222	0.338	0.590	0.162	0.136	0.569	0.397	0.615	0.044	0.980	0.342
baseline fast blood sugar	Pearson Correlation	-0.430	-.568*	0.335	1	.875**	-0.056	0.295	.637*	.703**	-0.465	-.601*	-0.220	-0.032	-0.124
	Sig. (2-tailed)	0.110	0.027	0.222		0.000	0.842	0.285	0.011	0.003	0.081	0.018	0.430	0.910	0.660
baseline HbA1c	Pearson Correlation	-0.270	-0.377	0.266	.875**	1	0.062	0.419	0.361	.643**	-0.294	-0.391	-0.131	0.173	-0.301
	Sig. (2-tailed)	0.330	0.166	0.338	0.000		0.827	0.120	0.186	0.010	0.287	0.149	0.641	0.538	0.276
Total Score	Pearson Correlation	0.346	0.280	-0.152	-0.056	0.062	1	-0.376	0.129	0.404	0.421	0.316	0.045	-0.206	-0.168
	Sig. (2-tailed)	0.207	0.313	0.590	0.842	0.827		0.167	0.648	0.135	0.118	0.251	0.872	0.461	0.549

Compliance	Pearson Correlation	0.180	0.231	0.380	0.295	0.419	-0.376	1	0.023	-0.092	0.068	0.163	0.441	0.334	-0.413
	Sig. (2-tailed)	0.520	0.407	0.162	0.285	0.120	0.167		0.936	0.745	0.810	0.562	0.100	0.224	0.126
endpoint FBS	Pearson Correlation	-0.155	-0.218	0.404	.637*	0.361	0.129	0.023	1	.764**	-0.180	-0.250	-0.045	-0.155	0.204
	Sig. (2-tailed)	0.581	0.435	0.136	0.011	0.186	0.648	0.936		0.001	0.521	0.369	0.873	0.582	0.466
endpoint HbA1c	Pearson Correlation	-0.204	-0.275	0.160	.703**	.643**	0.404	-0.092	.764**	1	-0.149	-0.244	-0.299	-0.082	0.238
	Sig. (2-tailed)	0.466	0.321	0.569	0.003	0.010	0.135	0.745	0.001		0.595	0.381	0.278	0.771	0.394
endpoint wt.	Pearson Correlation	.976**	.905**	0.236	-0.465	-0.294	0.421	0.068	-0.180	-0.149	1	.889**	.649**	-0.154	-0.085
	Sig. (2-tailed)	0.000	0.000	0.397	0.081	0.287	0.118	0.810	0.521	0.595		0.000	0.009	0.584	0.762
endpoint BMI	Pearson Correlation	.869**	.983**	0.141	-.601*	-0.391	0.316	0.163	-0.250	-0.244	.889**	1	.584*	0.086	-0.048
	Sig. (2-tailed)	0.000	0.000	0.615	0.018	0.149	0.251	0.562	0.369	0.381	0.000		0.022	0.760	0.864
Wt. loss	Pearson Correlation	.799**	.718**	.527*	-0.220	-0.131	0.045	0.441	-0.045	-0.299	.649**	.584*	1	-0.057	-0.409
	Sig. (2-tailed)	0.000	0.003	0.044	0.430	0.641	0.872	0.100	0.873	0.278	0.009	0.022		0.839	0.131
sex	Pearson Correlation	-0.138	0.033	0.007	-0.032	0.173	-0.206	0.334	-0.155	-0.082	-0.154	0.086	-0.057	1	-0.444
	Sig. (2-tailed)	0.624	0.906	0.980	0.910	0.538	0.461	0.224	0.582	0.771	0.584	0.760	0.839		0.097
age	Pearson Correlation	-0.185	-0.109	-0.264	-0.124	-0.301	-0.168	-0.413	0.204	0.238	-0.085	-0.048	-0.409	-0.444	1
	Sig. (2-tailed)	0.510	0.699	0.342	0.660	0.276	0.549	0.126	0.466	0.394	0.762	0.864	0.131	0.097	

Figures which are denoted with ** are significantly different at $p < 0.01$

Figures which are denoted with * are significantly different at $p<0.05$

4.7 Effect of dietary programme on the quality of life

The demographic, socioeconomic, clinical and diabetic characteristics of the control and interventional groups are shown in Table 8. Control group's average age was 56.1 years and female percentage was 25%. Their initial average HbA1c was 10.3% and endpoint HbA1c after 3 months-follow up period was 6.7. There were no significant differences between the control group and intervention group in their: personal (education), social (marital status) and socioeconomic (occupation and type of accommodation) factors. However, there were significant differences between the 2 groups in their means of endpoint BMI and endpoint of FBG ($p = 0.05$). Also the 2 groups shoed significant differences in duration with diabetes and taking medications for diabetes. The results of Whoqol-bref for both groups are shown in Table 9. All domains were out of 100 points. The intervention group has shown an improvement in all 4 domains of the questionnaire regarding their quality of life in comparison to the control group of patients with diabetes and taking regular medications. Analysis of variance and significances between means of all domains are summarised in Table 10.

4.7.1 physical domain

In this domain the control group has averaged a 57.7 point (±11.9) with a range between 31 to 69. While for intervention group it was 65.6 point (±5.4) with a range between 56 to 69. There was a significant difference between the means ($p < 0.05$).

4.7.2 Psychological domain

In this domain control group has averaged 42.9 point (±17.2) with a wide range between 6 to 75. While intervention group has recorded 64.8 (±6.6) with a range between 50 to 75. There was a high significant difference between the groups' means ($p<0.001$).

4.7.3 Social domain

In this domain control group has averaged 39.8 point (±17.4) with a range between 0 to 75 while the intervention group has recorded 72.6 (±14.4) with a range between 44 to 94. There was a high significant difference between the groups' means ($p<0.001$).

4.7.4 Environmental domain

In this domain control group has averaged 52.3 point (±12.9) with a range between 19 to 69.

While intervention group has recorded 60.5 point (±7.5) with a range between 44 to 75. There was a significant difference between the groups' means ($p<0.05$). Over all QOL for the control group was 48.15 while it was 65.9 for the interventional group.

Table (8) Demographic, socioeconomic, clinical status and diabetes parameters of control and interventional groups. Measurements were taken in parallel during a 12-week trial.

	Control group [a] n= 15	**Interventional group [b] n=15**	**Significant differences (p= 0.05)**
Female %	25 (n=3)	16.3 (n=2)	
Average age (year)	56.1 ±4.6	50.8 ± 6.5	
Education level o Primary or lower o Secondary o Tertiary (college or higher)	 5 5 5	 3 6 6	
Occupation o Not working o Working	 8 7	 3 12	
Marital status o Not married o Married o Had been married	 3 12 0	 1 14 0	
Average BMI o Baseline o Endpoint	 33.6 ±2.8 32.9 ±1.9	 30.2 ±5.2 28.6 ±4.3	 *
Place of residency o City o Village o Camp	 11 4 0	 9 4 2	
Average FBG mg/dL ±SD o Baseline o Endpoint	 204 ±56.8 138 ±18.6	 189 ±77.1 102.6 ±19.7	 *
Average HbA1c % ±SD o Baseline o Endpoint	 10.3±1.8 6.7±0.7	 9.4 ± 2.5 6.2 ±0.8	
On medication for diabetes o 1 medicine o 2 medicines or more	 13 2	 0 0	 *
Diabetes period o 1 year or more o less than 1 year	 100% 0	 13% 87%	 * *

a: represents a group of patients with type 2 diabetes who consume conventional diet and were prescribed medications for DM.

b; represents a group of patients with type 2 diabetes who consume plant-based diet for 12-week trial and were not prescribed any medication for DM.

* represents significant difference between the groups (p=0.05) in the same raw.

Table (9) Means of domains of quality of life for the control and intervention groups. Where domain1= physical, domain2= psychological, domain3= social and domain4= environment of WHOqol-bref questionnaire.

		N	Mean	Std. D	Std. Error	95% Confidence Interval for Mean	
						Lower Bound	Upper Bound
Domain 1	A	15	57.70	11.930	2.668	52.12	63.28
	B	15	65.60	5.383	1.390	62.62	68.58
	Total	30	61.09	10.354	1.750	57.53	64.64
Domain 2	A	15	42.90	17.189	3.844	34.86	50.94
	B	15	64.80	6.625	1.710	61.13	68.47
	Total	30	52.29	17.438	2.948	46.30	58.28
Domain 3	A	15	39.75	17.393	3.889	31.61	47.89
	B	15	72.60	14.382	3.713	64.64	80.56
	Total	30	53.83	22.940	3.878	45.95	61.71
Domain 4	A	15	52.25	12.867	2.877	46.23	58.27
	B	15	60.53	7.463	1.927	56.40	64.67
	Total	30	55.80	11.522	1.948	51.84	59.76

Where: A= control group B= intervention group

Table (10) Analysis of variance (one way- ANOVA) of control and intervention groups based on WHO qol-bref questionnaire.

		Sum of Squares	df	Mean Square	F	Sig.
Domain 1	Between Groups	534.943	1	534.943	5.677	.023
	Within Groups	3109.800	33	94.236		
	Total	3644.743	34			
Domain 2	Between Groups	4110.943	1	4110.943	21.782	.000
	Within Groups	6228.200	33	188.733		
	Total	10339.143	34			
Domain 3	Between Groups	9249.621	1	9249.621	35.315	.000
	Within Groups	8643.350	33	261.920		
	Total	17892.971	34			
Domain 4	Between Groups	588.117	1	588.117	4.944	.033
	Within Groups	3925.483	33	118.954		
	Total	4513.600	34			

5. DISCUSSION

To our knowledge this is the first study of its kind in Palestine addressing both dietary intervention and diabetes. Participants have been involved in an open randomized Pilot study. Although the study was conducted in a small geographic area i.e. Nablus city, the study can be further expanded to include more participants and geographical places to draw solid conclusions.

The dietary programme investigated in this study was also practised in many institutions and was recommended as safe approach. Plant-based diet is a life style for millions of people around the world, moreover, in our area Mediterranean diet which was prevalent few decades ago is another version of plant-based, whole plant diet with a limited consumption of red meat and dairy products. The participants clearly shifted their life style to the western type of life style with increasing consumption of meat and meat products, refined carbohydrates and sugars with very limited consumption of fruits and vegetables. Based on the United Nations Food and Agriculture Organization data, this change has been especially drastic in Asian countries. More meat and meat product with refined grain products have increased remarkably. This also has increased availability of fast foods which backed the unhealthful diets with high calorie content of sugary beverages, and unhealthy fats [10].

In this study changing the life style toward less risk factors and healthier factors, has its impact on diabetes features such as reduction in

fasting blood glucose by 45% and HbA1c by 35%. Such reductions can shift diabetic person to be none-diabetic by definition. Another important risk factor that significantly has been affected by the diet was endpoint body weight. This also has affected the endpoint BMI. Participants have lost 4.5 kg on average but very obese and obese participants have lost more in a way dropped their BMI sometimes by 7.7%. High BMI [33.5 kg/m^2) amongst Palestinian diabetics was also reported by Abu-Halaweh et al [2017] [4]. This result is in agreement with many researches which showed that obesity and weight gain are risk factor of diabetes, moreover, an increase of body weight above normal by 1 kg was associated with 4.5% increase in diabetes incidence. In this trial an average 1 kg loss of weight has resulted in decrease in average FBG equals 42 mg/dL and 0.7 % of HbA1c. Similar trend was found by McDougall et al [2014] who reported a 17 mg/dL drop in FBG for 1.7 kg loss body weight in 7-day trial [115].

Some participants who had normal baseline body weight and haven't got changes in their BMI may have their fat distribution changed, though, this wasn't measured by this study other studies have reported that fat distribution especially abdominal fat poses a risk factor for diabetes. All participants showed good level of adherence to dietary programme however, level of adherence was not correlated with either level of weight loss and blood parameters, this can be explained by that other factors, not studied here, (either genetic or environmental) may play a complementary effect as diabetes is a multifactorial disease. As the prevalence of obesity in the Palestinian population is worrying and will reach 35% in 2020 this

study has its significance in treatment and prevention of diabetes. If obesity declined by 1% every year for 10 years, a 5.3% reduction in diabetes prevalence can be achieved [2]. If obesity prevalence was reduced by 35% in 10 years, as suggested by the WHO, diabetes prevalence might be decreased by 20%.

Lifestyle intervention that restricts calories intake and enhances weight-loss, was reported to significantly reduce transformation of high risk patients to diabetes by 58% [10].

HbA1c represents average blood glucose over a period of 2–3 months in a single measure which can be performed without having special preparation such as fasting. HbA1c, although widely used as a tool to assess hyperglycaemia, its threshold was variable amongst studies. The broadly used threshold was 6.3 % which represents the average endpoint HbA1c in this study. Such a result is considered a huge benefit for diabetic patients if one has to consider that most Palestinian patients with HbA1c 9.4 % will suffer from macrovascular complications, including myocardial infarction, and/or stroke and who have 9.9% will be suffering from microvascular complications [4]. Roughly, in this study, for every 1% drop in HbA1c there was a 26 mg/dL drop in FBG. And as a consequence insulin sensitivity will be improved.

Similar trends have been reported by other researchers [100]. They conducted a 74-week intervention trial, a low-fat vegan diet, without energy restriction. Their results showed that weight-loss and improved

FBG, TG, and LDL cholesterol in the low-fat vegan diet was more than a conventional diet.

Insulin resistance is found in patients with type 2 diabetes and also in normal obese and not obese persons [121], insulin resistance means that muscle, fat and liver cells do not respond properly to insulin and thus cannot easily uptake glucose from the bloodstream. By administration of intravenous free fatty acids (FFAs) to healthy persons, increased FFAs in plasma cause insulin resistance which proposed the relation between FFA and type 2 diabetes [121]. High intake of lipids and FFA diets cause insulin resistance, which will inhibit glucose transport and phosphorylation in skeletal muscle [122]. A group of normal healthy men without a family history of diabetes, were given FFA and challenged with glucose. It was found that FFA cause insulin resistance. In addition, persons with normal glucose level was affected and the glucose absorption delayed after 160 min [123 and 124]. Fatty acids reduce glucose transport activity by affecting GLUT4 transporter directly or affecting insulin signalling result in decrease number of GLUT4 transporters and by altering their location towards plasma membrane. Fatty acid metabolites, fatty acetyl CoAs, diacylglycerol and ceramides affect insulin sensitivity by suppression its signalling [124]. One can increase glucose uptake by increasing insulin sensitivity via lowering FFA intake [125]. High fat (HF) diets was found to influence mitochondrial function in skeletal muscle [126]. HF diets increase Intramyocellular lipid (IMCL) contents in a short time [127]. On the other hand, concerns about reduction of muscle mass of patients on

PBD due to low protein quality, was discussed as some essential amino acids can be provided by plant sources and complementary amino acids can be obtained by mixing a range of sources. Therefore, a well-balanced, plant-based diet will provide adequate amounts of essential amino acids and prevent protein deficiency [109]. Moreover, a recent meta-analysis of nitrogen balance studies found no significant difference in protein needs due to the source of dietary protein. In addition to that reported according to the standard method for determining protein quality which found that isolated soy protein can meet protein needs as effectively as animal protein [82].

Diabetes can be viewed as an inflammatory disease. There is increasing evidence that maintained inflammatory status induced by cytokines is closely linked with the generation of insulin resistance and Type 2 diabetes mellitus. Researchers have connected T2DM with the presence of inflammatory and immune system biomarkers, including TNF-α, IL-1, IL-6, C Reactive Protein (CRP), leptin, adiponectin, and resistin [129]. These biomarkers have an adverse impact on the function of beta-cells directly by affecting pancreatic cells or indirectly by prohibiting cells to uptake glucose.

Plant based diet is one of the healthy regimens that contains a lot of antioxidants, anti-inflammatory, dietary fibre and sources of beneficial microbiota. All of these components, individually or combined will improve the inflammation status in the body leading to remarkable decrease in insulin resistance.

Another explanation for the improvement seen with low-fat diet with regard to diabetes, is that its effect on gut microbiota. It is well known that diet is a modulating factor of gut microbiota with diet rich in fibre being a good source for energy for a wider microflora community with beneficial metabolic end products such as short chain fatty acids (SCFA). SCFAs were reported to increase gene expression to produce peptides related to reduced hunger and appetite.

On the opposite, diet rich in processed meat/ high fat will reduce gut microbiota richness and may shift such communities towards gut dysbiosis [129]. Gut dysbiosis eventually will change bacterial translocation, obesity and weight gain. It was found that gut microbiota may help in fat gain by promoting adipocyte lipogenesis and suppressing Fasting Induced Adipocyte Factor (FIAF) expression. On the other hand, it was reported that *Bifidobacterium adolescentis* negatively had been associated with HbA1c [129], which may explain glucose lowering effects of the diet that enhancing its level in the gut, such as plant-based diet.

Quality of life, according to the World Health Organization Quality of Life Group [120], is defined as the individuals' perception of their position in life in the context of the culture and the value system they inhabit, in relation to expectancies, patterns and concerns. There are no cut-off points for WHoqol-bref on the national level and these cut-off points may vary from one country to another. Some researchers have predicted an international cut-off points for healthy people as references to compare

with. For example, Silva et al [2014][130] have set <60 as a cut-off for over-all quality of life (all domains). They recommended that for every age group there should be whoqol, moreover, there are no cut-off points above or below which quality of life could be evaluated as “poor” or “good”. It is about the individual satisfaction and self-image which can be affected by many factors. There are many studies (212 study) have included WHOqol as a tool to assess quality of life of them only 4 studies have recruited diabetic patients [131]. This is the first study in Palestine that studied quality of life of diabetic patients after a period of dietary intervention in comparison with diabetic controls.

In this study the intervention group has shown better scores in their quality of life than control (medicated) group in all domains. Although both groups showed decrease in HbA1c % levels, however, the intervention group’s life has improved to more ‘normal’ levels. In a similar trends Eljedi et al. (2006) have found that diabetic patients quality of life significantly reduced compared with a matching group of healthy individuals. The most affected domains were physical and psychological with women and older participants having the worst levels [131].

Finally, it is very important aspect to view the results of this study from economic perspective. The cost of medications, treatment of complications of T2DM and the time and efforts spent on these patients are heavily burdening countries budget. At least 147 billion USD was spent on diabetes healthcare in Europe, while North America and the Caribbean

spent 263 billion USD in 2013, such costs are potentially to be double by 2030 [132].

In Palestine where limited resources and health care budge are the norm, it is urged to adopt the dietary therapy as first step in diabetes treatment and of course prevention.

6. CONCLUSION AND RECOMMENDATIONS

Life style changes including dietary intervention should be considered as first line prevention for diabetes mellitus, moreover, dietary therapy for diabetes treatment is well documented to be effective alone or in conjunction with medication. Increasing awareness about lifestyle role in the disease progress amongst healthy or diabetic people should also be considered as it showed its efficiency.

In addition to its effectiveness dietary approach such as whole-plant based diet, is cost effective and provides better quality of life to T2DM patients. This also can decrease the financial bill of the diabetes complications.

Controlling body weight can be easily managed by plant based diet this also an advantage over medical approach alone.

In Palestine where health care system is highly physician-centred and patients may be oriented to medications, it is highly recommended to involve dieticians as part of the health care team who will perform counselling and monitoring the changes in patient's life style.

Limitations of this study have arisen from the small number of participants partly due to lack of awareness about the effect of diet on diabetes and as well due to the referral process. Increasing the awareness amongst health care providers about benefits of diet as an option for diabetics may help in conducting a wider clinical trial.

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APPENDICES

Appendix (1) Questionnaire about health status and food frequency of T2DM patients

دراسة حمية السكري

1. استبانه رقم ( ) التاريخ / / 2017

معلومات شخصية:

2. الاسم (الاحرف الاولى) العمر الجنس

3. الوزن كغم الطول سم BMI

التاريخ المرضي

4. تاريخ تشخيص المرض سنة شهر

5. التشخيص من قبل اخصائي وزارة الصحة طبيب خاص غير ذلك

6. هل يوجد في العائلة اصابة بالسكري نعم درجة القرابة

لا

7. هل تعاني من امراض اخرى:

ضغط دم

امراض العيون

امراض غدد

امراض في الاطراف (تقرحات القدم الخ)

امراض الكلى

مشاكل في الهضم او تحسس من الاغذية

مشاكل في المفاصل او روماتزم

8. هل تتناول اية علاجات غير تلك الخاصة بالسكري نعم اذكرها

لا

9. هل تم عمل فحوصات للدم خلال الاسبوع الماضي

FBS

HBA1C

10. الرجاء تعبئة النموذج المرفق والخاص بالاطعمة المتناولة اخر 3 شهور

نوع الغذاء	اكثر من مرة في اليوم	من مرة الى 3 في الاسبوع	مرة كل اسبوعين	مرة كل شهر	مرة كل 3 شهور	ولا مرة
خضار بانواعها (زهرة، ملفوف، بندورة، خيار)						
فواكه بانواعها						
بقوليات (عدس حمص فول)						
لحوم حمراء(عجل، غنم)						
لحوم بيضاء حبش دجاج						
اسماك بأنواعها						
منتجات الحليب (جبنة لبن لبنة)						
منتجات القمح والذرة (خبز بسكوت معجنات)						
لحوم مصنعة (مرتديللا نقانق)						
خضار معلبة (فاصولياء، بازيللاء)						
لوز وجوز						
مشروبات غازية						
عصائر محلاة او مركزة						
شاي						
قهوة						
حلويات كنافة بقلاوة						
اخرى غير مذكورة						

Appendix (2) Food list for PBD programme.

قائمة بالاغذية الممنوعة:

- طحين ابيض او الخبز والمعجنات المعتمدة عليه.
- السكر الابيض
- المقالي
- الزيوت النباتية المكررة او المهدرجة.
- اللحوم بأنواعها
- الاسماك
- الزبدة والسمنة الحيوانية.
- العصائر المحلاة
- المشروبات الغازية ومشروبات الطاقة بأنواعها
- مشتقات الحليب من لبن ولبنة وجبنة مصنعة وطازجة.
- المعلبات بانواعها حتى الخضار والفواكه المعلبة

قائمة بالاغذية المسموحة:

- الخضار الورقية والثمار كالبندورة والخيار والزهرة بانواعها.
- الفواكه بانواعها ما عدا الافوكادو
- البقوليات بانواعها

- الحبوب الكاملة او المكسرة بأنواعها قمح برغل شوفان رز حبة طويلة الذرة
- مكسرات والبذور بانواعها
- الطحين الاسمر والمعجنات والخبز الاسمر المحضر منه
- خلط اكثر من نوع من البقوليات او الحبوب

Appendix (3) Consent for in Arabic

إقــرار

انا طالب الماجستير خليل سعدالدين تخصص تغذية /جامعة النجاح الوطنية.

اود ان اقوم ببحث لدراسة اثر الحمية المعتمدة على النبات بكامــل مجموعهــا والخاليــة مــن المصادر الحيوانية على مرضى السكري نوع II .

وسأقوم بشرح هذه العملية لحضرتكم راجياً منكم بعد الموافقة التوقيع على هذا الاقرار لضــمان الالتزام في الحمية المطلوبة.

وفي حالة الاخلال بالحمية الرجاء تسجيل ذلك وسيتم تقييم ذلك اسبوعياً.

الحمية ليس لها تأثير سلبي على الصحة وفي حالة شعورك بأية مشكلة يمكنك مراجعة طبيبك او التوقف عن الحمية.

الاسم

التوقيع

هوية رقم

Appendix (4) Self assessment for diet compliance

نموذج تقييم ذاتي

يقسم هذا التقييم الى 10 نقاط بحيث يمثل رقم 10 الالتزام الكامل بالحمية وفي حالة عدم الالتزام بالحمية يتم خصم نقطة من 10 ويتم تسجيل هذا التقييم بشكل اسبوعي.

مثال:

الاسبوع الاول :

لم يتناول المريض اي من الاغذية الممنوعة سيتم تسجيل 10 نقاط.

الاسبوع الثاني:

تناول المريض قطعة جبنة في اليوم الاول و قطعة دجاج في اليوم الثالث وشرب حليب في اليوم السابع.

يتم خصم نقطة عن كل مخالفة بغض النظر عن الكمية وهي 3 نقاط في هذا الاسبوع وعليه يكون مجموع (score) المريض لها الاسبوع هو 7.

يتم معاملة كل اسبوع على حدة.

Appendix (5) Whoqol – bref

استبيان مختصر لجودة الحياة النوعية

النسخة العربية – مايو 1997م

برنامج عن الصحة النفسية

منظمة الصحة العالمية

جنيف

FOR OFFICE USE ONLY

	Equations for computing domain scores	Raw	Transformed scores	
		Score	4 - 20	0 - 100
Domain 1	(6- Q3) + (6-Q4) +Q 10 + Q15 + Q16 + Q17 + Q18 ❑ + ❑ + ❑ + ❑ + ❑ + ❑ + ❑	=		
Domain 2	Q5 + Q6 + Q7 + Q11 + Q19 + (6-Q26) ❑ + ❑ + ❑ + ❑ + ❑ + ❑	=		
Domain 3	Q20 + Q21 + Q22 ❑ + ❑ + ❑	=		
Domain 4	Q8 + Q9 + Q12 + Q13 + Q14 + Q23 + Q24+ Q25 ❑ + ❑ + ❑ + ❑ + ❑ + ❑ + ❑ + ❑	=		

أحوالك الشخصية

قبل أن نبدأ نود منك الإجابة على بعض الأسئلة العامة عن نفسك ، و ذلك بوضع دائرة حول الإجابة الصحيحة أو بملأ الفراغات الموجزة

I- المعلومات الشخصية

1- ما هو جنسك ❑ ذكر ❑ أنثى

2- ما هو تاريخ ميلادك اليوم____ الشهر____ السنة_____

3- ما هو أعلى درجة تعليم حصلت عليها

❑ لا شيء
❑ المرحلة الإبتدائية
❑ المرحلة الإعدادية
❑ المرحلة الثانوية
❑ الدراسات العليا

4- ما هي حالتك الإجتماعية ؟

❑ أعزب ❑ متزوج ❑ أرمل ❑ مطلق

5- هل تسكن في ؟

❑ مخيم للاجئين ❑ قرية ❑ مدينة

II- الوضع الإجتماعي و الاقتصادي

6- هل بيتك الذي تسكن فيه ؟

❑ بيت ملك ❑ بيت وكالة ❑ بالإيجار ❑ غير ذلك ، وضح .....

7- المهنة ❑ عامل ❑ عاطل عن العمل

8- الدخل الشهري حوالي : .....

9- كم شخص تعيل : .....

التعليمات

هذا الإستبيان يستفسر عما تشعر به فيما يتعلق بنوعية حياتك و صحتك و نواحي أخرى من حياتك ، نرجو الإجابة على جميع الأسئلة . إذا لم تكن متأكد من الإجابة على سؤال معين ، نرجو اختيار الجواب الأنسب . و هذا قد يكون ردك الأول في أحيان كثيرة . نرجو أن تضع في اعتبارك قيمك و آمالك و ما يمنعك و يشغلك . نطلب أن تفكر في نمط حياتك خلال الشهرين الماضيين مثلا . قد يكون السؤال :

	لا يوجد	قليلا	نوعا ما	كثيرا	دائما
هل تحصل على أي دعم أو مساعدة من الآخرين ؟	1	2	3	4	5

عليك وضع دائرة حول الرقم الذي يصف مقدار الدعم أو المساعدة من الآخرين خلال الشهرين الماضيين . و هكذا فإنك ستضع الدائرة حول الرقم (4) إذا كنت قد حصلت على دعم كبير من الآخرين كالآتي

	لا يوجد	قليلا	نوعا ما	كثيرا	دائما
هل تحصل على أي دعم أو مساعدة من الآخرين ؟	1	2	3	(4)	5

قد تضع الدائرة حول الرقم (1) إذا لم تحصل على أي دعم أو مساعدة تتمناها من الآخرين خلال الشهرين الماضيين .

*** يرجى قراءة كل سؤال و تقيم مشاعرك ووضع الدائرة حول الرقم الذي يعطي أفضل إجابة بالنسبة لك.**

	كيف تقيم جودة حياتك؟	سيئة للغاية	سيئة	لا بأس	جيدة	جيدة جداً
(G1)1		1	2	3	4	5

		غير راض مطلقا	غير راض	لا راض و لا غير راض	راض	راض تماما
(G4)2	كيف أنت راض عن صحتك ؟	1	2	3	4	5

*** الأسئلة التالية تستفسر عن مدى تعرضك لأشياء معينة خلال الشهرين الماضيين**

		لا يوجد	قليلا	بدرجة متوسطة	كثير جدا	بدرجة بالغة
(F1.4) 3	إلى أي حد تشعر بأن الوجع يمنعك من القيام بالأعمال التي تريدها ؟	1	2	3	4	5
(F11.3)4	كم تحتاج من العلاج الطبي لتتمكن من القيام بأعمالك اليومية ؟	1	2	3	4	5
(F4.1)5	إلى أي مدى تستمتع بالحياة ؟	1	2	3	4	5
(F24.2)6	إلى أي مدى تشعر بأن حياتك ذات معنى ؟	1	2	3	4	5
(F5.3)7	كم أنت قادر على التركيز ؟	1	2	3	4	5
(F16.1)8	كم تشعر بالأمان في حياتك اليومية ؟	1	2	3	4	5
(F22.1)9	إلى أي حد تعتبر البيئة المحيطة بك صحية ؟	1	2	3	4	5

*** الأسئلة التالية تستفسر عن مدى قدرتك على إتمام أمور معينة خلال الأسبوعين الماضيين**

		لا يوجد	قليلا	بدرجة متوسطة	كثير جدا	بدرجة بالغة
(F2.1)10	هل لديك طاقة كافية لمزاولة الحياة اليومية ؟	1	2	3	4	5
(F7.1)11	هل أنت قادر على قبول مظهرك الخارجي ؟	1	2	3	4	5
(F18.1)12	هل لديك من المال ما يكفي لتلبية إحتياجاتك ؟	1	2	3	4	5
(F20.1)13	كم تتوفر لك المعلومات التي تحتاجها في حياتك اليومية ؟	1	2	3	4	5
(F21.1)14	إلى أي مدى لديك الفرصة للأنشطة الترفيهية ؟	1	2	3	4	5

		سيئة للغاية	سيئة	لا بأس	جيدة	جيده جدا
(F9.1)15	كم أنت قادر على التجول بسهولة	1	2	3	4	5

* الأسئلة التالية تطلب منك أن تعبر عن مدى رضاك نحو جوانب مختلفة من حياتك خلال الشهرين الماضيين

		غير راض مطلقا	غير راض	لا راض و لا غير راض	راض	راض تماما
(F3.3)16	كم أنت راض عن نومك ؟	1	2	3	4	5
(F10.3)17	إلى أي مدى أنت راض عن قدرتك على القيام بنشاطاتك اليومية ؟	1	2	3	4	5
(F12.4)18	كم أنت راض عن قدرتك على العمل ؟	1	2	3	4	5
(F6.3)19	كم أنت راض عن نفسك ؟	1	2	3	4	5
(F13.3)20	كم أنت راض عن علاقاتك الشخصية ؟	1	2	3	4	5
(F15.3)21	كم أنت راض عن حياتك الجنسية ؟	1	2	3	4	5
(F14.4)22	كم أنت راض عن الدعم أو المساعدة من الأصدقاء ؟	1	2	3	4	5
(F14.4)23	كم أنت راض عن أحوالك السكنية ؟	1	2	3	4	5
(F19.3)24	كم أنت راض عن الخدمات الصحية المتوفرة لك ؟	1	2	3	4	5
(F23.3)25	كم أنت راض عن وسائل مواصلاتك ؟	1	2	3	4	5

* الأسئلة التالية تشير إلى كم من المرات شعرت أو تعرضت فيها لأشياء معينة خلال الشهرين الماضيين

		أبدا	نادرا	أحيانا	غالبا جدا	دائما
(F8.1)26	كم من المرات كانت عندك مشاعر سلبية مثل الحزن أو اليأس أو القلق أو الإكتئاب ؟	1	2	3	4	5

هل ساعدك أحد في ملء هذا الإستبيان ؟

_____

كم من الوقت إستغرقك لملء هذا الإستبيان ؟

_____

هل لديك أي تعليقات حول هذا الإستبيان ؟

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_____

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شكرا لمساعدتك

جامعة النجاح الوطنية
كلية الدراسات العليا

تأثير الغذاء المرتكز على النباتات بمجموعها والقليل المحتوى من الدهون على السيطرة على تحلون الدم وجوده الحياه في مجموعة من مرضى السكري النوع الثاني : دراسة استطلاعية

إعداد
خليل عبد اللطيف خليل سعد الدين

إشراف
د. محمد عبد الحفيظ التميمي

قدمت هذه الأطروحة استكمالاً لمتطلبات الحصول على درجة الماجستير في التغذية وتكنولجيا الغذاء بكلية الدراسات العليا في جامعة النجاح الوطنية في نابلس، فلسطين.

2018م

تأثير الغذاء المرتكز على النباتات بمجموعها والقليل المحتوى من الدهون على السيطرة على تحلون الدم وجوده الحياه في مجموعة من مرضى السكري النوع الثاني : دراسة استطلاعية

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الملخص

المقدمة: تشكل الامراض المزمنه في المجتمع الفلسطيني هما كبيرا لانها أصبحت السبب الرئيسي للوفاه. ان نمط الحياه مثل نوع الغذاء المتناول يعتبر عامل خطوره قابل للتعديل وهو يلعب دورا كبيرا للحد من انتشار مرض السكري والوفاة به.

الطرق والأدوات:

الدراسه الاولى: خمسة عشر مريض سكري من النوع الثاني بمتوسط عمري 50.9 سنة واصابة بالسكري بمتوسط 5 شهور شاركوا في دراسة استطلاعية لتقييم تأثير الحمية المرتكزة على النباتات بمجموع مكوناتها على مظاهر السكري لديهم ولمدة 12 اسبوعا. كان من المشاركين 2 اناث و13 ذكرا وكانت المقاييس الاولية لديهم 30.2 كغم/ م ^{2} ، 189 ملغم / دسل و 9.4 % لمعامل كتلة الجسم وسكر الدم (الصائم) والسكر التراكمي على التوالي. لم يكن هناك اي تقنين على مستوبات الطاقة والبروتينات المتناولة من المصادر النباتية ولكن تم منع المنتجات الغذائية المصنعة وتلك المنقاة.

الدراسة الثانية: تم توظيف مجموعتين من مرضى السكري(15 لكل مجموعة) متطابقتين من حيث العمر والعدد وذلك لدراسة جودة الحياة لديهم. تم تقسيمهم على التوازي الى مجموعة تتناول الحمية المرتكزة على النباتات والاخرى تتناول الغذاء التقليدي المتبع في البيئة الفلسطينية. المجموعة الثانية هي محموعة السيطرة والتي كان افرادها يتناولون الادوية الخاصة بالسكري. في نهاية المدة المقررة (12 اسبوعا) ملأ كل مشترك استبانة جودة الحياة والتي تحتوي 4 مجالات : البدني ، النفسي ، الاجتماعي والبيئي.

النتائج: الدراسة الاولى : كان تمسك المجموعة بالبرنامج الغذائي مقداره 8 من 10 اما معامل كتلة الجسم ومعدل سكر الدم (صائم) والسكر التراكمي فكانت 28.3 كغم/ م ^{2} ، 102.9 ملغم/دسل ، و 6.15 % على التوالي.

كانت علاقة خسارة الوزن بالوزن الاولي و معامل كتلة الجسم الاولية ومدة الاصابة بالسكري مرتبطة ارتباطاًمعنوياً. بينما علاقة سكر الدم (صائم) فكانت مرتبطة بالسكر التراكمي الاولي والنهائي [$p<0.01$] وعلى كلٍ لم يكن مرتبطاً بصورة معنوية مع الوزن النهائي [$p<0.08$] ومعامل كتلة الجسم .[$p<0.018$].

الدراسة الثانية: اوضحت الدراسة على جودة حياة مرضى السكري ان المجموعة المتبعة للحمية كان لديها تحسن في المجالات الارعة للمقياس مقارنة بمجموعة السيطرة. فقد كان المجال البدني 57.7 نقطة (±11.9) و 65.6 نقطة (±5.4) لمجموعة السيطرة والمعاملة على التوالي. وفي المجال النفسي (±6.6) 64.8 and (±17.2) 42.9 لمجموعة السيطرة والمعاملة على التوالي. وكان معدل المجال الاجتماعي (±14.4) 72.6 and (±17.4) 39.8 لمجموعة السيطرة والمعاملة على التوالي. وفي المجال البيئي 60.5 and (±12.9) 52.3 (±7.5) لمجموعة السيطرة والمعاملة على التوالي. وكانت كل الفروقات في جميع المجالات معنوية على المستوى ($p<0.01$ and 0.05).

الاستنتاجات اظهرت الدراسة وبشكل واضح ان ادارة الجسم من وزن ومعمل كتلة الجسم من خلال الحمية كمثل الحمية المرتكزة على النباتات قد انتجت انخافاضاً معنوياً في مؤشرات مرض السكري كسكر الدم (صائم) والتراكمي. بالاضافة الى التحسن الكبير في جودة الحياة لدى مرضى السكري النوع الثاني.