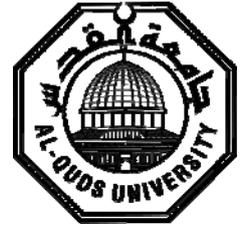


**Deanship of Graduated Studies**  
**Al-Quds University**



**Evaluation of the Diabetes Care Model at Augusta  
Victoria Hospital Diabetes Center (2005-2009)**

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**M.Sc. Thesis**

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**Evaluation of the Diabetes Care Model at Augusta  
Victoria Hospital Diabetes Center (2005- 2009)**

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**A thesis submitted in Partial Fulfillment of Requirement  
for the degree of Master of Public Health/School of  
Public Health.**

**1434/ 2013**

## **Dedication:**

**To my dear parents Musa and Siham.**

**To my dear husband Asa'ad, my daughter Jana and my son Sa'eed**

**To my dear brothers & sisters: Ahmad, Osama, Nisrine, Zena, Reem To  
my dear team at Diabetes Center/Augusta Victoria Hospital**

**Samah Khatib**

## **Declaration**

I certify that this thesis submitted for the degree of Master is the result of my own research, except where otherwise acknowledged and that this thesis (or any part of the same) has not been submitted for a higher degree to any other university or institution.

Singed:

Samah Khatib

Date: 19/12/ 2012

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## **Abstract**

**Background:** Nutritional intervention program is an integral and essential component of diabetes management and care. It aims to optimize diabetes control and to prevent complications. People with diabetes are advised to implement healthy diet; dietary changes including modifications in food habits and meal patterns for life long. However, a significant amount of patients remain with limited control.

**Study aim and objectives:** The aim of the study was to evaluate the effectiveness of the Diabetes Care Program in controlling diabetes among type 2 diabetic patients registered at the diabetes care center at Augusta Victoria Hospital. The objectives were to examine the effect of nutrition counseling on HbA1c level and the effect of the program on patients' physical health, body mass index throughout the follow up period and to identify patients socio-demographic characteristics in determining her/his response to the program.

**Methodology:** This evaluative file based study was conducted on 746 patients' with type 2 diabetes who were followed at the Diabetes Care Center of Augusta Victoria Hospital between years 2005 to 2009. Four visits were taken for every patient including the first and final results, but the period between these visits were not regular and similar for all patients. Personal, medical and family history, physical examination and laboratory evaluation data were extracted from the patients' files.

**Results:** Analysis of patients' data showed that the mean age of the patients was 57 years  $\pm$  9.34(mean  $\pm$  S.D). Of the study population, 84% were married and 53% were females. 74% did not work, 15% were illiterate, the mean duration of having diabetes was 10.08 years and 57.2% had MOH insurance.41% of the patients were given a diet of 1000 Calories during the study period .82% of the patients were classified as with light physical activity in the 1<sup>st</sup> visit and 76% were in the 4<sup>th</sup> visit. The mean HbA1c in the 1<sup>st</sup> visit was 9.08 $\pm$ 2.1 and in the 4<sup>th</sup> visit 8.46  $\pm$ 1.7. The mean BMI in the 1<sup>st</sup> visit was 31.2 $\pm$ 5.3 and in the 4<sup>th</sup> visit 31.9  $\pm$ 5.3. The study identified factors associated with good glycemic control, as measured by HbA1c levels. The percentage of patients with optimal control (HbA1c < 7%) increased from 19.2% at the first visit to22.1% at the 4<sup>th</sup> visit. 60.7% of the patients had good change in HbA1c between the 1<sup>st</sup> and 4<sup>th</sup> visit. The multivariate logistic regression model for the study population (n=746) showed that between the first and last

recorded visit, being registered in the center was associated with the good change in HbA1c but was inversely associated with good change in MAU. Age, residency, type of insurance, smoking, BMI, physical activity, cholesterol level and caloric intake did not show any significant associations with good change in HbA1c in this period of study.

**Conclusion:** This is the first study done in the Diabetes Care Center which identified the determinants of the change in HbA1c and evaluate the program which shows that there was an irregular follow up period between the visits of the patients, which was shown in the results as an important factor in determining the change in HbA1c level. Results recommends the need for modification of the dietary program through involving the patients in this modification to increase their adherence to the program , system of appointment for follow up and evaluation of the compliance of patients with the diet, physical activity and as well as the medication.

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## List of Abbreviations

ADA	The American Diabetes Association
AVH	Augusta Victoria Hospital
BMI	Body Mass Index
CDC	Center of Disease Control
DCCM	Diabetes Comprehensive Care Model
DCCT	Diabetes Control and Complication Trial
DM	Diabetes Mellitus
DSME	Diabetes Self Management Education
FBS	Fasting Blood Sugar
HbA1c	Glycosylated hemoglobin
IDF	International Diabetes Federation
IGT	Impaired Glucose Tolerance
MAU	Albumin creatinine ratio
MOH	Ministry of Health
PMRS	Palestinian Medical Relief Society
PCBs	Palestinian Central Bureau of Statistics

UKPDS	United Kingdom Prospective Diabetes Study
UNRWA	United Nation Relief Work Agency
UHCW	Union of Health Worker Committees
WHO	World Health Organization
WDF	World Diabetes Foundation

## **Chapter 1: Background and Significance**

### **1.1 Background:**

Type 2 diabetes mellitus (DM) is a global health problem and one of the major causes of morbidity and mortality (Polikandrioti et al,2009) . The incidence of the disease is high worldwide and varies between populations because of differences in genetic susceptibility and other modifiable risk factor (Polikandrioti et al, 2009). Diabetes mellitus is a metabolic disease, characterized by hyperglycaemia (increased concentration of blood glucose) and disturbance of glucose metabolism, as a result of reduced insulin secretion or insulin resistance or both (Quaseem et al, 2007; Hjelm et al, 2003)

The main disorder of diabetes mellitus is the decreased secretion of insulin from pancreas that regulates the metabolism of carbohydrates, proteins and fats. There are two types of diabetes, type 1 (insulin dependent) and type 2 diabetes (non-insulin dependent) that occurs most often in adults over the age of 40 and accounts for up to 95 percent of all diabetes cases. The main difference between the two is that type 1 is characterized by complete lack of insulin, while type 2 is a combination of reduced secretion of insulin from the pancreas and resistance to insulin action in peripheral tissues (Halimi et al, 2003; Lusignan et al, 2005; Harris et al, 2003).

The major issue of diabetes care is focused on preventing or delaying longstanding complications, which is the major drain of health care. However, patients with type 2 DM, before developing into chronic complications, remain symptomless for years without urgent characteristics (Larme and Pugh, 1998). Many complications are associated with type 2 DM, such as: hypertension, dyslipidemia, and obesity, which are preventable if the glycemic control is maintained within its normal range. (Hopkins et al.,1996).

Various measures are used to assess diabetes control. Larson et al. (1990) noted the importance of monitoring glycosylated hemoglobin (HbA1c) in diabetes management. HbA1c measurements assess the amount of hemoglobin that is glycosylated. Currently many organizations, such as the American Diabetic Association (ADA), recommend an

HbA1c target value for individuals with diabetes to be set at approximately <7.0% (ADA, 2003). However, new research suggests that complications related to diabetes may still occur at this HbA1c level. The American College of Endocrinology supports a lower HbA1c level, and has recommended HbA1c levels be <6.5% in individuals with diabetes (Cobin et al., 2002).

Many of the behavioral and lifestyle trends, such as eating foods with high fat and sugar and living a sedentary lifestyle, are linked with the obesity epidemic, which has been strongly suggested as the major risk factor for developing type 2 diabetes (Haffner, 1998; Berger, 2001; Grubb, 2002; Cleator and Wilding, 2003; ADA, 2008a). Physical inactivity and poor diet are potentially modifiable risk factors for chronic diseases (Yusuf et al, 1994).

Nutritional intervention is an integral part of diabetes management and self-care education, aiming at the attainment and maintenance of optimal metabolic outcomes, the prevention and treatment of medical complications, and the improvement of general health by addressing individual nutritional needs (Franz et al, 2002). Dietary management entails a series of eating behaviour changes regarding meal planning, food selection, food preparation, dining out, portion control, as well as appropriate responses to eating challenges (Yannakoulia, 2006). Diabetic people are routinely advised to adopt a healthy diet; dietary changes include modifications in food habits and meal patterns on a lifelong basis. However, a significant proportion of patients remain poorly controlled (Monnier et al, 2004; Harris et al, 2001; Saaddine et al, 2006; Maizlish et al, 2004; Azab et al, 2001). Diet, lifestyle behaviour, has been reported as a management domain with very low compliance among diabetics (Peyrot et al, 2005; Thanopoulou et al, 2004; Glasgow et al, 1997). Results from cross-sectional studies indicate low adherence to the dietary recommendations for macronutrient intake and fruit and vegetable consumption (Nelson KM et al, 2002).

There are no high quality data on the efficacy of the dietary treatment of type 2 diabetes. The data available indicate that the adoption of exercise appears to improve glycated haemoglobin (HbA1c) at six and twelve months in people with type 2 diabetes. There is an urgent need for well-designed studies which examine a range of interventions, at various points during follow-up (Nield, et al, 2007).

## **1.2 Study problem:**

Palestine is in a nutritional transition, which is a state when countries face both the burden of under and over nutrition (Popkin, 1998). This double burden causes significant strains on health care providers. The health system in Palestine is already facing many challenges because of the political situation. There are four main health care providers for Palestinians in West Bank and east Jerusalem. The Palestinian Ministry of Health (MOH), United Nations Relief Works Agency (UNRWA), private sector, the non-governmental organizations (ex. East Jerusalem hospitals) and the Israeli Sick Fund providing care for Palestinians living in Jerusalem (Mataria et al, 2009).

Universal guidelines and consistent care, especially concerning diabetes, are lacking because of the fragmented health care system. Sustainability of the Palestinian health care system is a concern because much of it is sustained by international donors or costs are paid out of pocket by individuals. In addition, accessibility to health care centers is a major challenge both because of security restrictions from the Israelis in the West Bank itself and closures or restrictions of movement out of the West Bank and Gaza (Mataria et al, 2009).

In response to above issues and the rising prevalence of diabetes and other risk factors for cardiovascular diseases in Palestine, such as obesity and hypertension (Abdul-Rahim et al, 2001), and in the context of quality of services for diabetes patients, the Augusta Victoria Hospital (AVH) in Jerusalem, initiated a project funded by the World Diabetes Foundation (WDF) on “Incorporating diabetes prevention and nutrition counseling into medical treatment of diabetes patients”. This program aimed “to promote access to prevention and quality care for diabetic patients and high risk groups in the West Bank”. Therefore, this diabetes program combines diagnostics, medical treatment, nutrition counseling, prevention and foot care.

Since year 2005, a total of 1375 diabetic patients has been assessed by the project team. According to the project protocol, each patient must be referred for nutrition consultation. Each referred diabetic type 2 patient must go through a dietary assessment and follow a group educational program. This dietary assessment falls within the guidelines of the daily food guide pyramid. The details of this program objectives and implementation will be explained in the methodology chapter (chapter 4). However, and since the start of the project, with all the bulk of data presented, from year 2005 only an evaluation was done concerning the management of the program but not the specific productivity of the dietary

program. The dietary and education programs have gone for five years without evaluation. This means that an evaluation study is a necessity to evaluate the dietary program and the education programs content and its effectiveness on the patients' diabetes complications and control. Therefore, we aimed in this study to carry out this evaluation for this five years period. The outcome of this evaluation will be used to inform the project planners and team to modify the program after evaluation if needed.

### **1.3 Justification of the study:**

The association between poor nutrition and risk of chronic diseases later in life is more complex in Palestine than in other developed countries. The Palestinian society is in the stage of nutrition transition that is characterized of low-income countries, where under nutrition and over nutrition coexists (Jackson et al, 2002).

Studies in Palestine identified major risk factors for chronic diseases such as overall and central obesity and high triglycerides (Abdul-Rahim et al, 2001)). In late 1990s, it was observed that high prevalence of type 2 diabetes and obesity in the urban and rural Palestinian areas occurred and the rates are still rising (Abdul-Rahim , 2001; PCBs, 2000). In the demographic health survey in year 2004, it was reported that diabetes, hypertension, and cardiac diseases among all age groups in the West Bank have increased from 2.1%, 2.4%, and 0.6% in year 2000 to 2.4%, 3.4%, and 1.4%, respectively, in 2004. The prevalence among adults aged 35 years and older was 10.2% for diabetes (PCBS, 2006). Cigarette smoking, a key risk factor associated with chronic diseases, was also prevalent in the West Bank, reaching 22% among those aged 10 years and older, and rates were much higher among men (41%) than among women (3%) (PCBs, 2006). Death from acute myocardial infarction is higher among Palestinian men and women living in Jerusalem than among Israeli Jews, this difference is most likely attributable to the high prevalence of risk factors such as obesity and diabetes in both populations; and the stress of the complex political situation and socioeconomic inequalities (Kark et al, 2006).

Abu Rmeileh et al. showed in their analysis of studies on diabetes in Palestine that the prevalence of diabetes in the rural areas was 10% in comparison with 12% in the urban areas, which is considered high (Abu-Rmeileh et al, 2008).

Cross-sectional data for adults (age 30-65 years) in two Palestinian communities in the West Bank showed high rates of obesity (defined as body-mass index  $>30 \text{ kg/m}^2$ ) (Abdul-

Rahim et al, 2003). Obesity is associated with an increased risk of developing hypertension and diabetes. In fact, the prevalence of diagnosed hypertension and diabetes has increased significantly from 1988–1994 to 2001–2004 (21.7% versus 26.7% for hypertension, 5.4% versus 7.3% for diabetes). In addition, the prevalence of obesity has doubled from 25.7% during 1976–1980 to 50.8% during 1999–2004 among people with hypertension. Moreover, strong associations between a higher body mass index (BMI) and risk of hypertension or diabetes exist even among people within a normal BMI range (Zhao et al, 2009).

According to UNRWA's reports, they indicate that there is a steady increase in the burden of disease because they lack human and financial resources. They also lack institution capacity building programs. They are also lacking community participation in reducing the burden of disease. There is an average of 98 patients per doctor per day. Good documentation processes are also limited for diabetics and diabetes care. The current system does not allow enough time and resources for education, essential testing and screening (HbA1c) or diet counseling.

No published study or report reflects the presence of any structured comprehensive program for prevention of diabetes complication in Palestine. Most health education and promotion programs are targeting patients either at the institute setups like hospitals or clinics or very limited health education programs such as the education campaigns done by several charitable organization, example the campaigns of the Union of Health Worker Committees (UHC) and Palestinian Medical Relief Society (PMRS Chronic Disease Program). Other international organizations are just providing educational material for diabetes but none of them supported such programs at the community level.

The implementation of the Diabetes Comprehensive Care Model (DCCM) focused and structured awareness raising and community programs that could target the wider community about healthy lifestyles. The partnership between Augusta Victoria Hospital and UNRWA became much more formalized in 2009 with the additional support from the Danish Representative Office of the Palestinian National Authority to establish a Diabetes center in one of the refugee camps in the West Bank. Due to this project, UNRWA staff members have been trained intensively at AVH and in the new center and HbA1c has been introduced as a central protocol of the testing of some 20,000 registered Diabetics in the West Bank. In addition, this new center provides a foot care service and they have a trained

group of professionals who can respond to this urgent need in their center. AVH has also helped to build the capacity of the health staff within the UNRWA system to act as Dietitians in support of the overall Diabetes work in the clinic.

#### **1.4 Aim of the Study:**

To evaluate the effectiveness of the Diabetes Care Model in controlling diabetes among type 2 diabetic patients registered at the Diabetes Care Center at Augusta Victoria Hospital between the years 2005-2009.

#### **1.5 Objectives:**

1. To examine the effect of nutrition counseling on HbA1c level throughout the follow up period.
2. To examine the effect of the Diabetes program on patients' physical health, body mass index, and lipid profiling throughout the follow up period.
3. To identify patient socio -demographic characteristics determining her/his response to the program.

#### **1.6 Limitation of the Study:**

Many diabetic patients living in the West Bank who joined the program had problems in accessing the center in Jerusalem due to Israel permission restrictions, and the geographic distance which limited the number of patients included in the study.

Detailed data about some aspects of patient management at baseline were not available in this study, such as changes in drug management and compliance of patients with the treatment protocol.

#### **1.7 Expected outcome:**

The expected outcome of this evaluative study is to provide evidence to improve the quality of services provided to diabetic patients including modification of the dietary program, for the next phase of the project that will be expanded to cover other areas in the West Bank.

## **1.8 Thesis chapters:**

The thesis will consist of six chapters. In chapter one, we present study problem statement, study justification, aim and objectives. Chapter two presents the literature review of previous studies that are related to research topic. While in chapter three, the theoretical and conceptual frame work for the study will be discussed. In chapter four the nature and content of the intervention program at the AVH is explained in details. Study setting, study population, type of collected data, method of selecting the patients and extraction of data from patients' files, inclusion and exclusion criteria, ethical consideration, and the study statistical analysis of data are presented. While in chapter five, study results will be presented and demonstrated in form of tables and figures which is built on the univariate and multivariate analysis. While in chapter six, the study findings are discussed and compared to the reviewed literature are presented, in addition, study conclusion and recommendations are presented.

## **Chapter 2: Literature review:**

### **2.1 Introduction:**

Diabetes is a chronic condition of abnormalities in the metabolism of fat, protein and carbohydrates. It is found that in type 1 diabetes there is an absolute insulin deficiency and in type 2 there is relative insulin deficiency and defects in insulin action (Burant, 2004). In the developed countries type 2 diabetes accounts for 85% to 95% of all diabetes cases, while it is even higher in the developing countries (IDF, 2008).

Complications of diabetes account for much of the social and financial burden of diabetes (IDF, 2004). Its complications are severe and might be leading to serious conditions such as kidney failure, blindness, micro and macrovascular complications, cardiovascular disease, and amputation (IDF, 2004).

Type 2 diabetes has been shown to have genetic links but is most often caused by lifestyle factors such as obesity, smoking, and stress. Lifestyle intervention programs that combine regular exercise, dietary modulation and/or oral blood glucose lowering medication have proven to be an effective therapeutic strategy in type 2 diabetes (Mataria et al, 2009).

Therefore, in this chapter, literature related to type 2 diabetes control, in particular lifestyle intervention programs will be presented.

### **2.2 Epidemiology of type 2 Diabetes Mellitus:**

The diabetes burden was estimated to be over than 100 million people in the world by the International Diabetes Foundation (IDF) (IDF, 2011). It is expected that the number of adults with diabetes worldwide to increase from 150 million in 2000 to 300 million in 2025 (Day, 2001). The IDF expects the number will reach 430 million by 2030 (Adebayo, 2011). The spread of type 2 diabetes increases with age and it is estimated to affect nearly 17% of the people aged 65-74 old in USA (Dunstan et al, 2002). The World Health Organization (WHO) year 2002 report indicates that about 58% of the diabetes worldwide can be attributed to body mass index (BMI) above 21 kg/m<sup>2</sup>. Type 2 diabetes and obesity

are closely linked with weight gain resulting in insulin resistance (Adebayo, 2007). In the United States, a study on 17,306 participants aged 20 year between years 1999 to 2006 found that the prevalence of diagnosed diabetes was 6.5% from 1999 to 2002 and 7.8% from 2003 to 2006 ( $P < .05$ ) (Cheung, 2009).

In the Eastern Mediterranean area, it is predicted that the number of diabetics will increase from 22 million to 30 million by 2025 (IDF, 2003). This rapid increase is attributed to different factors such as westernization, economic development, unhealthy diet, urbanization the increase in the number of aging population, obesity and over weight in addition to physical inactivity (Husseini et al, 2009).

In Palestine, according to the WHO estimations, the prevalence of diabetes is increasing. In a study conducted in cooperation between Al-Quds University and the Palestinian Ministry of Health in year 2000 showed that the prevalence of diabetes in Palestine was 9% (Abdeen, 2006). The Union of Palestinian Medical Relief Committee screened 2,482 men and women between the age of 35-65 for obesity, hypertension, diabetes and dyslipidemia. The results showed that 77% of the sample was overweight (BMI > 25), 47% was obese (BMI > 30), 31% with hypertension, 18% with diabetes, and 49% with dyslipidaemia (Abdeen, 2006). Abdul Rahim et al. investigated the prevalence of diabetes and associated factors in a cross-sectional survey of an urban Palestinian population of 492 men and women aged 30-65 years. Diabetes was found in 12.0% of the survey population, including 9.4% previously diagnosed, and impaired glucose tolerance in 5.9%. Logistic regression analysis, controlling for age and sex revealed body mass index, waist-to-hip ratio and family history of diabetes to be significantly independently associated with diabetes (Abdul Rahim et al., 2001). In a study that was conducted in 1996, revealed that, clinical services offered to diabetic patients have no or minimal effect in determining the health status of population. Low quality of educational services was due to lack of trained human resources (Shaar, 1996). In a master thesis on diabetic patient type 1 in Ramallah revealed the prevalence of diabetic complications among type 1 diabetics as follows: retinopathy 36.4%, neuropathy 26.2 and nephropathy 7.5%. The study results showed a significant association between retinopathy and neuropathy with HbA1c, disease duration and patients' sex ( $P < 0.05$ ) (Al-Khdoor, 2007).

In the West Bank, the MOH report for year 2010 showed that diabetes was the six leading cause for death and accounts of 5.7% of all deaths and which was higher among females

(6.95%) compared to males (4.52%) (MOH report 2010). This rate varied by age which was 1.6% among age group 20-59 years and 13.6% among individuals 60 years and above. The report showed that the incidence rate was increasing. In year 2009 the incidence rate was 154 per 100,000 and was 174 per 100,000 populations in year 2010 (MOH report 2010).

### **2.3 Diabetes management:**

In order to prevent diabetes and its complications it is necessary to raise awareness about diabetes, make changes in lifestyle and to improve the quality of care (Quinn, 2008). In this section, literature on the various methods of controlling type 2 diabetes is reviewed.

#### **2.3.1 Glycemic control measure to control diabetes: Glycated hemoglobin HbA1c**

HbA1c mirrors the average glycemia over several months, in addition to its strong value in predicting complications (Alcal et al, 2009; Martin et al, 2006). Its quarterly testing shows if the treatment targets are being met. It is enough for the people with stable glycemia to do the test twice a year. The availability of the results of HbA1c testing when the patient is seen had a great influence on the treatment process and leads to better and improved glycemic control (Stratton et al, 2000; Miller et al, 2003). In clinical practice, optimal glycemic control is difficult to obtain on a long-term basis because the reasons for poor glycemic control in Type 2 diabetes are complex (Wallace , 2000). Both patient- and health care provider related factors may contribute to poor glycemic control (Rhee et al., 2005; Wallace, 2000). In Emirates, the mean HbA1c for diabetic patients with type 2 diabetes in primary health care was 8.3%, and only 38% of patients had good glycemic control (HbA1c < 7.0%) (Juma Al-Kaabi et al, 2008). In Amman-Jordan the percentage of patients with optimal control (HbA1c ≤ 7%) increased from 25.4% at the first visit to 27.5% at 12-month follow-up (M. Adham et al , 2010). In Al-Ain, UAE the mean HbA1c declined from 8.5% in 2008 to 7.5% in 2010.(Layla Alhyas et al, 2012) . In Iraq the mean HbA1c levels at the start of the study was  $9.8 \pm 1.9$  % and after 3 years it was  $8.1 \pm 1.6$  % (Mansour et al, 2011). In Saudi Arabia 27% of the patients reached target level of glycemic control (Akbar, 2001). In Kuwait, only 17.6% of patients had achieved the goal of HbA1c < 7% and In Trinidad, 15% of the patients had HbA1c ≤ 7% (Ezenwaka & Offiah, 2001). Baseline data of newly diagnosed patients enrolled to the Korea National Diabetes Program (KNDP) cohort study conducted in Korea showed that mean HbA1c was

8.2 ± 2.4%. (Choi et al, 2011). In Sweden a survey revealed that from type 2 diabetes patients only 34% had good glycemic control (Holmström IM et al, 2005). In Finland, only 25% of a study group had HbA1c < 7.3%. (Valle T et al, 1999). The authors suggested that the difficulty to obtain optimal glycemic control ( HbA1c <7) is attributed to the rapid urbanization, poor lifestyle habits, obesity, physical inactivity and the poor adherence and follow up of diabetic patients to structured diabetes care programs.

Diabetic patients are advised to do the HbA1c testing on a regular basis as part of their ongoing treatment. It was found that lowering HbA1c levels reduces the development of diabetes complications. As HbA1c decreases by 1%, micro-vascular complication decreases by 37%, as well as macro-vascular complications (Ousman et al, 2011). Micro vascular and neuropathic complications of diabetes were reduced when the HbA1c was reduced to 7% or below. It is also accompanied with a long-term reduction in macro vascular disease if it was implemented soon after the diagnosis of diabetes (ADA, 2011). In Sweden a survey revealed that from type 2 diabetes patients only 34% had good metabolic control (Holmström IM et al, 2005).

Significant decrease in the rates of micro vascular (retinopathy and nephropathy) and neuropathic complications resulted from improved glycemic control was shown in two important epidemiological studies, i.e. the Diabetes Control and Complication Trial (DCCT) and the UK Prospective Diabetes Study (UKPDS) (Ohkubo Y et al, 1995; UKPDS, 1998). As suggested by these studies, analyses of large portion of diabetes complications were avoided by moving patients from weak control to good or fair control. Furthermore, studies analyses suggest that lowering HbA1c from 7% to 6% is accompanied with reduction in the risk of microvascular complications (Gerstein, 2008).

A cross-sectional, case-control study in Negri Bergamo Laboratories in Italy explored the association of proliferative diabetic retinopathy (PDR) with insulin resistance (IR) in type 2 diabetics. PDR patients (n= 29) had higher IR and low-density lipoprotein cholesterol (LDL) and triglyceride levels than Bilateral Diabetic Retinopathy (BDR) patients (n=29), but comparable levels of HbA1c. Compared with patients without retinopathy (n = 58), those with PDR had higher IR, low-density lipoprotein cholesterol, and albuminuria; those with BDR had higher HbA1c, but comparable IR (Parvanova, et al. 2004).

A study in Saudi Arabia examined the impact of glycemic control on diabetic lipid profile and determining that HbA1c as an indirect marker of dyslipidemia. 1011 type 2 diabetes

patients were chosen (males, 574; females, 437) mean age was 59.76 years. HbA1c levels, FBS and LDL were similar in the case of males and females. Serum cholesterol levels and HDL were higher in females and TG levels were lower among females compared to males. HbA1c levels and FBS had a strong relationship and both showed strong correlation with TG, cholesterol and LDL, and inverse relation with HDL. There was a linear relationship between HbA1c and dyslipidemia. The levels of serum cholesterol was significantly higher among patients with worse glycemic control as compared to patients with good glycemic control. The findings of this study clearly indicate that HbA1c is a good predictor of lipid profile. (Khan HA et al., 2007)

In the National Health and Nutrition Examination Survey the trends in HbA1c levels was examined for adults with diabetes using three periods: 1999–2000, 2001–2002, and 2003–2004. Mean HbA1c levels decreased from 7.82% in 1999–2000 to 7.47% in 2001–2002 and 7.18% in 2003–2004. Controlled Diabetic patients with HbA1c < 7.0% increased from 37.0% in 1999–2000 to 49.7% in 2001–2002 and 55.7% in 2003–2004; this indicates corresponding betterment over time (Hoerger et al, 2007).

Effective diabetes management programs, assessment of the target population's needs, implementing programs that include screening, surveillance and involvement of patients in the programs and evaluation of diabetes programs are all key characteristics of effective diabetes management. Glasgow et al studied using a cross over design study that involved 162 diabetic patients with type 2 diabetes over the age of 60 years using a multidisciplinary team that included also a dietitian. Reduction in caloric intake and percentage of calories from fat was significant in the intervention group compared to the control group. When control group patients crossed over to the intervention group, their HbA1c levels decreased from 7.4% to 6.4% (Glasgow et al. 2001)

### **2.3.2 Lifestyle Changes and diabetes control:**

There are lots of ways designed to help specialists to control diabetes, from changing eating habits to increasing physical activity. However, the responses to the illnesses of some patients are influenced by their beliefs, attitudes, and experiences (Hamlets, 2011). It was found that intensive lifestyle intervention make long-term valuable modification in diet, physical action, and clinical and biochemical parameters. This helps preventing type 2

diabetes and should be implemented as one of the most important health care system (Lindstrom et al, 2003).

It was assured that diet and exercise can postpone the onset of type 2 diabetes in persons at risk strongly exists. In one intervention trial in year 1986, 110,660 men and women from 33 health care clinics in the city of Da Qing in China where 577 subjects with impaired glucose tolerance were randomized to control, diet, and exercise groups. Over a period of six years, 67% of the control group but only 41 to 43% of the intervention groups developed type 2 diabetes, which is around 25% risk reduction (Pan X et al, 1994).

Prospective cohort study examined associations of lifestyle factors, measured using repeated assessments later in life, with incident diabetes mellitus during a 10-year period (1989-1998) among 4883 men and women 65 years or older enrolled in the Cardiovascular Health Study. Low-risk lifestyle behaviors were defined by physical-activity levels above the median and never smoking or smoking  $\leq 5$  pack-years or having quit smoking  $\geq 20$  years ago. Alcohol use in this cohort was rare, with 94% consuming less than two drinks daily. Individuals were also assigned a dietary score based on their intake of dietary fiber, low glycemic index foods, lower trans-fats, and a higher polyunsaturated-to-saturated-fat ratio. Assessments of adiposity were also performed, with a low-risk body-mass index (BMI) defined as not being overweight, or a BMI  $< 25$ , while a low-risk waist circumference for men was  $< 92$  cm and  $< 88$  cm for women (Mozaffarian et al, 2009).

917 type 2 diabetic patients were randomly selected for the study for a period of 6 months in 2008. The objective of this study is to evaluate and determine the factors associated with poor glycemic control among Jordanian type 2 diabetics. Weight, height and waist circumference were measured for the sample in addition to the last HbA1c, fasting blood sugar and lipids. "Poor glycemic control was defined as HbA1c  $\geq 7$ . 65.1% among the patients studied appeared to be within the poor glycemic control% had HbA1c  $\geq 7$ %. In the multivariate analysis, increased duration of diabetes (N $> 7$  years vs.  $\leq 7$  years) (OR=1.99, P $\leq$ .0005), not following eating plan as recommended by dietitians (OR=2.98, P $\leq$ .0005), negative attitude towards diabetes, and increased barriers to adherence scale scores were significantly associated with increased odds of poor glycemic control. The authors concluded that Educational programs, raising awareness, campaigns and lifestyle modifications will bring benefit in glycemic control among diabetics. (Khattab et al., 2008)

Zgibor et al conduct a survey to identify patient behavior change goals and diabetes educator responses including 954 diabetics with type 1 and 2 diabetes. 74% and 54% of diabetics identified that healthy eating and being active respectively as the most common behavior-change goal (Zgibor et al, 2007).

In a systematic review and Meta analysis research to study the association between active smoking and incidence of type 2 diabetes. The research composed of 25 cohort studies (N= 1.2 million participants), reported that 45,844 incident cases of diabetes during a follow up period ranging from 5 – 30 years. In this study, participant selection was based on having impairment in fasting glucose; those with impaired glucose tolerance; or type 2 diabetic patients with having their smoking status at baseline. While excluded if they were diabetic at baseline. Results showed that "the risk of diabetes was greater for heavy smokers (more than 20 cigarettes/ day; RR, 1.61; 95% CI, 1.43-1.80) than for lighter smokers (RR, 1.29; 95% CI, 1.13-1.48) and lower for former smokers (RR, 1.23; 95% CI, 1.14-1.33) compared with active smokers". As a conclusion, active smoking is coupled with an increase risk of type 2 diabetes (Willi et al, 2007).

### **2.3.3 Dietary Control in type 2 diabetes and diabetes management:**

Nutritional intervention is an essential element of diabetes prevention, management, and self-care education. It is important at all levels of diabetes prevention, in addition to its role in preventing and controlling diabetes (Bantle et al, 2008). People with diabetes are normally advised to implement a healthy diet; dietary changes include modifications in food habits and meal patterns for lifelong. However, a significant amount of patients remain with limited control (Yannakoulia, 2006). In a study that took place in Iran with a goal of examining the association of glycemic control with the demographic, anthropometric, clinical and other data among Iranian diabetic females. The percentage of patients with poor glycemic control was 56.3%. Controlled and uncontrolled patients' glycemic control did not differ with respect to age, education, marital status, smoking, duration of disease, medication, blood pressure, duration of disease, waist circumference and presence of dislipidemia. (Ghazanfari et al., 2010)

The treatment of type 2 diabetes through dietary control has been found effective and it is known with the name Medical Nutrition Therapy (MNT). This kind of therapy depends on diagnosing, treatment and counseling. It must be provided by a nutrition specialist or

dietitian. The steps of MNT include assessment of individuals and follow up. The nutrition specialist designs or plans the meals for the patient. Routine visits to the nutrition specialist are vital in order to adapt and improve the treatment (Campbell et al, 2009).

It was obviously noticed that MNT proved to be helpful for diabetics. Sustained improvements in HbA1c at 12 months and longer was seen among those consulting with registered dietitian that provided follow-up visits ranging from monthly to three sessions per year. HbA1c have decreased by 1% in type 1 diabetes and by 1-2% in type 2 diabetes. Improvements were clear after 3 to 6 months of starting MNT. Studies have shown a decrease in HbA1c during the same period by 0.25% to 2.9%. Reductions were higher for type 2 diabetes in a shorter period of time (ADA, 2008). Furthermore, studies on non-diabetic people showed that MNT reduces LDL cholesterol by 15–25 mg/dl up to 16% and play a role for lifestyle modification in treating hypertension (Franz et al, 1995; Van Horn, 2008). Success in nutrition therapy lies in the food choices that are made. Research evidence proved that nutrition advice in the form of guidelines for healthy food choices is equally effective in producing changes in glycemic control as the traditional exchange-based dietary regime (Ziemet et al, 2003).

A case study showed that abiding to moderate lifestyle of light supper with morning swimming for 40 minutes decreased HbA1c level from 6.7 to 6.0 in six months and to keep this level for the following six months. The results also indicate that the recovery time of the postprandial blood glucose level can be adjusted to 4 hours (Hsin-i Wu, 2005). Also, a high intake of total fat increases the risk of developing impaired glucose tolerance. Substituting saturated by unsaturated fatty acids improve glucose tolerance and increase insulin sensitivity (Parker DR et al, 1993).

The potential role for dietary fiber in diabetes was first promoted more than 30 years ago by Trowell on the basis of his experience in East Africa where he noted a virtual absence of what is now known as type 2 diabetes in association with the consumption of traditional diets which were extremely high in 'lightly processed' cereal foods. Uncontrolled clinical studies from Anderson's group in Kentucky demonstrated that introduction of a high carbohydrate high fiber diet was associated with a dramatic improvement in glycemic control and reduction in insulin dose for a small number of insulin-treated patients (Mann, 2001)

The low glycemic index (low-GI) diets were proved to improve insulin sensitivity, HbA1c level, blood lipid concentrations and increase blood HDL cholesterol concentrations. In a trial to compare the effects of low-GI diet with the high cereal fiber diet, it was shown that HbA1c was decreased by 0.5% in the low-GI diet and by 0.18% in the high cereal fiber diet. Another study showed a reduction by 0.43% in HbA1c in the low-GI diets. The experts from the WHO and FAO encourages the low-GI diets (Adebayo, 2007).

Three self-assessed daily blood glucose profiles over a 1-week period, including 18 glucose readings before and 2 hours after meals, were obtained from 3,284 unselected outpatients (men 51%; age  $63\pm 10$  years) with non-insulin-treated type 2 diabetes mellitus attending 500 different diabetes clinics operating throughout Italy. More than 84% of people with type 2 diabetes experience significantly elevated post-meal blood glucose (Bonora et al, 2006). This is a main worry due to the link between elevated post-meal glucose and diabetes complications (Ceriello, 2005).

The nutritional advice for people with diabetes was recognized as major issue in treatment of the disease. The aim of dietary recommendations is to prevent and treat diabetes through improving glycemic control and lipid profile and optimizing the blood pressure, as high risk of microvascular abnormalities and cardiovascular diseases in diabetic subjects is linked to increased postprandial glucose response (ADA, 2011).

In a cross-sectional study conducted in the regional diabetes clinic at the Prince of Wales Hospital (PWH) of Hong Kong. This study investigated a total of 562 consecutive newly-referred to type 2 diabetic patients (57% women) during a 12-month period. All patients underwent a structured assessment with documentation of clinical and biochemical characteristics. At the time of referral, 70.5% ( $n=396$ ) were on drug therapy (9% on insulin and 62.8% on oral agents), 20.6% ( $n=116$ ) were on diet and 9% ( $n=50$ ) had not received any form of treatment. HbA1c was lower in patients who had seen a dietitian (7.9% vs. 8.7%,  $p<0.001$ ) or diabetes nurse (7.8% vs. 8.7%,  $p<0.001$ ) or who performed self blood glucose monitoring (7.9% vs. 8.6%,  $p=0.001$ ) and higher among smokers (8.9% vs. 8.2%,  $p=0.003$ ) (Chan, 2000).

To describe diet and exercise practices from a nationally representative sample of U.S. adults with type 2 diabetes, Karin et al analyzed data from 1,480 adults older than 17 years with a self-reported diagnosis of type 2 diabetes in (NHANES III). Fruits and vegetables consumption was obtained from a food frequency questionnaire. The percentages of total

calories from fat and saturated fat were obtained from a 24-h food recall. Physical activity was based on self report during the month before the survey. Results of individuals with type 2 diabetes show that 31% reported no regular physical activity and another 38% reported less than recommended levels of physical activity. Sixty-two percent of respondents ate fewer than five servings of fruits and vegetables per day. Almost two thirds of the respondents consumed >30% of their daily calories from fat and >10% of total calories from saturated fat. Lower income and increasing age were associated with physical inactivity. Thirty-six percent of the sample was overweight and another 46% were obese. Mexican Americans and individuals over the age of 65 years ate a higher number of fruits and vegetables and a lower percentage of total calories from fat (Karin et. al, 2002).

Anderson et al examined in one meta analysis of eight studies the effects of very low and low calorie diets in 219 obese subjects with type 2 diabetes. The eight studies concluded that 11.1% of their initial weight and fasting plasma glucose decreased by 14.7% at 48 weeks (Anderson et al, 2003).

Another meta-analysis examined eleven randomized controlled trials including 402 participants to study the efficacy of low glycemic index diets in people with type 1 and type 2 diabetes. Data for six trials measuring HbA1c showed a mean reduction of 0.5% for patients on low glycemic index diets compared to patients with higher glycemic index diets (Thomas et al, 2009).

In a study, 102 of patients with type 2 diabetes were randomly divided into two groups to receive group education and individual dietary advice for six months. One of the groups received a diet with 13% of carbohydrates of their daily energy intake and the other group received 33% of carbohydrates from their daily energy intake. In patients who adhere to a low carbohydrate diet a reduction in weight was greater than the other group (Daly et al, 2006).

A randomized crossover study examined the beneficial effects of high dietary fiber intake in patients with type 2 diabetes mellitus. Thirteen patients with type 2 diabetes were recruited to follow two different diets for six weeks. One of the diets contains moderate amounts of fiber as the ADA recommends and the other is a high-fiber diet. During the sixth week, the high-fiber diet, as compared with the sixth week of the ADA diet. Mean daily pre-prandial plasma glucose concentrations was 13 mg/dl lower, and also reduced

plasma total cholesterol concentrations by 6.7 percent, triglyceride concentrations by 10.2 percent, and very-low-density lipoprotein cholesterol concentrations by 12.5 percent (Chandalia et al, 2000). Also, in a study that investigated the effect of a low-glycemic index diet versus a high-cereal fiber diet on glycemic control and cardiovascular risk showed that HbA1c decreased by 0.50 percent in the low-glycemic index diet compared with 0.18 percent in the high-cereal fiber diet (David et. al, 2008).

In a prospective randomized trial, in USA, that used two levels of MNT on metabolic control in persons newly diagnosed with or currently under treatment for non insulin dependent diabetes, showed that “with more intensive nutrition intervention, changes in lifestyle can lead to significant improvements in glucose control. The fasting plasma glucose level decreased by 50–100 mg/dl and the HbA1c dropped by 1–2%. The average duration of diabetes for all subjects was 4 years and the decrease in HbA1c was 0.9% (from 8.3 to 7.4%). In the subgroup of subjects with duration of diabetes  $\geq$  1 year, the decrease in HbA1c was 1.9% (Franz et al, 1995).

In a randomized trial study in a teaching hospital in Naples-Italy, showed greater benefit from a low-carbohydrate, Mediterranean-style diet compared with a low-fat diet in patients with newly diagnosed type 2 diabetes mellitus. This trial included 215 overweight patients with newly diagnosed type 2 diabetes mellitus who had never been treated with antihyperglycemic drugs and whose HbA1c levels were less than 11% were assigned to either a Mediterranean-style diet (< 50% of daily calories from carbohydrates) ) ( $n = 108$ ) or a low-fat diet (<30% of daily calories from fat) ( $n = 107$ ). After 4 years results showed that the participants assigned to the Mediterranean-style diet had lost more weight and had more improvement in some measures of glycemic control and coronary risk than had participants consuming the low-fat diet. About 44% of patients in the group adhering to the Mediterranean diet required anti hyperglycemic drug therapy, compared with 70% of those in the low-fat diet group (Esposito et al, 2009).

A study examined the association between the magnitude of weight loss and changes in CVD risk factors at 1 year showed that weight loss was strongly associated with improvements in glycemia, blood pressure, triglycerides, and HDL cholesterol. Also when compared with weight-stable participants, those who lost 5 kilograms or less than 10% of their body weight had increased odds of achieving a 0.5% point reduction in HbA1c (Wing et. al, 2011).

### **2.3.4 Diabetes and physical exercise:**

Exercise is an important element of diabetes management. People with diabetes should be advised to perform at least 150 min/week of moderate-intensity aerobic physical action. Standard exercise proved to improve blood glucose control, reduce cardiovascular risk factors, improve well-being, and contribute to weight loss (ADA, 2004).

Trials have provided strong evidence for the HbA1c-lowering value of resistance training in older adults with type 2 diabetes and for an additive benefit of combined aerobic and resistance exercise in adults with type 2 diabetes. It was shown that designed physical exercises of at least 8 weeks are helpful in lowering HbA1c by an average of 0.66% in type 2 diabetic people. The improvements in HbA1c are better if the exercises were higher in levels (ADA, 2011). Also, it was shown that continuous endurance-type exercise lowers blood HbA1c, increase insulin sensitivity, increase the risk profile for cardiovascular disease and reduce adipose-tissue mass in patients with type 2 diabetes (Hansen, 2009).

In a randomized controlled trial to study the effect of high-intensity progressive resistance training combined with moderate weight loss on glycemic control and body composition in sedentary, overweight (BMI > 27 and < or equal to 40) in 36 men and women aged 60–80 years with non insulin treated diabetes who were diagnosed with for more than 6 months and had HbA1c of 7-10%. HbA1c decreased significantly more in resistance training and weight loss than in weight loss alone at 3 months and 6 months. When compared with moderate weight loss, resistance training was more effective for improving HbA1c than moderate weight loss without resistance training. The author recommended this form of exercise in the management of glycemic control of adult patients with type 2 diabetes. (Dunstan et al, 2002)

A randomized controlled trial was performed in a population of Latino older adults with poor glycemic control and no personal history of regular exercise adults with type 2 diabetes ( n=62) to determine the ability of high intensity, low-volume progressive resistance training (PRT) to improve glycemic control and other metabolic abnormalities. Glycemic control, metabolic syndrome abnormalities, body composition, and muscle glycogen stores were determined before and after the intervention. Sixteen weeks of PRT (three times per week) resulted in reduced HbA1c levels (from 8.7 to 7.6), and reduced the

dose of prescribed diabetes medication in 72% of exercisers compared with the control group,  $P = 0.004$ – $0.05$ . Control subjects showed no change in HbA1c, and a 42% increase in diabetes medications. PRT subjects versus control subjects also reduced systolic blood pressure ( $-9.7$  vs.  $+7.7$  mmHg). Author concluded that supervised high intensity resistance training proved both feasible and effective among high-risk older adults with type 2 diabetes, resulting in improved glycemic and metabolic control (Castaneda et al 2002).

A meta-analysis of randomized, controlled clinical trials of at least 12 weeks duration evaluated the ability of structured exercise training or physical activity advice to lower HbA1c levels as compared with a control group in patients with type 2 diabetes. A total of 47 RCTs studies ( $n=8538$  patients) were included. Overall, structured exercise training in 23 studies was associated with a decrease in HbA1c level ( $-0.67\%$ , to  $-0.49\%$ ) compared with control participants. In addition, structured aerobic exercise, structured resistance training, and both combined were each associated with declines in HbA1c levels compared with control participants. Further analysis indicated that interventions which included structured exercise durations of more than 150 minutes per week were associated with HbA1c reductions of  $0.89\%$ , while structured exercise durations of 150 minutes or less per week were associated with HbA1c reductions of  $0.36\%$ . In 24 studies interventions of physical activity advice were associated with lower HbA1c levels compared with control participants. Combined physical activity advice and dietary advice was associated with decreased HbA1c ( $-0.58\%$  to  $-0.43\%$ ) as compared with control participants. Physical activity advice alone was not associated with HbA1c changes (Umpierre, 2011).

A Meta analysis study evaluated the effect of exercise interventions (duration  $\leq 8$  weeks) in adults with type 2 diabetes (11 randomized and 3 non-randomized) using controlled trials. The mean HbA1c post physical exercise intervention was lower in the exercise groups compared with the control groups ( $7.65\%$  versus  $8.31$ ). The authors concluded that exercise training reduces HbA1c by an amount that should prevent the risk of suffering diabetic complications, but no significantly greater change in body mass was found when exercise groups were compared with control groups (Boule et. al, 2001).

### **2.3.5 Diabetes and overweight:**

Obesity is the main reason behind the onset of diabetes. Estimations say that 60 to 90% of type 2 diabetes is attributed to obesity. An increase in the prevalence of obesity in several populations has been noticed after transition from traditional diets to western diets (Adebayo, 2007).

Controlling body weight is of great importance in reducing risks related to diabetes. Due to the effects of obesity on insulin resistance, weight loss is an important therapeutic objective for individuals with pre-diabetes or diabetes (ADA, 2008). Moderate weight loss (5% of body weight) in people with type 2 diabetes is associated with decreased insulin resistance, improved measures of glycemia and lipemia, and reduced blood pressure as proved by short-term studies. Moreover, weight gain, the degree of obesity and its duration, all separately predict the commencement of type 2 diabetes. It was calculated that nearly 65 to 75% of diabetes cases could be avoided in white people if the BMI of the population did not exceed 25 kg/m<sup>2</sup> (Seidell, 2000). Also, it was noted that an increasing amount of planned weight loss was accompanied with a linear decrease in diabetes occurrence among obese adults; active weight loss is a valuable way to the treatment of diabetic people (Colditz et al, 1995; Will et al, 2002).

In the United States, a study on 17,306 participants aged 20 year between years 1999 to 2006 found that the prevalence of diagnosed diabetes increased significantly in women, non-Hispanic whites, and obese people (Cheung, 2009). Another study in which type 2 diabetic patients were treated in a behavioral weight control program and followed up for one year showed that weight loss was significantly correlated with improvements in HbA1c. Patients who lost more than 6.9 kg or had more than 5% reduction in body weight had significant improvements in HbA1c values at one year (Wing, 1987).

In 2004 a meta-analysis assessed the effectiveness of lifestyle and behavioral weight loss and weight control interventions in adults with type 2 diabetes. A total of 22 studies were included. In this analysis, persons who adhere a physical activity and very low calorie diet lost 3 kilogram more than those who adhered to a very low-calorie diet alone. Persons who underwent a more intense physical activity intervention lost 3.9 kg more than those who received a less intense or no physical activity intervention with adhering to the same dietary and behavioral intervention. Several studies reviewed in this meta-analysis reported a significant reduction in HbA1c of 1.0% to 2.6% with lifestyle intervention corresponding

to weight loss (Norris et al, 2004). In the UKPDS, the degree of weight loss required to normalize the fasting blood glucose was 10 kg (16% of initial body weight) if the initial value was 6-8mmol/L versus 22 kg (35%) if the initial value was 12-14 mmol/L (NHS, 2008).

In a randomized control trial weight loss of 8.5% through an intensive education and support program decreased HbA1c by 0.64% (6.99mmol/mol) and decreased fasting blood glucose by 1.19mmol/l. The use of glucose-lowering medication was reduced from 86.5% to 78.6% (Pi-Sunyer, 2007).

The prevalence of obesity was found to be high at 41% among the Palestinian urban population (49% among women and 30% among men). This was indicated in a study to show the relations between the prevalence of obesity and central obesity and selected co-morbidities, including diabetes, hypertension and dyslipidaemia in the Palestinian urban society (Abdul-Rahim, 2001). A significant relation was found between obesity and diabetes, low HDL cholesterol and elevated triglycerides. Furthermore; a substantial link between hypertension and central obesity was found. The prevalence of central obesity in men was more than in women (59% compared to 25% in women) (Abdul-Rahim, 2001).

### **2.3.6 Self care management:**

Self management is very essential for preventing further diabetes complications. Adherence and self care are two of the biggest challenges in managing diabetes. Self management in practice is complex and difficult since it should include meal planning, being physically active, skin care, taking medicines, foot care, avoiding smoking and tobacco, and other health monitoring tasks (Ahmed, 2006).

Studies showed that one-in-four (28%) were poor adherers to their diabetes (Gatt, 2008)) and as many as 50% do not take their medication regularly (WHO and IDF, 2004). Factors such as stress, eating certain foods, or being physically inactive can dramatically change blood glucose readings (Ahmed, 2006).

Research has shown that various factors influence patients adherence to diabetes management some of these include their personal beliefs, perceptions of the health system, trust of doctors, emotional and psychological status; and outside support (Ahmed ,2006; Donnan, 2002; Collins, 2009). Adherence is particularly difficult for the elderly and for patients receiving long term care (Donnan, 2002).

The role of Self management was shown in several studies to affect the control of HbA1c. It has been found that there is not always time for primary health care providers to conduct diabetes specific assessments or discuss self care management with patients. Yet improved status of the Glycated hemoglobin (HbA1c) and other diabetes indicators has been found when sustained health care is provided (Quinn et al, 2008).

In a cross-sectional survey in U.S in 2004 for adults with type 2 diabetes who had HbA1c checked in the past 6 months (n=686). 66% reported that they did not know their last HbA1c value and only 25% accurately reported that value. Participants who knew their HbA1c values reported better diabetes care understanding and assessment of their glycemic control than those who did not. It was concluded that knowledge of HbA1c level alone was not sufficient to increase better understanding of diabetes care necessary to improve patients' diabetes self-management. (Heisler et. al, 2005)

From 2003 to 2005, a telephone survey of adults with type 2 diabetes was performed to examine self-management behaviors and glycemic control. Analyses compared patient characteristics and self-management behaviors to recent HbA1c levels. Of 139 patients contacted, (74%) completed the study. Mean HbA1c was 7.7%, and the average duration of diabetes was 2.0 years. More than 80% of patients reported  $\geq 75\%$  medication compliance, and 59% monitored blood glucose  $> 2$  times daily  $> 70\%$  of patients reported exercising  $\geq 2$  times a week, but 68% reported watching  $\geq 2$  hours of television daily. Although patients reported good medication and monitoring adherence, they also reported poor diet and exercise habits and multiple barriers. Non white race were significantly associated with higher HbA1c. As authors concluded this may be related to difference in lifestyle behaviors and that additional studies are needed for further assessment of self-management behaviors and potential racial disparities in adults with type 2 diabetes (Russell et al, 2008).

### **2.3.7 Diabetes Self-Management Education (DSME) and its education programs:**

Diabetes Self Management Education DSME is the process of teaching individuals with diabetes to manage their disease and is an integral component of the treatment plan (CDC, 2003).

Patients must receive accurate diabetes education from the healthcare team in order to be able to self-manage their disease. This team includes the primary physician, nurse, certified

diabetes educator, registered dietician, pharmacist, podiatrist, ophthalmologist and the patient (Carney, 2010).

When diabetes is diagnosed; it is recommended that the patient should receive diabetes self management education by a qualified health care provider according to the National Standards of Diabetes Self Management Education (DSME). The diabetes health care educator should be skilled, experienced and with up to date knowledge and skills in diabetes, educational principles and behaviour change strategies (AADE,1999) (Gigina, 2007).

A meta-analysis of randomized and controlled trials of diabetes patient education published from 1990–2000 and evaluated educational interventions in adult outpatients with diabetes, and reported on HbA1c concentrations before and after the intervention and at  $\geq 12$  weeks after the intervention was conducted. This study included 21 articles, with 28 educational interventions (n=2439). It was noted that the net glyceimic change was 0.32% lower in the intervention group than in the control group. Further analysis indicated that interventions which included face to face delivery, cognitive reframing teaching method, and exercise content were more likely to improve glyceimic control. The authors concluded that current patient education interventions modestly improve glyceimic control in adults with diabetes (Ellis et al, 2004).

Several studies have shown that DSME is associated with improved diabetes knowledge and improved self-care behavior, improved clinical outcomes such as lower HbA1c, lower self-reported weight, improved quality of life, healthy coping, and lower costs (Norris, 2001).

The results were better when the DSME interventions lasted for longer periods and included follow-up. Patients who participate in diabetes education are more likely to follow the best treatment recommendations. Both individual and group approaches have been proved helpful (ADA, 2011).

In a small study, confirmed in a similar group of patients that an intensive educational program, including dietary instruction, had the potential to improve glyceimic control to the extent that delaying the introduction of insulin was considered appropriate (Coppell et al, 2011).

A meta analysis of 31 studies showed that self management education (DSME) decreased HbA1c by 0.76%. HbA1c decreased more with additional contact time between participant and educator; a decrease of 1% was noted for every additional 23.6 hour of contact. The authors concluded that the meta-analysis provides evidence of the efficacy of DSME for patients with type 2 diabetes for glycemic control and that further research is needed to develop interventions effective in maintaining long-term glycemic control (Norris et al.,2002).

A Cochrane systematic randomized controlled and controlled clinical trials evaluated group-based education programs for adults with type 2 diabetes compared with routine treatment, waiting list control or no intervention. The review included only studies that assessed outcome measures six months or more from baseline. The results of this meta-analyses that favoured group-based diabetes education programs included: reduced HbA1c at four to six months, 12–14 months and two years; reduced fasting blood glucose levels at 12 months; reduced body weight at 12–14 months; improved diabetes knowledge at 12–14 months; and reduced systolic blood pressure at four to six months. The authors concluded that group-based training for self-management strategies in people with type 2 diabetes positively impacts health outcomes by improving fasting blood glucose levels, HbA1c and diabetes knowledge and reducing systolic blood pressure levels, body weight and the requirement for diabetes medication (Deakin et al.,2005).

A randomized, controlled study to determine the effects of a diabetes self-management program on glycemic control, coronary heart disease (CHD) risk, and quality of life was conducted on 147 type 2 diabetic patients. The patients were randomized into two groups for a six months period. The experimental group received the diabetes self-management program and the control group received the usual nursing care. The results indicated that the experimental group had statistically significant lower HbA1c than the control group at 24 weeks. 12% patients in the experimental group reached the HbA1c level recommended by ADA (HbA1c <7%) compared to 1.39% in the control group. The experimental group was noted to have a decrease in the CHD risk factors, including total cholesterol, triglycerides, LDL cholesterol, diastolic blood pressure and body mass index (BMI) and a greater increase in HDL cholesterol levels as compared to the control group. The authors concluded that the diabetes self-management program was effective for improving metabolic control and quality of life for individuals with diabetes and that further studies should be replicated using larger groups over a longer time frame. (Wattana et al, 2007).

A study was done in a sample from the Old American Nutrition Program OANP, where 105 was the number of participants, with a mean age of 73 years, and 70% among them were women. The study tested the hypothesis that A1C knowledge is positively correlated to demographic and health characteristics, and that an education intervention would increase HbA1c knowledge and decrease HbA1c blood levels. In regression analyses, higher HbA1c knowledge at baseline was negatively associated with age ( $P < 0.0001$ ) and HbA1c blood levels ( $P < 0.07$ ). In the subset of participants that completed the intervention, the percent of participants who scored 40% or higher on HbA1c knowledge increased from 48% to 82% ( $n = 99$ ). After the intervention, blood HbA1c decreased 0.66% in participants with initial HbA1c  $> 6.5\%$  ( $n = 43$ ) (Burnett, 2003).

A randomized study investigated 170 subjects with type 2 diabetes, who were assigned to two different groups either group ( $n = 87$ ) or individual ( $n = 83$ ) educational settings over a period of 6 months. Outcomes included “changes in knowledge, self management behaviors, weight, BMI, HbA1c, health related quality of life, patient attitude and medication regimen. Education material included information on carbohydrate counting, portion control, meal spacing, self-monitoring of blood glucose, physical activity, heart-healthy eating, foot care, sick day management, monitoring for diabetes complications, self-management problem solving, and information regarding the progression of type 2 diabetes. They found that knowledge scores increased significantly in both treatment groups. In addition, “HbA1c decreased in both groups. However, the individuals receiving group education had an HbA1c reduction of 2.5% compared to the 1.7% reduction seen in the individuals receiving individual treatment. Therefore, the authors concluded that group diabetes education was as effective as individual diabetes education (Rickheim et al, 2002). Foods like bread, pasta, rice, cereal, milk, fruit and starchy vegetables such as corn and peas are considered carbohydrate foods and consumed daily by the majority of the people. All these foods cause higher levels of blood sugar. As indicated by many studies; the intake of nutrients plays a major part in Diabetes Self Management Education (DSME) programs. Teaching people how to distribute their consumption of carbohydrates during the day is vital to the nutrition management of diabetes and allows diabetic people to control what they eat by choosing the most suitable carbohydrate and non-carbohydrate foods (Carney, 2010).

The patients are taught through DSME programs to plan their meals according to the recommended amounts of carbohydrates they should consume during the day (Carney, 2010).

The major areas of DSME programs are: Nutrients in food and their effect on blood glucose levels, carbohydrate exchanges, the plate method and portion control, food labels, and sweeteners (Carney, 2010).

An intervention study aimed to determine the benefits of diabetes education and dietician counseling in New York city, allocated patients into two groups, a treatment group (include patients referred to a diabetes educator and dietician for counseling by their primary care physician, n=150), and a control group (those not referred to a diabetes educator or dietician, n=150). Weight and HbA1c levels were compared before the study and six months after study initiation. Mean HbA1c was significantly reduced by 1.02% among patients who had contact with a diabetes educator and dietician compared with a 0.59% decrease among patients who did not. Weight decreased by 2 lb among patients in the treatment group ( $P<0.05$ ) compared with 0.71 pounds among patients in the control group ( $P=0.36$ ). Researchers recommend that physicians should refer as many patients as possible with type 2 diabetes to diabetes educators as it is essential for good glycemic control (Hildegarde, 2009).

In a study conducted to identify how selected factors influence patient use of diet regimens for diabetes and to determine the effect of demographic characteristics reported that personal motivation, social support, continuity of care and the understanding of meal plans and diet positively affects the diabetes self management. On the other hand, emotional factors, busy schedules and holidays negatively affect patient's self care and diabetes management. Travis used 75 item questionnaire designed to collect responses from non insulin dependent diabetic patients. Five factors were assessed during the study, which are: age and emotions, age and schedule, gender and emotions, diet plan control and follow up visits. The study elaborated that increased education promoted increased adherence to dietary recommendations (Travis, 1997).

In a randomized controlled trial of medical nutrition therapy at the UK Prospective Diabetes Study involved 30,444 newly diagnosed diabetic patients (type 2) at 15 centers. All groups received nutrition counseling from dieticians for three months. During the

study, when the nutrition counseling was the primary intervention, “the mean HbA1c decreased by 1.9% fasting plasma glucose was reduced by 46 mg/dl, and there were average weight losses of 5 kg after 3 months (Pastors et al, 2002).

## **2.4 Summary of Literature**

In summary, studies conducted on Diabetes Management show the following results:

- It has been demonstrated that a structured care approach improves outcomes. The conclusion is that structured care saves lives and reduces morbidity. (CDA, 2003)
- In order to prevent diabetes and its complications it is necessary to raise awareness about diabetes, make changes in lifestyle and to improve the quality of care (Quinn, 2008).
- There are lots of ways designed to control diabetes, from changing eating habits to increasing physical activity. Intensive lifestyle intervention make long-term valuable modification in diet, physical action, and clinical and biochemical parameters and should be implemented as one of the most important health care system (Lindstrom et al, 2003).
- Intensive educational and support programs, raising awareness, campaigns and lifestyle modifications including dietary instructions improve HbA1c control. (Khattab et al.,2008; Zgibor et al, 2007; NHS, 2008; Ellis et al, 2004; Rickheim et al, 2002; Coppell et al, 2011).
- Optimal glycemic control is difficult to obtain because various factors influence patients adherence to diabetes management and the responses to the illnesses of some patients are influenced by their beliefs, attitudes, and experiences beliefs, perceptions of the health system, trust of doctors, emotional and psychological status; and outside support (Ahmed ,2006; Donnan, 2002; Collins, 2009; Hamlets, 2011).

## **Chapter 3: Study Conceptual Frame Work**

### **3.1 Introduction:**

In this chapter we will discuss variables and definitions related to type two diabetes mellitus control. In addition, an overview of the study conceptual model used will also be presented.

### **3.2 Definitions:**

#### **3.2.1 HbA1c:**

Various definitions of HbA1c are used. The American Diabetes Association (ADA) defines HbA1c as "a test that measures a person's average blood glucose level over the past 2 to 3 months". Hemoglobin is the part of a red blood cell that carries oxygen to the cells and sometimes joins with the glucose in the bloodstream. Also called hemoglobin A1C or glycosylated hemoglobin, the test shows the amount of glucose that sticks to the red blood cell, which is proportional to the amount of glucose in the blood (ADA, 2012). According to the WHO HbA1c reveals the average plasma glucose over the previous eight to twelve weeks, which requires no specific conditions to be performed such as fasting and could be done during any time of the day (WHO, 2011). HbA1c reflects average plasma glucose over the previous 2–3 months in a single measure which can be performed at any time of the day and does not require any special preparation such as fasting. These properties have made it the gold standard for assessing glycemic control in people with diabetes and have resulted in its consideration as an option for assessing glucose tolerance in people without diagnosed diabetes (WHO, 2006).

HbA1c is an indicator of the average blood glucose concentrations over the preceding 2–3 months and is currently considered the best index of metabolic control in individuals with diabetes (Viswanathan et al, 2010). According to the International Diabetes Foundation (IDF), HbA1c is defined as a measure used by health care providers in relating blood glucose control to the possible risk of diabetes complications (IDF, 2007).

Hemoglobin A1C indicates how well the diabetic patient blood sugar has been controlled over the last 2-3 months, thus giving an indication of long-term blood glucose control. HbA1c is formed when the glucose in the blood binds irreversibly with Hemoglobin to form a stable glycated Hemoglobin complex. Since the normal life span of red blood cells is 90-120 days, the HbA1c will only be eliminated when the red cells are replaced; HbA1c values are directly proportional to the concentration of glucose in the blood over the full life span of the red blood cells. The American Diabetes Association recommends HbA1c as the best test to find out if the patient blood Sugar is under control over time and that patients with type 2 diabetes do the test twice per year (ADA, 2010). Since blood glucose levels can fluctuate significantly, self-monitoring may not accurately reflect the long-term effectiveness of a person's blood glucose control. The HbA1c test is a valuable measure of the overall effectiveness of blood glucose control over a period of time (Diabetes care, 2007). The range for HbA1c for people without diabetes is between 4.0% and 5.9 %. In people with poorly controlled diabetes, it is 7.0% or above; in people with good blood glucose control, it is less than 7.0% (ADA, 2007). Consistently high HbA1c levels increase the risk for long-term disabling and potentially life-threatening complications, including cardiovascular disease, stroke, kidney disease, eye damage and nerve damage. IDF recommends HbA1c values below 6.5% in most people with type 2 diabetes but individual targets are set in some groups (e.g. the elderly). (Diabetes care, 2007). ADA and the American Association of Clinical Chemists have determined that the correlation ( $r = 0.92$ ) is strong enough to justify reporting both an HbA1c result and an estimated average glucose (EAG) result when a clinician orders the Hb A1c test (ADA,2012). The correlation between A1C levels and mean plasma glucose levels is shown in table 3.1.

**Table (3.1): HbA1c categories and Mean blood sugar (mg/dl):**

HbA1c %	Estimated Average Glucose ( EAG in mg/dl)
6	126
6.5	140
7	154
7.5	169
8	183
8.5	197
9	212
9.5	226
10	240

Source: adapted from The American Diabetes Association, 2012

### **3.2.1.1 Limitations of HbA1c:**

HbA1c has several advantages to the fasting plasma glucose, including greater convenience, since fasting is not required, evidence to suggest greater preanalytical stability, and less day-to-day perturbations during periods of stress and illness. These advantages must be balanced by greater cost, the limited availability of HbA1c testing in certain regions of the developing world, and the incomplete correlation between HbA1c and average glucose in certain individuals. The HbA1c can be misleading in patients with certain forms of anemia and hemoglobinopathies. Analyses of NHANES data indicate that, assuming universal screening of the undiagnosed, the HbA1c cut point of  $\geq 6.5\%$  identifies one-third fewer cases of undiagnosed diabetes than a fasting glucose cut point of  $\geq 126$  mg/dl. A large portion of the population with type 2 diabetes remains unaware of their condition. (ADA, 2011) (WHO, 2006).

Because HbA1c is based on hemoglobin, quantities or qualitative variations in hemoglobin can affect the HbA1c value and interpreting of results (Bloomgarden, 2008). These Variations include the case of reduced total Hb or turnover of red blood cells that cause reduced level of HbA1c even in the presence of high ambient plasma glucose (Tran et al., 2004) Generally, abnormal results of HbA1c test may get with sickle-cell disease, glucose-6-phospahte dehydrogenase deficiency, B12 or folate deficiency, alcoholism, chronic renal or liver disease, splenectomy or splenomegaly, chronic opiate use, large doses of aspirin,

vitamin C and vitamin E supplements, creatine and drugs such as dapsone, ribavirine and so forth (Gallagher et al., 2009; Tran et al., 2004). Other conditions or treatments that might interfere with the measurement of HbA1c such as diseases that might require steroid therapy or that might interfere with the putative relationship between HbA1c and average glucose values, including anemia, high erythrocyte turnover as evidenced by reticulocytosis, blood loss and/or transfusions, or high-dose erythropoietin treatment (ADA, 2008).

Genetic variants and chemically modified derivatives of hemoglobin (carbamylated Hb in patients with renal failure, HbS trait and HbC trait) all can impact the reading of the HbA1c. Any condition that shortens erythrocyte survival will falsely lower HbA1c test results regardless of the test method (recovery from acute blood loss, hemolytic anemia). Vitamins C and E are believed to falsely lower test results by inhibiting glycation of hemoglobin. Iron deficiency anemia will increase results, hypertriglyceridemia, hyperbilirubinemia, uremia, chronic alcoholism, chronic ingestion of salicylates, and opiate addiction are reported to falsely increasing results (NGSP, 2010).

So HbA1c by itself is not enough to assess the type 2 diabetic patients, although it is a good indicator; it has to be accompanied by other tests such as Hb.

### **3.2.2 Overweight and Obesity:**

Overweight and obesity are defined as abnormal or excessive fat accumulation that may impair health. Body mass index (BMI) is a simple index of weight-for-height that is commonly used to classify overweight and obesity in adults. It is defined as a person's weight in kilograms divided by the square of his/her height in meters ( $\text{kg}/\text{m}^2$ ). A BMI greater than or equal to 25 is overweight and a BMI greater than or equal to 30 is obesity. BMI provides the most useful population-level measure of overweight and obesity as it is the same for both sexes and for all ages of adults. However, it should be considered a rough guide because it may not correspond to the same degree of fatness in different individuals. Overweight and obesity are the fifth leading risk for global deaths (WHO, 2011).

According to the Center for Disease Control and Prevention, overweight and obesity are both labels for ranges of weight that are greater than what is generally considered healthy for a given height. The terms also identify ranges of weight that have been shown to

increase the likelihood of certain diseases and other health problems. For adults, overweight and obesity ranges are determined by using weight and height to calculate a BMI. BMI is used because, for most people, it correlates with their amount of body fat (CDC, 2010).

Unhealthy eating habits together with sedentary lifestyle are considered major factors responsible for obesity. As body fat increases in the body, the secretion of a number of toxic substances also increases and thus leads to less insulin action. (Arora, 2007)

High BMI is directly related to CVD and retinopathy. As BMI rises above 30 kg/m<sup>2</sup> a significant relationship with CVD appears. (Latika et al., 2006) In another study, the time needed to develop retinopathy among young diabetic adults was related to high BMI and hyperglycemia (Henricsson et al., 2003)

Being overweight or obese make controlling blood sugar more difficult, so to assess if the patients are overweight, the body mass index (BMI) = ( kg/m<sup>2</sup>) is measured and classified according to World Health Organization's criteria as can be seen in table 3.2 (WHO 1995, 2000 and 2004)

**Table 3.2: Classification of Overweight and Obesity According to WHO:**

**BMI:** weight (kg) / height\* height (m)

	<b>Obesity Class</b>	<b>BMI (kg/m<sup>2</sup>)</b>
<b>Underweight</b>		<18.5
<b>Normal</b>		18.5 - 24.9
<b>Overweight</b>		25.0 - 29.9
<b>Obesity</b>	I	30.0 - 34.9
<b>Obesity</b>	II	35.0 - 39.9
<b>Obesity</b>	III	≥40

### **3.2.3 Microalbuminuria (MAU):**

Microalbuminuria (MAU) measures the functioning level of the kidney cells in the initial stages of renal damage and it is a powerful detector of future cardiovascular and kidney

disease (IDF & ISN, 2003) below 30mg/g is considered normal, where as 30-300mg/g is considered microalbuminuria and 300mg/g and above is classified as macroalbuminuria the presence of small amounts of albumin, a protein, in the urine.(IDF, 2005) Microalbuminuria is an early sign of kidney damage, or nephropathy, a common and serious complication of diabetes. The ADA recommends that people diagnosed with type 2 diabetes be tested for microalbuminuria at the time they are diagnosed and every year thereafter; Microalbuminuria is usually managed by improving blood glucose control, reducing blood pressure, and modifying the diet. (ADA, 2012)

Microalbuminuria refers to an abnormally increased excretion rate of albumin in the urine in the range of 30-299 mg/g creatinine. It is a marker of endothelial dysfunction and increased risk for cardiovascular morbidity and mortality especially, but not exclusively, in high-risk populations such as diabetics and hypertensive. Physicians should screen all diabetics for albuminuria and strongly consider screening for hypertension to identify those at higher risk for cardiovascular disease. Appropriate intervention, including use of drugs that block the renin-angiotensin-aldosterone system, may be appropriate in such cases as suggested by the American Diabetes Association and the Seventh Report of Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (Hypertens, 2004).

### **3.2.4 Lipid profiles:**

Lipid profile test is a blood test that measures total cholesterol, triglycerides, HDL and LDL cholesterol. ADA recommends that total cholesterol should be below than 200mg/dL; HDL above 40mg/dL for men and above 50 mg/dl for women; LDL cholesterol below 100 and triglyceride below than 150mg/dl. (ADA, 2004)

The lipid profile and body fat play a major role in metabolic disturbances, these include dyslipidaemia, hypertension, diabetes and cardiovascular diseases. Changes in the level of lipids in the body make the people more prone to develop those diseases. The body fat and lipid profiles are main reasons for developing diabetes as was revealed by the research findings. (Arora, 2007)

Increase amount of triglycerides and LDL-C increase the risk of heart diseases and have been reported to predict diabetic retinopathy and diabetic nephropathy (Orchard et al., 1998).

Despite the association between hyperlipidemia and cardiovascular events decline with age, a significant association has been shown to continue into the eighth decade of life (Corti et al.,1997). Further, primary prevention trials with older adults up to age 73 years and secondary prevention trials involving adults up to age 75 years clearly manifested that lowering cholesterol levels can significantly reduce cardiovascular event rates in older adults with and without diabetes (Downs et al., 1998; Sacks et al., 1996; Pyorala et al., 1997).

### **3.2.5 Blood Pressure:**

Blood pressure is measured through systolic and diastolic, cutoffs if below 140/90 is normal and above should be considered for treatment (bhsoc, 2009)

Lowering blood pressure in patients with type 2 diabetes has been associated with decreased cardiovascular events and mortality. The UKPDS was among the first studies demonstrating a reduction in macro vascular disease with treatment of hypertension in type 2 diabetes (Fowler, 2008).

Although blood pressure may not be important in the initiation of diabetic retinopathy, a higher diastolic BP, even within the normal range, may increase the risk of progression of retinal lesions (Lloyd et al, 1995)

Controlling the high blood pressure in type 2 diabetic patients plays a major role in reducing the rates of cardiovascular diseases and mortality. This was demonstrated firstly by the U.K. Prospective Diabetes Study. Increased systolic and diastolic blood pressure is a strong indicator of micro vascular complications as was proved by numerous studies. (klein et al., 1995) Baseline blood pressure data from recent trials indicate that in diabetic patients there is nearly a fourfold excess in systolic pressure over diastolic pressure with respect to the recommended systolic/diastolic target pressure of <130/80 mmHg. Diabetic hypertensive individuals showed 2–3 mmHg higher systolic pressure and 1–3 mmHg lower diastolic pressure when compared to non diabetic individuals which adds ~4 mmHg to pulse pressure and also to the difference between the excess systolic and excess diastolic pressure. (Etty et al., 2008)

The U.K. Prospective Diabetes Study may have been the first to discover the unique advantage offered to diabetic subjects by effective antihypertensive treatment, the rate of

diabetic related death and stroke was lower in diabetics with reduced blood pressure (144/82 mmHg) in comparison with patients with higher blood pressure (154/87 mmHg), this was proved firstly by the U.K. Prospective Diabetes Study. The Hypertension Optimal Treatment (HOT) proved that the diastolic pressure should be lowered to below 80 mmHg as the lowest rate of major cardiovascular events were observed at patients with treated hypertensive diabetic patients with that diastolic pressure rate. (Osher et al., 2008).

Spread of hypertension in type 2 diabetic patients rises from 40% at age 45 to 60% by age 75, a factor that contributes significantly to both macro- and micro vascular disease complications (Vijan et al.; UKPDS 38, 1998). Therefore, screening for and aggressive treatment of hypertension are critical components of diabetes care. In most cases, therapy should be instituted if blood pressure (BP) exceeds 140/90 mmHg, and expert opinion suggests a treatment goal of BP <130/85 for patients with type 2 diabetes (JNCDETHBP, fifth Report, 1993).

Measuring BP to diagnose hypertension and monitor therapy is problematic. Clinic BP measurements have great variability, which can affect accurate classification of patients. Reliable clinic measurements require adequate rest period prior to measurement, observer training, adjustment of the cuff size to the arm circumference, and slow deflation of the cuff. Clinic BP measurements have several limitations. BP measurements may not represent the usual BP outside of the clinic setting or the burden of BP throughout a day. BP may rise in the clinic in response to the medical environment may be normal in the clinic but not outside of the clinic. Additional problems with clinic BP measurement include terminal digit bias and variability in a small number of readings. (Ghuman N et al., 2009)

### **3.3 Diabetes complications:**

The risk of experiencing diabetic complications is dependent on the degree of glycemic control in patients with diabetes. Clinical trials such as the Diabetes Control and Complications Trial (DCCT) and Kumamoto study have demonstrated that tight glycemic control achieved with intensive insulin regimens can reduce the risk of developing or progressing retinopathy, nephropathy or neuropathy in patients with type I or II diabetes. The EDIC trial, a follow-up to the DCCT, has shown that the previous degree and duration of glycemic exposure are also important determinants of risk of developing micro vascular

diabetic complications (Bretzel, 2004). The progression of diabetic retinopathy in patients with high HbA1c and long duration of diabetes was twice comparing to patients without these risk factors ( Bonney et. al, 1995)

Several factors have been suggested to be of importance for the development of long term complications in diabetes. Some associations have asserted that the duration of diabetes and metabolic control are well established risk factors, while others have been more controversial with partly contradictory findings in different studies. The causal relationship between these factors and the development of complications is unclear and a better term would be risk markers. The importance of different risk factors also differs in patients with short or long diabetes duration (Karamanos B, et al 2000).

Chronic complications of diabetes include micro vascular and macro vascular complications. Micro vascular complications include retinopathy, nephropathy and neuropathy (ADA, 2004). These complications are influenced by several factors such as glycemic control, hypertension and hyperlipidemia (Bate and Jerums, 2003).

### **3.4 Duration of Diabetes:**

Many complications are related to diabetes, and these can be prevented through healthy life style, medication, follow-up and self management (ADA, 2009).

Macro vascular complications and micro vascular complications are caused by hyperglycemia. The most common micro vascular complication of diabetes is diabetic retinopathy; which cause around 10,000 new cases of blindness annually in the U.S (Fowler, 2008).

The risk of developing micro vascular complications of diabetes depends on both the duration and the severity of hyperglycemia. The U.K. Prospective Diabetes Study (UKPDS) found that development of diabetic retinopathy in patients with type 2 diabetes is related to both severity of hyperglycemia and presence of hypertension. (UKPDS 33, 2007) Prevalence of retinopathy increases with increasing duration of diabetes, since one third of patients with duration between 10 and 12 years have retinopathy. (Kernell et al., 1997) Patients with shorter diabetes duration were more concerned about the management of their diabetes than were patients with a long duration. The fear of chronic complications increased with diabetes duration.

### **3.5 Gender:**

Females with Type II diabetes appear more likely than males to experience symptoms and vascular complications related to diabetes (Summerson et al, 1999 ). The incidence rate of coronary heart disease was slightly higher in males, while lower- extremity arterial disease incidence rate was slightly higher in females (Forrest et al., 2000). The risk of ESRD did not significantly differ between sexes (Finne, 2005)

Men seemed to underestimate problems related to diabetes more than women. They worried less about long-term complications and hypoglycemia, but were more troubled by the limitation of personal freedom caused by their diabetes (Gåfvels et al, 1993).

### **3.6 Smoking:**

It is proven now that smoking is an independent risk factor for diabetes, and amongst diabetes patients it increases the risk of complications. Diabetes complications include heart disease, stroke and circulation problems and smoking adds to the risk of developing these complications. In some cases, smoking may double the likelihood of these problems, as well as double the chances of suffering from kidney problems and erectile dysfunction . Many studies have found significant association between cigarette smoking and advanced stages of diabetic nephropathy ( Muhlhauser et al., 1996). Significant association between the development of microalbuminuria and smoking was reported in few studies (Chaturvedi et al., 1995)

Smoking is also related to the premature development of micro vascular complications of diabetes and may even have a role in the development of type 2 diabetes. Several randomized clinical trials have demonstrated the efficacy and cost-effectiveness of certain forms of behavioral counseling in changing smoking behavior of primary care and hospitalized patients. This work, combined with the more limited studies specific to individuals with diabetes, suggests that smoking cessation counseling is effective in reducing tobacco use in this high-risk group (ADA, 2004).

### **3.7 The Management Goal of DM:**

The goal of effective DM management is to prevent macrovascular complications such as hypertension, stroke, and heart disease, as well as debilitating acute and chronic

microvascular complications, including nephropathy, neuropathy, and retinopathy. Other possible complications of diabetes include birth defects and spontaneous abortion, immune system dysfunction, and periodontal disease.

Individuals with type 2 diabetes should receive medical care and supervision from a team that may include, among others, physicians, physician assistants, nurses, nurse practitioners, dietitians, pharmacists, lab technicians and psychosocial professionals with expertise in treating individuals with diabetes (standard of care, 2012)

In addition, however, individuals with type 2 diabetes must take an active role in self-care. Self-care includes self-monitoring of blood glucose, adhering to an appropriate diet, exercising regularly, and managing behavioral and psychological issues as they arise.

Such care requires the followings:

1. Appropriate glycemic control goal setting and achievement.
2. Regular monitoring for complications
3. Dietary management
4. Life style modifications (physical activity, smoking cessation, weight management, salt reduction...).
5. Medications as needed
6. Appropriate self-monitoring of blood glucose (SMBG) testing.

### **3.7.1 HbA1c control:**

When starting treatment of diabetic patients, the aim is to achieve treatment goals for glycemic control according to the following table (3.3):

**Table (3.3) Goals of glycemic control according to the Palestinian National Authority Ministry of Health Diabetes Disorder Protocol 2008**

<b>Parameters</b>	<b>Targets of control</b>
<b>Glycemic control</b>	
Fasting or pre-prandial plasma glucose	90-130 mg/dl
Post prandial plasma glucose ( 1-2 hrs after the beginning of the meal)	140-180 mg/dl
Bedtime glucose	110-150 mg/dl
HbA1c	<7%
<b>Lipids</b>	≥ 40 mg/dl men
HDL-Cholesterol	≥ 50 mg/dl women
LDL-Cholesterol	< 100 mg/dl
<b>Triglycerides</b>	< 150 mg/dl
<b>Blood pressure</b>	< 130/80 mmHg

EMRO stated in the guidelines for the prevention, management and care of diabetes mellitus that the treatment plan for diabetes may include diabetes education, meal planning and nutritional recommendations, exercise, anti-diabetic agents, insulin and management of associated conditions and complications.(WHO, 2006)

Healthy life style behaviors play an important role in the prevention of chronic diseases such as elevated blood pressure and diabetes. (Sabbah et. al, 2007)Most Arab Middle East countries suffer from chronic diseases that are mainly attributed to unhealthy diet.(Abudayya et. al ,2009)

The Palestinians have been subjected to a number of dynamic factors in the last century, which inflicted big changes on their lifestyle and health conditions. Some of these changes were attributed to imported factors such as the undergoing regional and global transition in dietary care and living standards. Food consumption patterns have changed to a more 'Westernized' diet with high intake of foods rich in fat and cholesterol, while being low in dietary fiber. Other nutritional changes that have occurred are attributed to the uniqueness of the Palestinian political situation presented in border closures, town sieges, road blocks, imprisonment of family bread winners, house demolitions, farms and orchards uprooting, enforcing high taxes, denial/withdrawal of residency/citizenship and construction of the apartheid wall. The brutal Israeli measures against the Palestinians over the long decades of occupation have certainly affected the households' economical status and their ability to purchase healthy food. The first chapter of the “change” story started

when millions of Palestinian refugees lost access to their traditional food bases in 1948, which were characterized by high-fiber and low-fat/cholesterol contents. More chapters were added to the story as the years of occupation and oppression continued; the mating of the Israeli and Palestinian economy, the close attachment to the global market, and the flow of donations to the refugees are important elements for these dietary changes (Abudayya et. al ,2009).

### **3.7.2 Diabetes and balanced diet:**

Obesity and diet are risk factors in type 2 diabetes mellitus, not only for determining the disease onset but also dictating its progression (WHO study group, 1994). According to Russell-Jones and Khan over 80% of diabetics are obese (Joshi & Joshi 2009; Russell-Jones & Khan 2007). Studies have also shown that increased dietary intake of saturated fats and decreased intake of dietary fibre can result in decreased insulin sensitivity and abnormal glucose tolerance (Zimmet, 1992). A realistic weight loss goal of between 5-10% of body weight has been proposed because it is associated with significant improvement in glycaemic control and there is no need in getting people to ideal body weight (Joshi & Joshi 2009). Therefore, attention should be paid to patient education and compliance.

Diet alone has varying degrees of success. Elderly patients with diabetes are able to improve diabetes control with diet and weight loss. However, they may find it difficult to adhere to a strict dietary regimen and maintain weight loss. (Kenneth L, 2002).

A diabetic diet is relatively high in carbohydrates (50%-60% of total calories), low in fat (30% of total calories from fat, with 10% saturated fat, 10% polyunsaturated fat, and 10% monosaturated fat), and moderate in protein (~20% of total calories). (Kenneth L, 2002)

In 2005 the United States Department of Agriculture (USDA) released a new food guidance system (figure 3.1) replacing the former Food Guide Pyramid. The new system, called "My Pyramid," provides a set of tools based on caloric requirements to help individual make healthy food choices. The Diabetes Food Pyramid divides food into six groups. These groups or sections on the pyramid vary in size. The largest group: grains, beans, and starchy vegetables, is at the bottom. The smallest group fats, sweets, and alcohol are at the top of the pyramid. (American Diabetes Association, 2009).



Figure 3.1: The food guide pyramid<sup>1</sup>

In human intervention studies, replacement of saturated by unsaturated fatty acids leads to improved glucose tolerance and enhanced insulin sensitivity. A high intake of total fat has been shown to predict development of impaired glucose tolerance (Vessby et al, 2001).

In many controlled experimental studies, high intakes of dietary fiber have been shown to result in reduced blood glucose and insulin levels in people with type 2 diabetes and impaired glucose tolerance (Mann J, 2001). A randomized controlled trial showed that an increased intake of wholegrain cereals, vegetables and fruit was a feature of the diet associated with a reduced risk of progression of impaired glucose tolerance to type 2 diabetes. (Tuomilehto J et al, 2002).

Generally, the emphasis should be on a low fat diet and a more complex high fibre carbohydrate diet, including foods with soluble fibre such as leafy vegetables, fruits, cereals, roots and pulses. Brown bread or whole grains should be the main part of meals. Saturated fats should be restricted and monosaturated fats (such as Olive oil) should be the replacement. Salt intake should be limited to <6gm/day and even less if the patient is hypertensive(WHO, 1994; Joshi & Joshi 2009).

Foods with high glycemic index (GI) are said to cause a higher peak in post-prandial blood glucose and a greater overall blood glucose response in the first 2hours after consumption than foods with a low GI (Powell, Miller, 2002).

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<sup>1</sup> Source: <https://stage.diabetes.org/nutrition-and-recipes/nutrition/foodpyramid.jsp>

There are studies which have provided evidence showing that low-GI diets are associated with improvement in insulin sensitivity and blood lipid concentrations (Frost et al, 1998).

### **3.7.3 Physical exercise:**

The goal for physical activity focuses on maintaining healthy body weight. The recommendation is for a total of one hour per day on most days of the week of moderate-intensity activity, such as walking. This level of physical activity is needed to maintain a healthy body weight, particularly for people with sedentary occupations. The recommendation is based on calculations of energy balance and on an analysis of the extensive literature on the relationships between body weight and physical activity. (Lyon, 2002)

Exercise is important in the management of diabetes because of its effect on blood glucose and free fatty acids. Exercise burns calories and helps to control weight, eases stress and tension, and maintains a feeling of well-being. In addition, regular exercise improves the body's response to insulin and may make oral anti-diabetic drugs and insulin more effective. It also promotes circulation, and lowers cholesterol and triglyceride levels, thus reducing the risk of cardiovascular disease. Persons with diabetes should be encouraged to lead a normal life and participate in sports and exercise programs. The main risk when exercising is hypoglycemia, therefore blood glucose should be checked before, and if appropriate, medication dosage may need to be reduced before exercise, or the individual may need to take an extra carbohydrate snack. Before starting any exercise programme, the health provider should do a thorough physical examination to find out whether or not it is safe for the patient to exercise.(WHO, 2003)(Pan X et al, 1997)

Current guidelines recommend that patients with type 2 diabetes should perform at least 150 minutes per week of moderate-intensity aerobic exercise and should perform resistance exercise 3 times per week. (ADA, 2011)

### 3.8 Study conceptual framework

According to the literature review and study objectives, we developed this study conceptual framework. Several definitions and factors affecting diabetes as summarized in figure 3.2 were defined and discussed and will be discussed later to be of importance for the management and control of HbA1c.

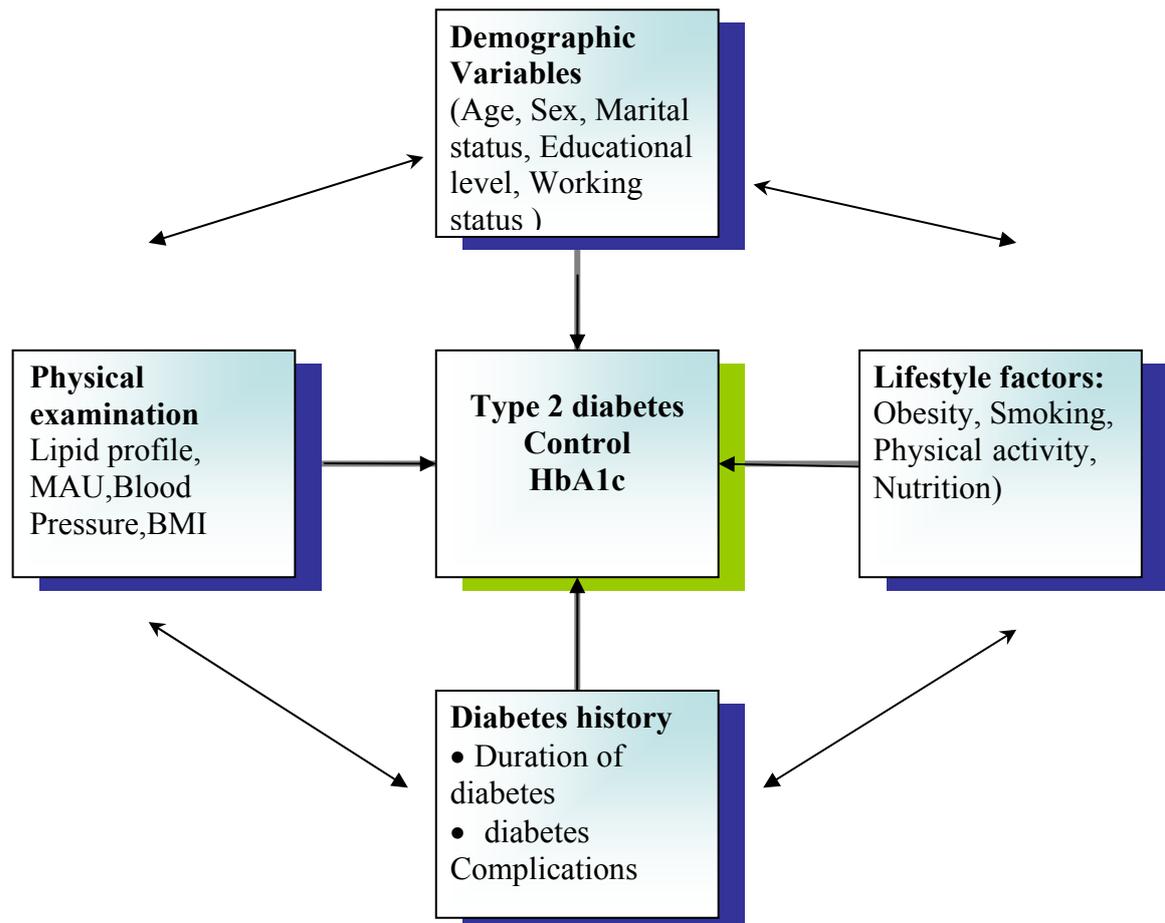


Figure 3.2 Study conceptual framework

## **Chapter four: Study methodology**

### **4.1 Introduction:**

This study focuses on the control of type 2 diabetic patients' attending the Diabetes Care Center at Augusta Victoria Hospital / East Jerusalem. In this chapter the research's methodology will be presented. The study setting, study population, study design, study tools, and the sampling method are described.

### **4.2 Study setting: Description of the diabetes program at Augusta Victoria Hospital (AVH).**

Augusta Victoria Hospital established a Diabetes Center. The Diabetes Center addresses diabetes holistically, considering both the clinical and social factors that influence the diagnosis as well as the quality of care. Also the behavioural patterns that increase the risk of either acquiring diabetes or worsening an already existing diabetic condition are considered by this approach. The center follows three strategies involving treatment, prevention and capacity building; addressing people with diabetes, high risk groups care and the general public.

In 2003, with the support from the World Diabetes Foundation, Dan Church Aid, the Augusta Victoria Hospital initiated a diabetes project with the purpose of establishing a diabetes center at the Augusta Victoria Hospital. The aim was to create a center of excellence for the introduction of a holistic approach to diabetes care and prevention, thus challenging the biomedical approach that has dominated the diabetes care in the Palestinian areas for decades (WDF report 2010).

As a first step in this center, a diabetes program was initiated. This program aimed to promote access to prevention and quality care for diabetes patients and high risk groups in the West Bank. Therefore, this diabetes program combines diagnostics, medical treatment, nutrition counseling, prevention, eye care and foot care.

#### **4.3 Source of Diabetes center patients: (participants)**

##### **1.AVH patients in outpatient and inpatient clinics:**

Patients admitted to AVH departments or those coming to have consultation at the outpatients clinics in the hospital were recruited through the daily rounds conducted by the Center team. In those rounds, team members visited outpatient and inpatient clinics daily to identify self-reported persons with diabetes and to inform them about the services available at the Center. The staffs of those inpatient and outpatient clinics have also been acquainted with the Center's services, and they may advise persons with diabetes to visit it.

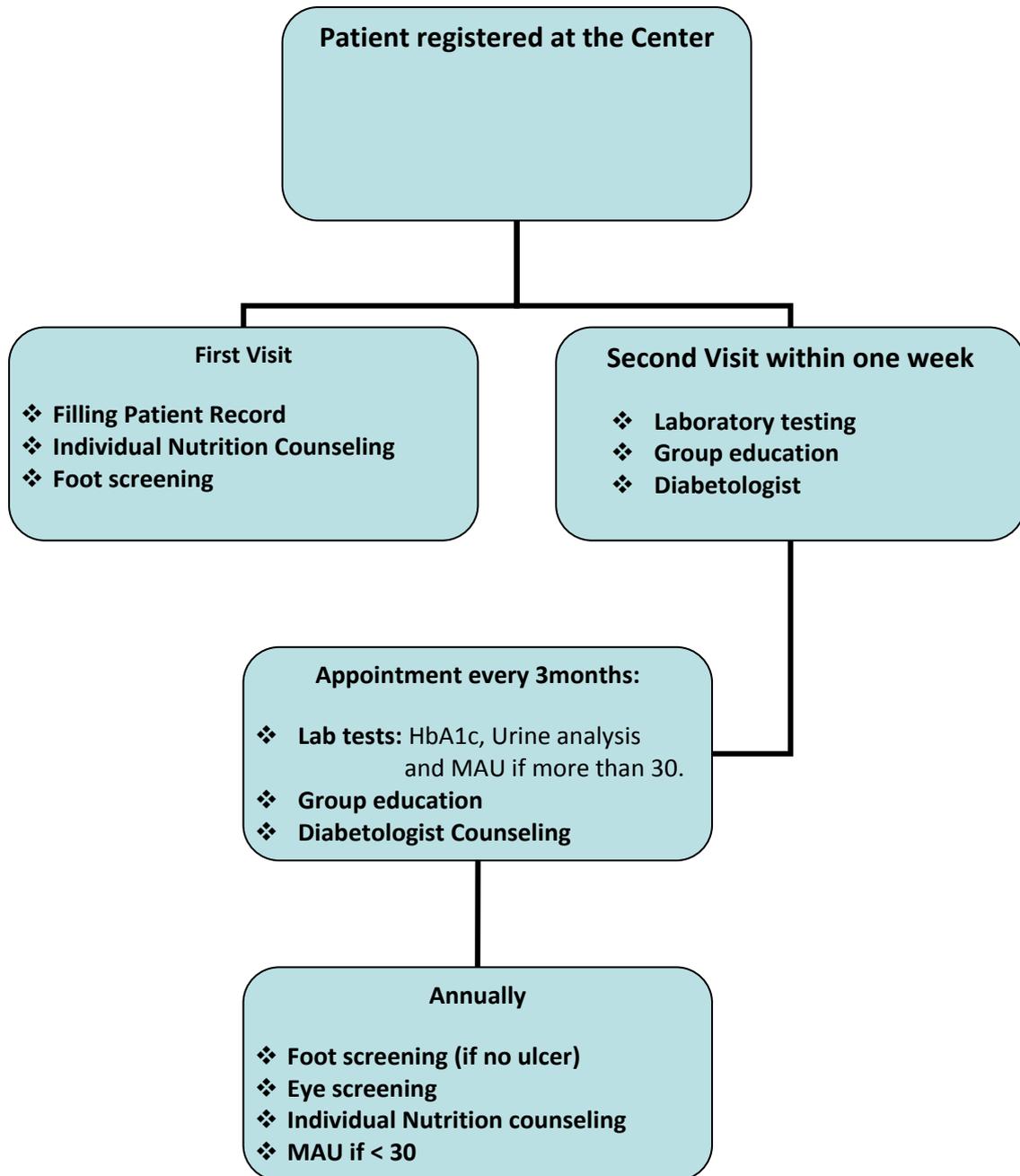
**2.Patients from outside AVH:** those include patients identified through outreach activities as well as patients referred by other health providers that cooperate with the Center, such as UNRWA and MoH.

**3. Self-recruited patients:** those are patients who have heard about the Center and its services through friends and/or family or have read the advertisements posted around the hospital.

#### **4.4 Management of the Diabetic patient at the Diabetes Center:**

The center targets persons with diabetes and involves providing services which include regular monitoring through clinical and laboratory investigations as well as individualized counseling and general health education. Patients with type 2 diabetes receive medical care and supervision from a team that include physicians, nurses, foot care specialists, dieticians, lab technicians and psychosocial professionals with expertise in treating individuals with diabetes.

Since the program was initiated a total of 1375 diabetic patients has been assessed and evaluated by the team. All services are done according to diabetes protocol shown in figure 4.1.



**Figure 4.1:** Diabetes center protocol for patient's visits

As a first step, each patient is assessed by a team of health professionals that include a diabetologist who prescribe the proper treatment according to patient's condition and level of control, a dietitian for individual nutrition assessment and counseling, and specialized diabetes care nurses. Healthy lifestyle strategies are discussed with all diabetics and their families. Group education sessions for topics related to diabetes self management, complications, treatment and control are regularly done. Also, all necessary laboratory tests mainly HbA1c and creatinine albumin ratio are done to all diabetics. Feet-exam and retinopathy screening are done regularly for all diabetics.

Each patient goes through the following:

- 1- Medical care: Diabetes patients attending the Center for the first time are registered and a file is opened which contains demographic data, subjective data (e.g. education, occupation, social support system, information about reported diagnosis and treatment), and objective data (e.g. weight, height, and blood pressure).
- 2- Each patient has to do baseline laboratory investigations include blood glucose (either random or fasting, urine analysis, lipid profile, HbA1c, and albumin creatinine ratio (ACR).
- 3- In addition to the clinical examination and laboratory testing: each patient has to be seen by the diabetes specialist
- 4- Each patient receive a host of other services, including individual nutritional counseling, group health education sessions and materials, counseling with a social worker, referral to other specialized clinics at AVH when needed, and ophthalmic examination.
- 5- Self care training: In addition the diabetic patients at the diabetes center are taught to take an active role in self-care. Self-care includes self-monitoring of blood glucose, adhering to an appropriate diet, exercising regularly, and managing behavioural and psychological issues as they arise.
- 6- Follow up: Patients are provided with follow-up cards, and they are given an appointment after 3 months, unless otherwise requested by the doctor.

#### **4.4.1 Dietary management:**

##### **Diet plan used at the Diabetes center in Augusta Victoria Hospital**

The diet of the diabetics is planned using the ADA exchange lists. The plan falls within the guidelines of the daily food guide pyramid.

- Each patient is assessed by the dietician that performs the following tasks:
  - Monitors the patient medical condition, psychosocial and economic status, physical activity and lifestyle.
  - Learns about the patients' usual eating habits.
  - Determines a reasonable bodyweight and the energy intake necessary to maintain this body weight.
  - Teaches patients how to tailor the diet to meet their own preferences (food from starch, fruit, milk lists contain similar amounts of energy and CHO and can be substituted from one another from time to time). In order to have an idea about the amount of food items usually consumed by the participants, examples of portion sizes were provided as demonstration, using cups, plates and spoons.
- Teaches the patient to eat regularly at the right times to balance the effects of any tablets or insulin.
- Monitors regularly the patient through clinical and laboratory investigations as well as individualized counseling and general health education.

Diet Forms with different calorie content ranging from 1000 Cal to 2400 Calories (See annex 2) are used following the below criteria:

- Determine the daily energy requirements based on the equations shown in table 4.1 and 4.2.
- Determine the recommended grams of protein, CHO, and fat based on the Calories ( CHO: 45-60% , Protein: 10-20%, Fat $\leq$  30% )
- Use the exchange list, the number of servings from each group is determined.

- Then translation of the diet prescription into meal plan. First the dietician plan servings of food that contain carbohydrates (Starch, Dairy, fruit, Vegetables) then protein (meat and products) and then fat.
- Food is distributed into meals that fit the patients usual eating pattern.
- Modification on the diets is done for special cases when needed.
- The patient is regularly seen by dietician upon every scheduled visit to the diabetes center.

**Table 4.1: Calculations used for estimation of the energy requirements:** (David H. et al, 2008)

**Male calculation equations:**

Age	Total calorie
10-18	$((17.5 * IBW) + 651) * \text{activity level}$
18-30	$((15.3 * IBW) + 679) * \text{activity level}$
30-60	$((11.6 * IBW) + 879) * \text{activity level}$
>60	$((13.5 * IBW) + 487) * \text{activity level}$

**Female calculation equations:**

Age	Total calorie
10-18	$((12.2 * IBW) + 746) * \text{activity level}$
18-30	$((14.7 * IBW) + 496) * \text{activity level}$
30-60	$((8.7 * IBW) + 829) * \text{activity level}$
>60	$((10.5 * IBW) + 596) * \text{activity level}$

**Table 4.2: Calculations used for estimation of the physical activity requirements:** (David H. et al, 2008)

Activity level	Male	Female
Very light	1.3	1.3
Light	1.6	1.5
Moderate	1.7	1.6
Heavy	2.1	1.9
Very heavy	2.4	2.2

## 4.5 Study design

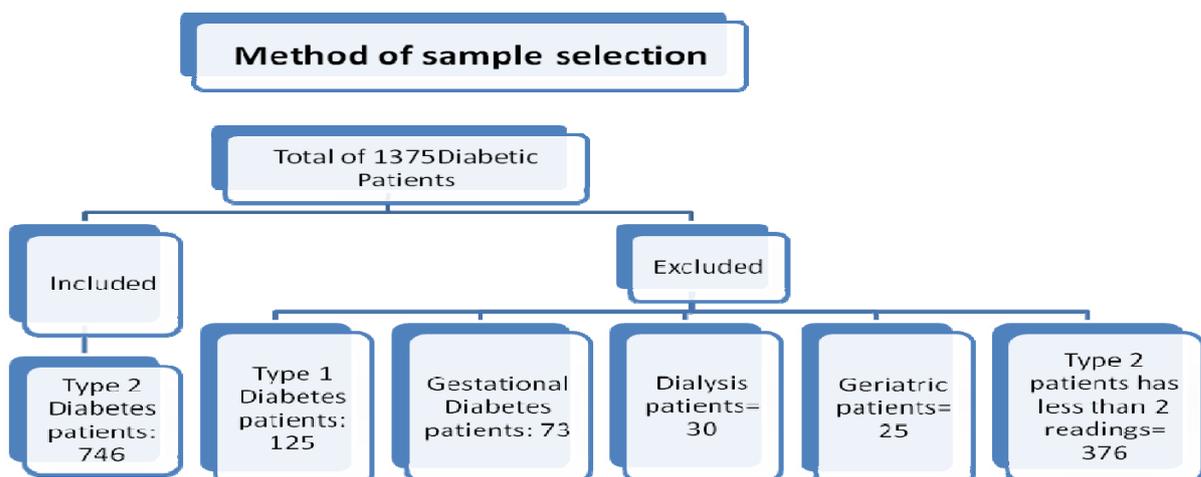
The study design was an evaluative file based study

## 4.6 Sample frame:

A total number of 1,375 diabetic patients are registered at the Diabetes Care Center at Augusta Victoria Hospital (AVH). The sample results were taken from all the patients who were followed up in the center and had at least two visits with HbA1c test done from year 2005 to 2009.

### 4.6.1 Inclusion and exclusion criteria:

All registered patients with type 2 diabetes attending AVH between years 2005 – 2009 and had at least two visits since the beginning of 2006 were included in this study. We excluded type one diabetes patients, women with gestational diabetes, type two diabetes patients who are on dialysis or patients who are long staying in geriatric department because the management and control status and tool for these patients differ than that for the included type two diabetes patients. The inclusion-exclusion criteria is shown in figure 4.2.



**Figure 4.2: Inclusion-exclusion criteria of the study sample**

## **4.7 Data collection**

Data was collected from June 2009 to February 2010. The researcher is a dietician at the Diabetes Center since 2005 and trained a research assistant who is also a qualified dietician and work at Augusta Victoria Hospital since 2003. The file of the patient was used as the sole instrument of data collection for this study. The information collected from file was taken from five sections (see Annex 1 patient file).

### **4.7.1 Description of patient's file:**

The system of following up the patients from the day they are included in the center, consist of 3 forms; the assessment sheet, follow up sheet, the educational Planning Sheet (see Annex 1 patient file).

#### **4.7.1.1 The assessment Sheet form**

This form is filled out when the patient first comes to the Center. It gives the team an idea of the patient's medical condition, life style and living conditions, which could be very useful in personalizing counseling and health education. The form is usually filled out once at the beginning of the patient's visits to the Center. A clinical assessment is performed and documented for every patient with diabetes; immediately upon registering in the center. The assessment covers the following:

#### **A. Personal, Medical and Family history**

1. Patient Identification and demographic information (Name, ID, Residency.....)
2. Age at onset
3. Review of previous treatment
4. History of diabetes-related complications.
5. Eating patterns, physical activity habits, nutritional status, smoking and weight history
6. Family history of type 2 diabetes
7. Others: psychosocial problems, oral disease

8. Current treatment of diabetes, including medications, meal plan, physical activity patterns, and results of glucose-self monitoring

## **B. Physical Examination**

1. Height, weight, to calculate BMI.

2. Blood Pressure

3. Comprehensive foot examination

## **C. Laboratory Evaluation**

1. HbA1c, within the past 3 months

2. fasting lipid profile, including total, LDL- and HDL-cholesterol and triglycerides

3. Test for urine albumin excretion with spot urine albumin/creatinine ratio

**4.7.1.2 The follow-up Sheet form** contains Data on date, weight, BMI, activity level, and dilated eye exam, in addition to lab tests and results.

**4.7.1.3 The educational Planning Sheet form** lists the topics that are discussed with the patient in counseling sessions.

### **4.8 The objective testing used:**

The patients at the diabetes center underwent certain laboratory investigation at their first visit such as HbA1c, MAU, lipid profile, Body mass index (BMI), and blood pressure. In addition patients undergo testing for HbA1c, MAU (if > 30 mg/dl), and blood pressure every three months. The lipid profile and MAU (if < 30mg/dl) is repeated annually.

#### **a- Biochemical blood testing:**

A blood sample (fasting or random) is taken by vein puncture, this sample is divided into two tubes. One tube has an EDTA anti coagulant used for measurement of HbA1c, the second tube is a plain tube used for measurement of glucose and lipid profile.

**- Glycolcylated Hemoglobin A1c:**

HbA1c determination was done by High Performance Liquid Chromatography HPLC method using Hi-Tech produced by Tosoh company.

**- Microalbuminuria:**

MAU determination was done by Cytochemistry, impedance, absorbance and flow cytometry method produced by DYN Company.

**-Fasting / Random blood testing:**

Glucose determination was done by glucose oxidase method using thermo kit produced by Konelab company.

**- Lipid profile:**

Cholesterol determination was done by cholesterol esterase method using thermo kit produced by Konelab Company.

**- Urine analysis**

Urine analysis examines sugar, protein, ketone, blood, PH, specific gravity, nitrate, leukocyte using Siemens multi-stix 10 SG.

**b- Blood pressure measurement**

Trained nurses made resting blood pressure under standardized conditions using the WelchAllyn blood pressure machine.

**c- Body mass index**

Calculated by using the equation:  $BMI = \text{weight in Kg} / \text{Height in m}^2$ .

**d- Foot care (Screening and treatment for foot abnormalities):**

Trained and specialized nurses are responsible for foot care screening and treatment for foot abnormalities according to the IDF consensus.

**e- Ophthalmic examination:** Every month nurses from Saint John Eye Hospital do screening for diabetic patients at the diabetes care center at AVH. Every patient registering

in the center is given an appointment of eye screening annually. If the patient has any complications, they will be referred to St. John Eye Hospital for

#### **4.9 Dietary assessments and food groupings.**

Dietary intake was assessed using the special diets that the dietician in the diabetes center gives to patient. The food grouping scheme was based on Nutrition exchange list in order to divide the amount of food items given to the patient (see annex 2 examples of diet).

Participant were given their diets according to their requirements and follow-up with the dietician every visit

#### **4.10 Ethical considerations**

The study was approved by AL Quds University, school of Public Health-graduate study committee and the university graduate study accepted the study proposal. The study was also approved by the director of the Diabetes center at Augusta Victoria Hospital.

The study was conducted in accordance with the ethical guidelines of Augusta Victoria Hospital. According to these guidelines, participants were informed upon registration that data from their own file will be used for research purposes. Anonymity and confidentiality of the participants were maintained throughout the study by using file numbers.

#### **4.11 Data Analysis:**

The collected data was entered and analyzed by using the statistical package for the social science (SPSS version 17.0). Missing Values were replaced using the strategy last observation carried forward (LOCF) .First stage includes descriptive frequencies of all variables. Second stage a univariate analysis was done to study the associations between HbA1c change with all other variables (Demographic, follow up tests, lifestyle factors) using person chi-square test of significance at 5% significance level. Third stage included multivariate analysis, six logistic regression models for each HbA1c visits was performed. Variables that showed a significant difference at the univariate analysis were included in the multivariate analysis. Our Main focus was the HbA1c change between the first and fourth visit. But we did univariate and multivariate analysis of HbA1c among the other visits to see the change in HbA1c through them ( see Annex 5 )

Since the period of the study was long and the period between the four visits was irregular we couldn't use repeated measure analysis. We analyzed a subsample that included 255 patient from the original main sample (n=746) that had their four visits within two years and with regular periods between the visits (3-6 months) using repeats measures , univariate and multivariate analysis (see Annex 6).

## Chapter Five: The Results

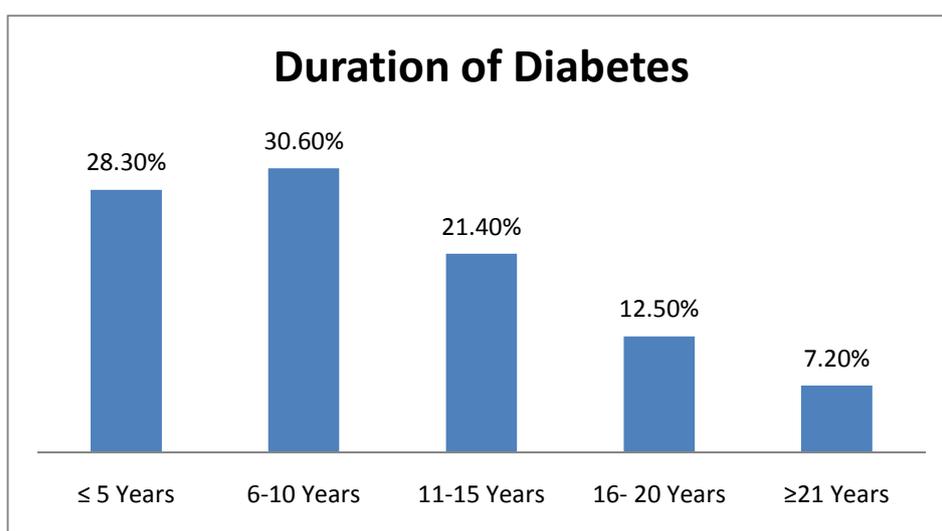
### 5.1 Introduction

In this chapter, results will be presented in three sections. Section one presents the descriptive data from the patients' files; section two describes the univariate analysis while section three represents the multivariate analysis.

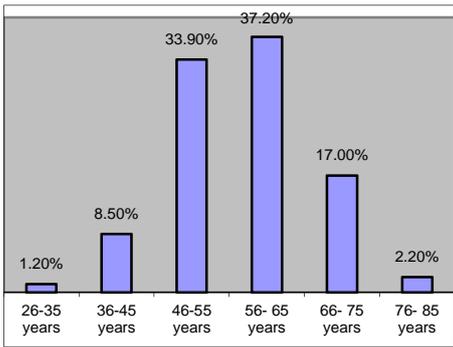
### 5.2 Section 1: Descriptive analysis

#### 5.2.1: Socio-demographic characteristics

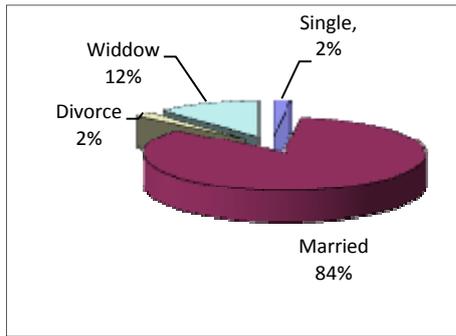
Among those who met the study's inclusion-exclusion criteria, 746 patients' files with diabetes type 2 were included in this analysis. The mean duration of having diabetes was 10 years (SD 6.51) (see figure 5.1). The mean age of the group was 57 years (SD 9.34) (see figure 5.2). Of the study population, 84% were married (see figure 5.3) and 53% were females (see figure 5.4). Three quarter did not work (see figure 5.5), 44 % lived in the middle region of the West Bank (see figure 5.6), 15% were illiterate (see figure 5.7), 96% lived within a family, and 57.2% had MOH insurance (see figure 5.8).



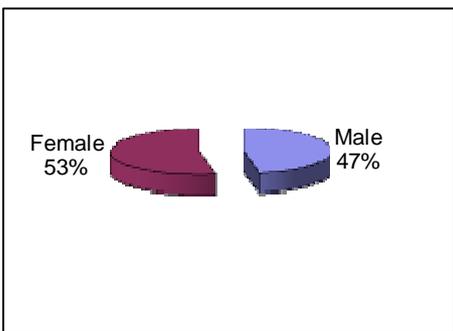
**Figure 5.1 Distribution of study population by Duration of diabetes**



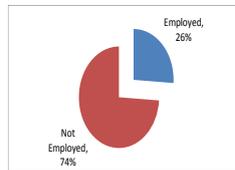
**Figure 5.2: Distribution of study population by age group**



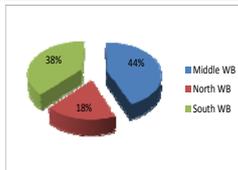
**Figure 5.3: Distribution of study population by marital status**



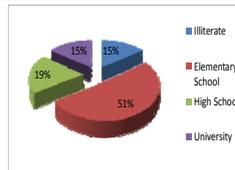
**Figure 5.4: Distribution of study population by gender**



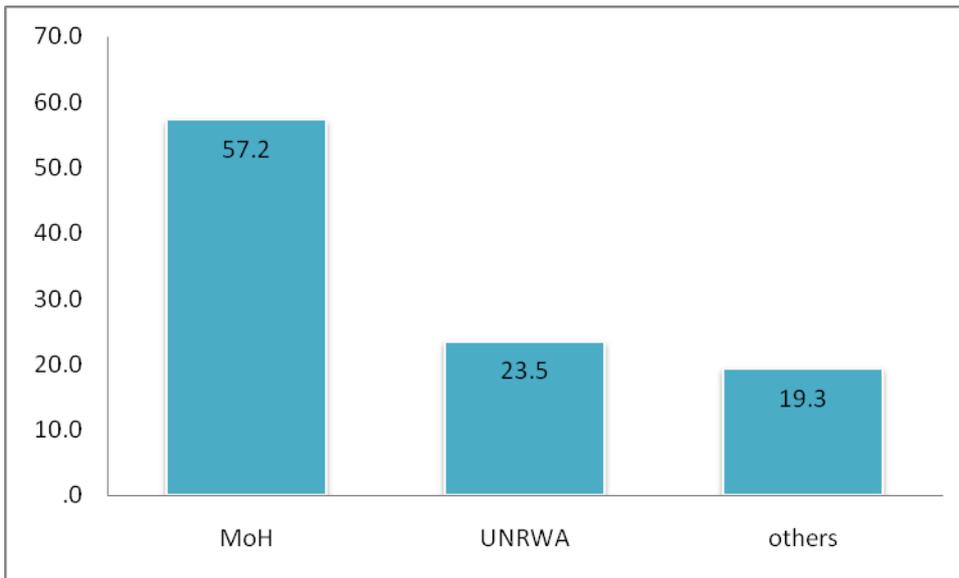
**Figure 5.5: Distribution of study population by Occupation Status**



**Figure 5.6: Distribution of study population by place of residency**



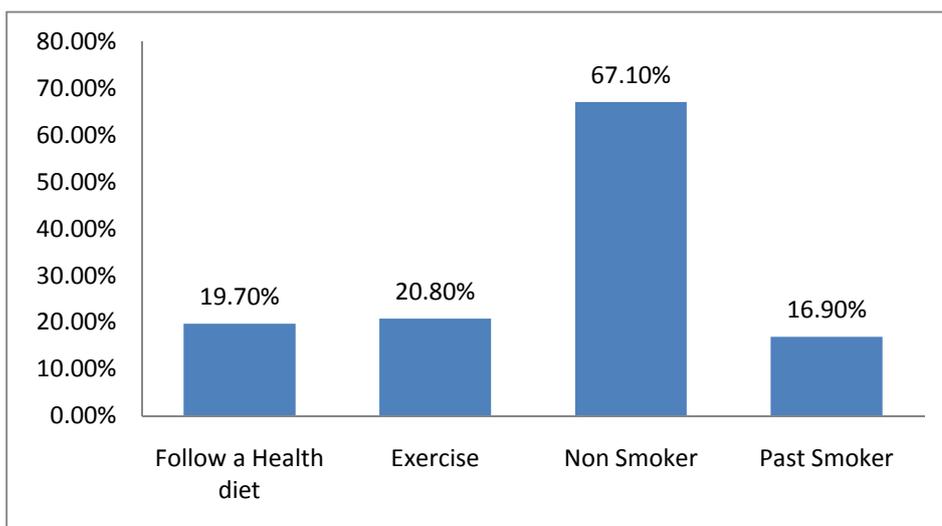
**Figure 5.7: Distribution of study population by Educational level**



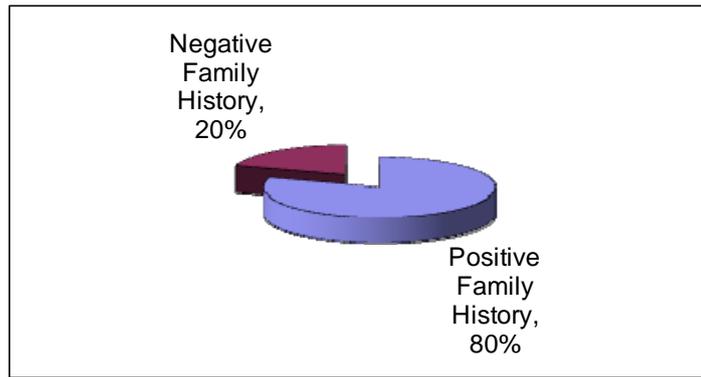
**Figure 5.8: Distribution of patients participating in the diabetes program according to health provider**

### 5.2.2 Health characteristics of study population before registering in the diabetes center

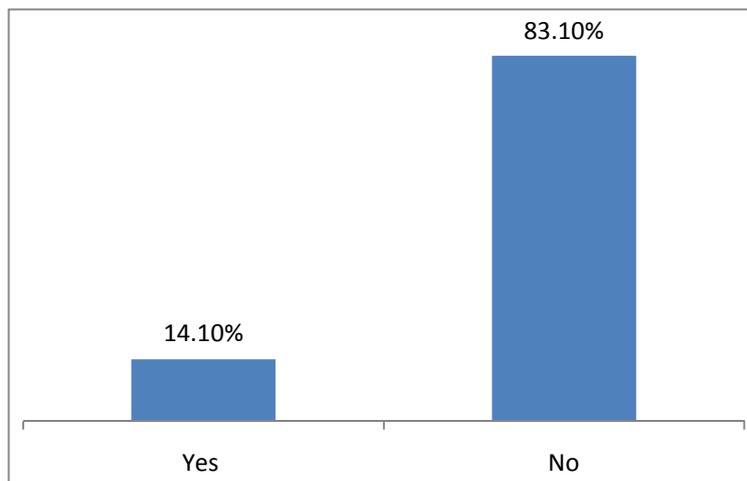
Of the sample, 67% were non smokers (see figure 5.9) and 80% had a family history of diabetes (see figure 5.10). Of the women, 14.1% reported having gestational diabetes (see figure 5.11). Of the study sample, 53.1% had peripheral neuropathy followed by hypertension and dyslipidemia (see figure 5.12).



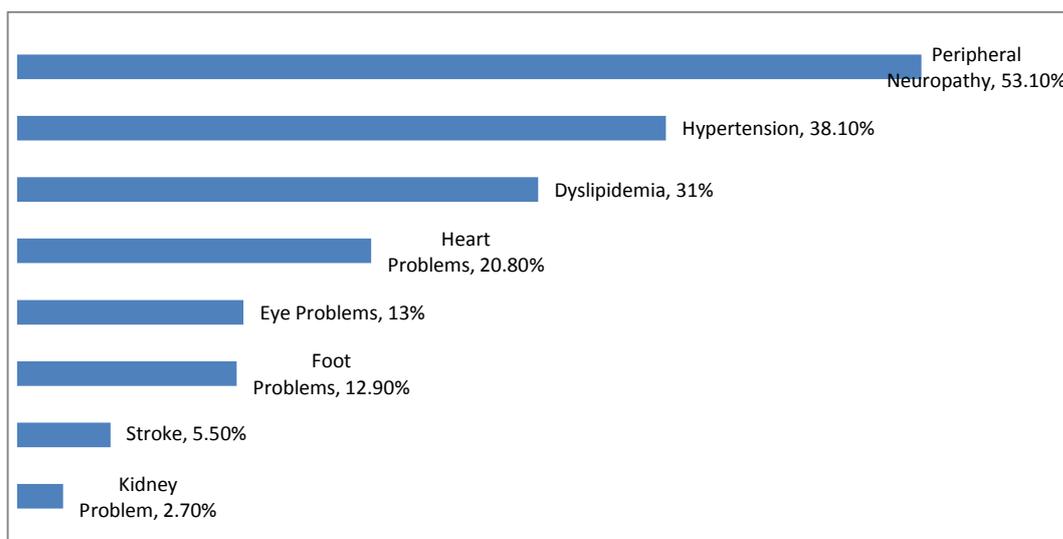
**Figure 5.9: Life style behavior of study population before registering in the diabetes center**



**Figure 5.10: Distribution of study population by family history of diabetes**



**Figure 5.11: Distribution of women by having history of gestational diabetes**



**Figure 5.12: Distribution of study population by having health complications**

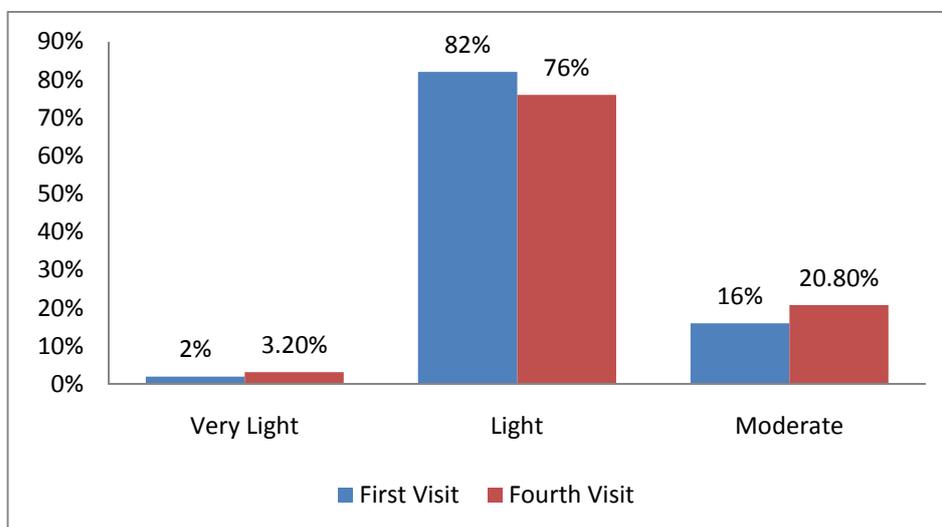
### 5.2.3 Laboratory testing (HbA1c, cholesterol, Microalbumin) and BMI distribution at the four visits used in this study:

HbA1c average change by visit decreased from 9.1% (SD 2.1) in the first visit to 8.5% (SD 1.7) in the fourth visit. The mean cholesterol in the first visit decreased from 208 mg/dl (SD 90) to 195 mg/dl (SD 88.8) in the fourth visit. The mean Microalbuminuria (albumin/creatinine ratio) in the fourth visit increased compared to the first visit. The distributions by visit are presented in Annex 4.

According to WHO classification of obesity, less than 10% of the sample had normal weight throughout the study period and 10% were obese 3. The mean systolic and diastolic pressure didn't change in the four visits. The distributions by visit are presented in Annex 2.

### 5.2.4 Physical activity

In figure 5.13, the activity level of the patients was shown as light in 82 % in the first visit and 76% in the fourth visit and moderate level increase by following up those patients from 16% in the first visit to 20.8% in the fourth visit.



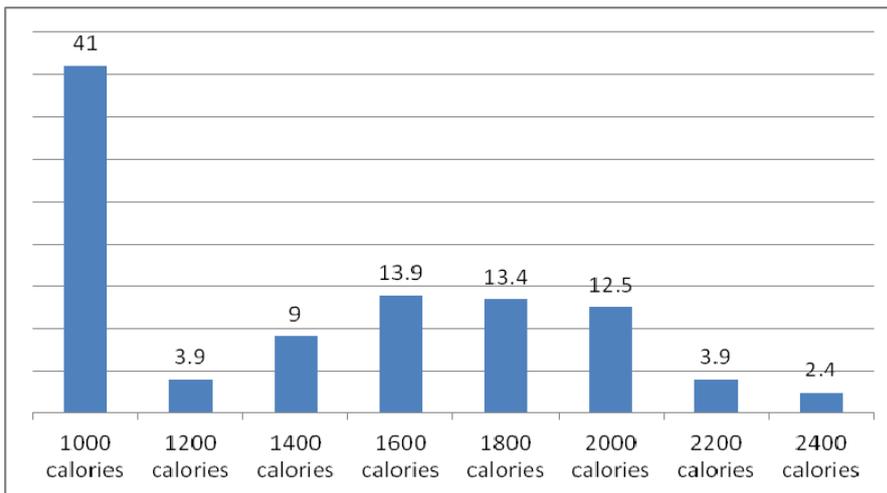
<sup>2</sup> **Figure 5.13: Distribution of study population by physical activity in four visits**

<sup>2</sup> **Note:** Very light physical activity: Extremely inactive, light: Sedentary and getting little or no exercise; moderately active: walking or exercising 150 minute per week (3 times a week).

## 5.2.5 Medical regimen

### 5.2.5.1 Medical nutrition Therapy (MNT)

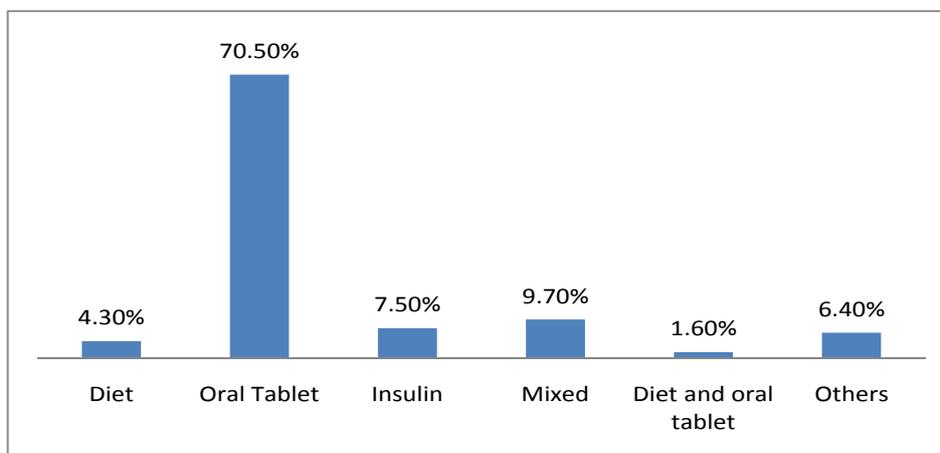
The distribution of caloric intake for the patients was the same in the four visits .The majority of the study population (n=307) were given a diabetic diet with 1000 calories to control diabetes and reduce body mass index (see figure 5.14).



**Figure 5.14: Distribution of caloric intake**

### 5.2.5.2 Medication

The history of medication of the patients show that 70.5% were treated by oral medication , 7.5% were treated by insulin, 9.7% were treated by insulin and tablets and 1.6 was treated by diet and oral medication together, but only 4.3 %managed their diabetes by diet regime only (see figure 5.15).

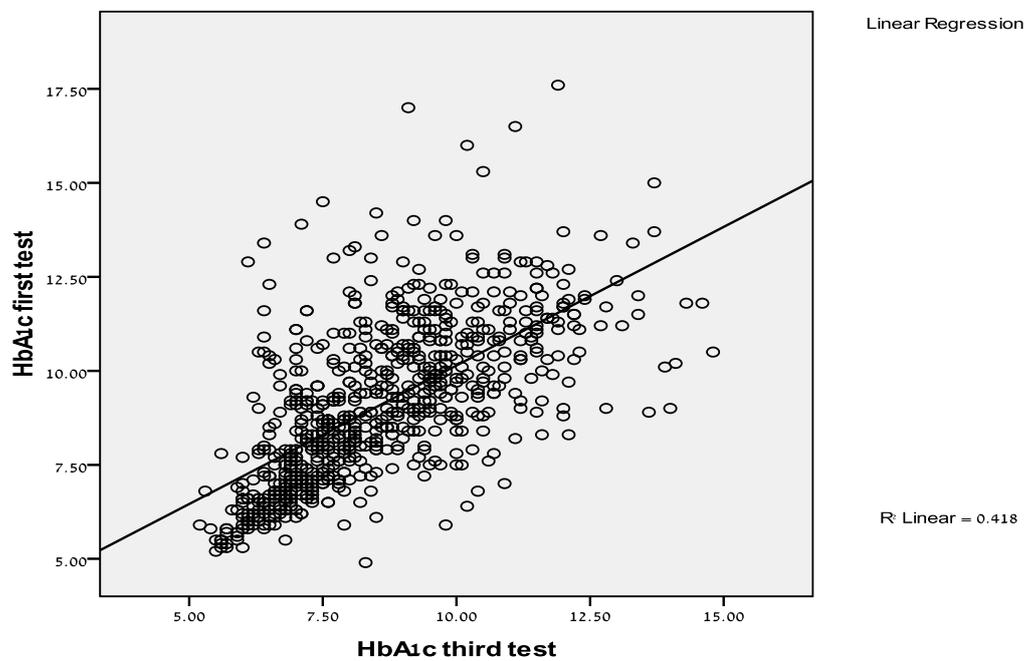
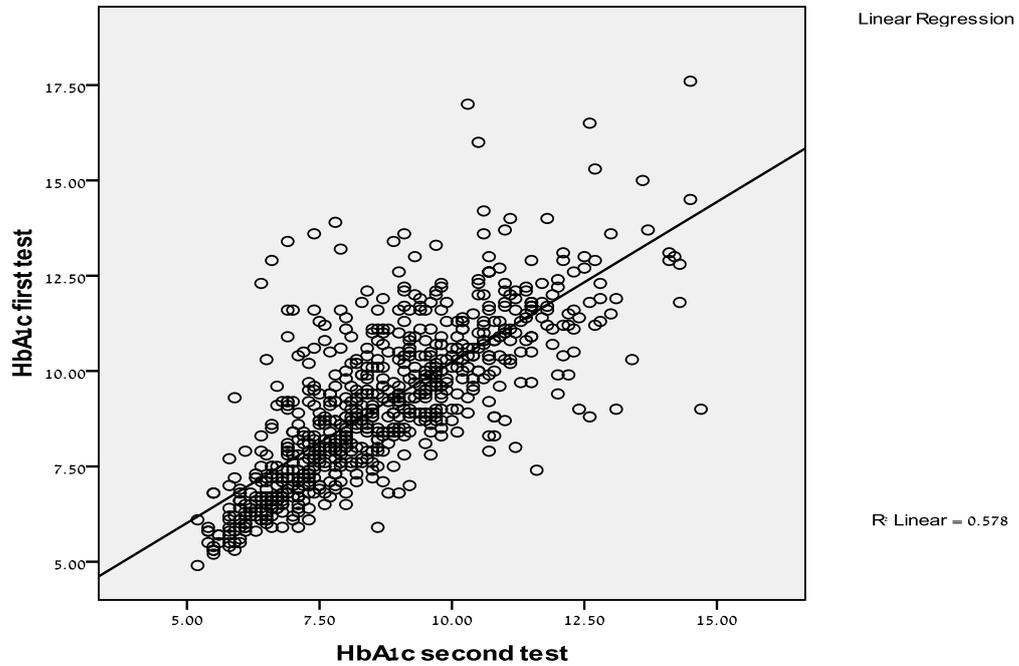


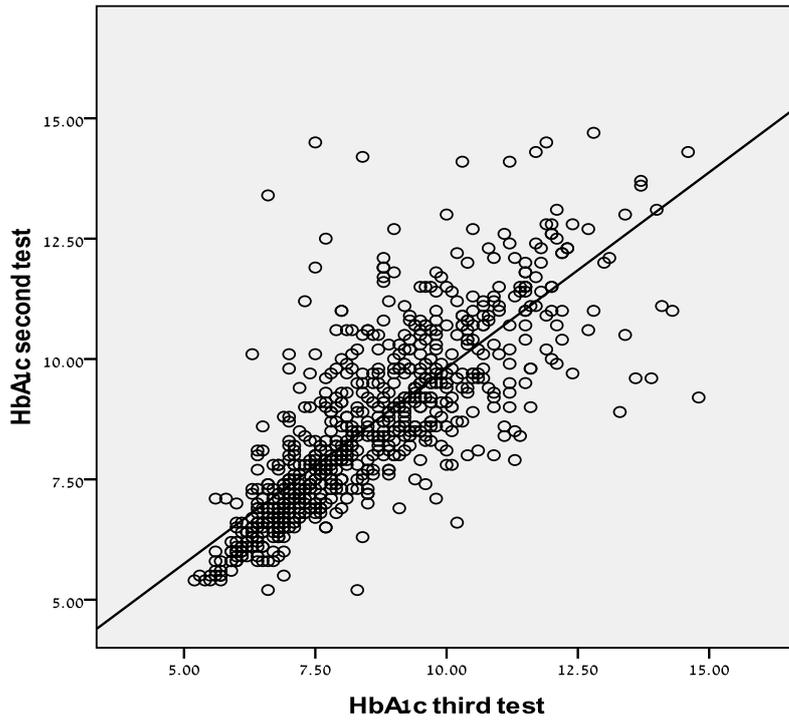
**Figure 5.15: Distribution of study population by medical regime type**

## Section two: Univariate analysis

### 5.3.1 Association between HbA1c levels in the four visits

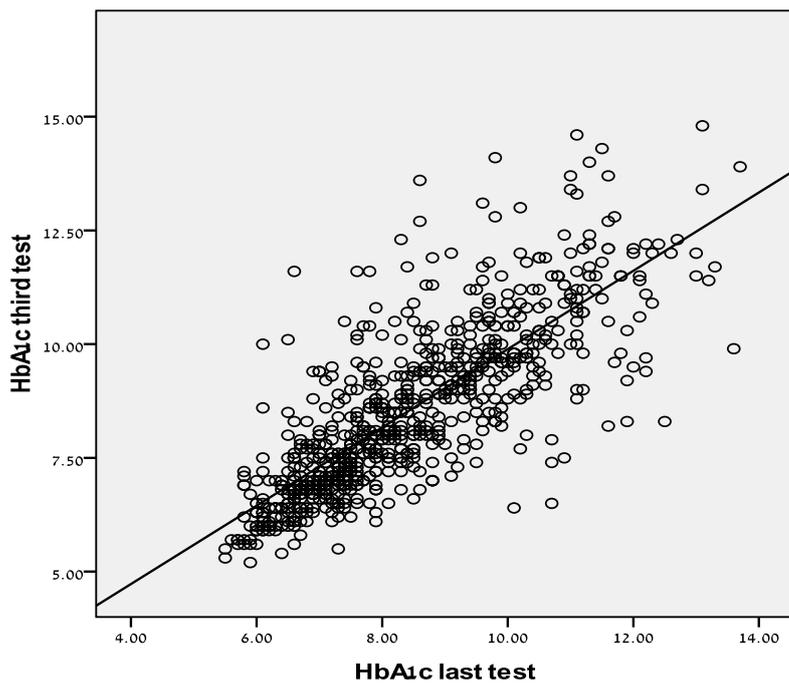
Figure 5.16 shows that the strongest association is between the third and fourth visit ( $r^2=0.63$ ), and the weakest is between the first and fourth visit ( $r^2=0.37$ ).





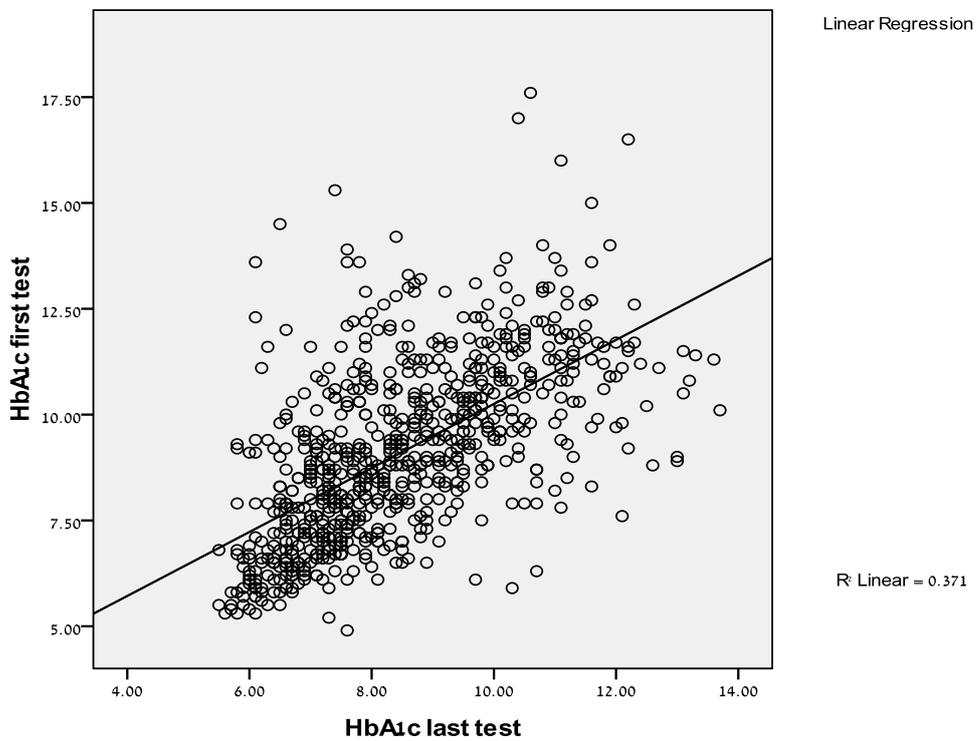
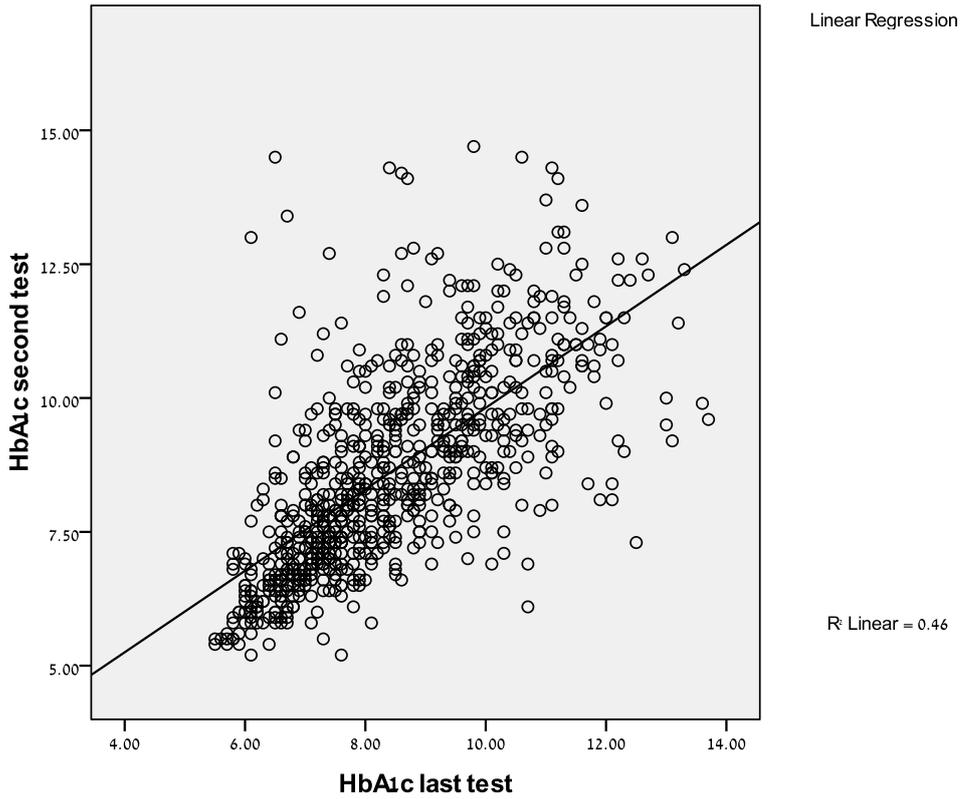
Linear Regression

R: Linear = 0.623



Linear Regression

R: Linear = 0.625



Note  $r^2$ : 1<sup>st</sup>-2<sup>nd</sup> = 0.58, 2<sup>nd</sup>-3<sup>rd</sup> = 0.62, 3<sup>rd</sup>-4<sup>th</sup> = 0.63, 1<sup>st</sup>-4<sup>th</sup> = 0.37

**Figure 5.16: Linear regression for the 4 HbA1c visits**

### 5.3.2 Associations between HbA1c with the study demographic variables

Table 5.1 presents data for the relationship between changes in mean HbA1c of the 746 patients with the socio demographic variables in the various visits. Age and type of profession showed no significant association with HbA1c ( $p>0.05$ ). Male patients had better HbA1c compared to female patients in the 3<sup>rd</sup> and 4<sup>th</sup> visit ( $p<0.05$ ). Highly educated patients had better HbA1c compared to illiterate patients among the four visits ( $p<0.05$ ). Patients with MoH insurance had higher mean of HbA1c than patients insured with other insurance (private and Israeli sick fund) ( $p<0.05$ ) in the four visits. Patients who were employed had lower HbA1c than unemployed patients among the four visits ( $p<0.05$ ). Patients who were Single had better HbA1c than patients who were widowed among the visits ( $p<0.05$ ). (see table5.1)

**Table 5.1: Associations between HbA1c among the 4 visits with demographic variables**

Variable		HbA1c 1st visit		HbA1c 2nd visit		HbA1c 3rd visit		HbA1c 4th visit	
		Mean $\pm$ SD	T.sig.	Mean $\pm$ SD	T.sig.	Mean	T.sig.	Mean $\pm$ SD	T.sig.
Age	$\leq 40$	8.7 $\pm$ 2.3	0.77	7.9 $\pm$ 1.9	0.14	7.9 $\pm$ 2.0	0.14	7.8 $\pm$ 1.8	0.07
	41-50	9.1 $\pm$ 2.2		8.7 $\pm$ 2.0		8.6 $\pm$ 1.8		8.6 $\pm$ 1.7	
	51-60	9.1 $\pm$ 2.1		8.7 $\pm$ 1.8		8.5 $\pm$ 1.7		8.5 $\pm$ 1.6	
	> 60	9.1 $\pm$ 2.0		8.7 $\pm$ 1.9		8.7 $\pm$ 1.9		8.4 $\pm$ 1.7	
Gender	Male	9.08 $\pm$ 2.1	0.87	8.56 $\pm$ 1.86	0.21	8.42 $\pm$ 1.76	<b>0.04</b>	8.29 $\pm$ 1.61	<b>0.01</b>
	Female	9.1 $\pm$ 2.07		8.73 $\pm$ 1.9		8.7 $\pm$ 1.87		8.61 $\pm$ 1.73	
Residency	South	9.1 $\pm$ 2.1	0.91	8.6 $\pm$ 2.0	0.74	8.6 $\pm$ 1.9	0.92	8.5 $\pm$ 1.8	0.98
	North	9.0 $\pm$ 2.1		8.8 $\pm$ 1.9		8.6 $\pm$ 1.8		8.5 $\pm$ 1.6	
	Middle	9.1 $\pm$ 2.1		8.6 $\pm$ 1.8		8.5 $\pm$ 1.8		8.5 $\pm$ 1.6	
Education level	Illiterate	9.5 $\pm$ 2.1	<b>0.03</b>	9.1 $\pm$ 1.9	<b>0.01</b>	9.0 $\pm$ 2.0	<b>0.00</b>	8.7 $\pm$ 1.7	<b>0.02</b>
	School	9.1 $\pm$ 2.2		8.7 $\pm$ 1.9		8.7 $\pm$ 1.9		8.6 $\pm$ 1.8	
	High school	8.9 $\pm$ 1.9		8.5 $\pm$ 1.9		8.4 $\pm$ 1.7		8.3 $\pm$ 1.6	
	University	8.7 $\pm$ 2.0		8.3 $\pm$ 1.6		8.1 $\pm$ 1.5		8.2 $\pm$ 1.4	
Insurance	MOH	9.3 $\pm$ 2.1	<b>0.00</b>	8.8 $\pm$ 1.9	<b>0.00</b>	8.6 $\pm$ 1.8	<b>0.00</b>	8.5 $\pm$ 1.6	<b>0.00</b>
	UNRWA	9.1 $\pm$ 2.0		8.8 $\pm$ 1.9		8.8 $\pm$ 2.0		8.8 $\pm$ 1.8	
	Others	8.5 $\pm$ 2.0		8.1 $\pm$ 1.9		8.1 $\pm$ 1.7		8.1 $\pm$ 1.7	
Profession	worker	9.0 $\pm$ 2.1	0.09	8.6 $\pm$ 2.0	0.11	8.4 $\pm$ 1.8	0.10	8.3 $\pm$ 1.6	0.07
	Highly educated	8.5 $\pm$ 1.7		7.9 $\pm$ 1.4		7.8 $\pm$ 1.3		7.7 $\pm$ 1.3	
	health sector	8.0 $\pm$ 1.9		8.0 $\pm$ 2.2		8.2 $\pm$ 2.3		7.9 $\pm$ 1.4	
Employment	Yes	8.8 $\pm$ 2.1	<b>0.04</b>	8.4 $\pm$ 2.0	<b>0.01</b>	8.2 $\pm$ 1.8	<b>0.00</b>	8.1 $\pm$ 1.6	<b>0.00</b>
	No	9.2 $\pm$ 2.1		8.8 $\pm$ 1.8		8.7 $\pm$ 1.8		8.6 $\pm$ 1.7	
Marital status	Single	9.25 $\pm$ 2.19	<b>0.03</b>	8.18 $\pm$ 1.54	<b>0.01</b>	7.86 $\pm$ 1.96	<b>0.04</b>	8.12 $\pm$ 1.52	0.18
	Married	9.02 $\pm$ 2.07		8.61 $\pm$ 1.86		8.52 $\pm$ 1.8		8.42 $\pm$ 1.64	
	Divorced	10.59 $\pm$ 2.12		10.32 $\pm$ 2.1		9.33 $\pm$ 1.98		8.99 $\pm$ 1.85	
	Widow	9.37 $\pm$ 2.08		8.81 $\pm$ 1.93		8.95 $\pm$ 1.95		8.76 $\pm$ 1.92	

### 5.3.3 Association between HbA1c with the Period in study and duration of diabetes

Table 5.2 shows that patients who were registered in the center for  $\leq 6$  months had higher HbA1c in the 1<sup>st</sup> visit compared to patients who had been registered in the study for  $>36$  months ( $p < 0.05$ ). There was no significant association between period being registered in the center and HbA1c in the other visits ( $p > 0.05$ ). Patients who were diagnosed with diabetes for  $\leq 5$  years had much better HbA1c than patients who were diagnosed for  $>20$  years ( $p < 0.05$ ). (See table 5.2)

**Table 5.2: Association between HbA1c among the four visits with the Period in study, duration of diabetes.**

Variable		HbA1c 1 <sup>st</sup> visit		HbA1c 2 <sup>nd</sup> visit		HbA1c 3 <sup>rd</sup> visit		HbA1c 4 <sup>th</sup> visit	
		Mean	T. sig.						
Period in study	$\leq 6$	9.1 $\pm$ 1.9	<b>0.03</b>	8.6 $\pm$ 1.9	0.93	8.6 $\pm$ 1.9	0.7	8.3 $\pm$ 1.9	0.29
	7-12	9.5 $\pm$ 2.1		8.9 $\pm$ 1.8		8.7 $\pm$ 1.7		8.8 $\pm$ 1.8	
	13- 18	9.1 $\pm$ 2.5		8.6 $\pm$ 2.2		8.4 $\pm$ 2.0		8.1 $\pm$ 1.8	
	19- 24	9.1 $\pm$ 2.1		8.6 $\pm$ 1.9		8.3 $\pm$ 1.6		8.3 $\pm$ 1.6	
	25- 30	9.5 $\pm$ 2.3 $\pm$		8.8 $\pm$ 2.1		8.6 $\pm$ 1.9		8.6 $\pm$ 1.9	
	31- 36	9.2 $\pm$ 2.0		8.6 $\pm$ 1.8		8.6 $\pm$ 1.9		8.5 $\pm$ 1.7	
	$> 36$	8.7 $\pm$ 1.9		8.6 $\pm$ 1.9		8.6 $\pm$ 1.9		8.4 $\pm$ 1.5	
Duration of diabetes	$\leq 5$	8.1 $\pm$ 2.0	<b>0.00</b>	7.6 $\pm$ 1.8	<b>0.00</b>	7.6 $\pm$ 1.6	<b>0.00</b>	7.6 $\pm$ 1.5	<b>0.00</b>
	6-10	8.8 $\pm$ 1.9		8.4 $\pm$ 1.7		8.5 $\pm$ 1.6		8.4 $\pm$ 1.5	
	11-15	9.8 $\pm$ 2.0		9.4 $\pm$ 1.7		9.2 $\pm$ 1.7		9.0 $\pm$ 1.5	
	16-20	10.3 $\pm$ 1.8		9.5 $\pm$ 1.7		9.4 $\pm$ 1.6		9.4 $\pm$ 1.7	
	$> 20$	9.7 $\pm$ 1.7		9.8 $\pm$ 1.8		9.7 $\pm$ 2.0		9.3 $\pm$ 1.8	

### 5.3.4 Association between HbA1c and life style factor:

Table 5.3 presents data for the relationship between mean HbA1c with lifestyle factors in the four visits. Calorie intake showed no significant association with mean HbA1c in the four visits ( $p>0.05$ ). Patients who had normal BMI had higher mean HbA1c compared to patients who were classified as obese 3 in the 1<sup>st</sup> visit ( $p<0.05$ ), no association was found among the other visits ( $p>0.05$ ). Patients who were with very light physical activity had higher mean HbA1c than patients who were moderately active among the four visits ( $p<0.05$ ). Patients who were non smokers had lower mean HbA1c compared to patients who were past smokers in the first visit ( $p<0.05$ ), no association was found among the other visits ( $p>0.05$ ).

**Table 5.3: Associations between HbA1c at the four visits with BMI, physical activity and smoking**

Variable		HbA1c 1 <sup>st</sup> visit		HbA1c 2 <sup>nd</sup> visit		HbA1c 3 <sup>rd</sup> visit		HbA1c 4 <sup>th</sup> visit	
		Mean	T. sig.						
<b>BMI</b>	<b>Underweight</b>	-----	<b>0.00</b>	-----	0.07	----	0.65	-----	0.1
	<b>Normal weight</b>	10± 2.49		9.1± 1.94		8.8± 2.04		8.4±1.82	
	<b>Overweight</b>	9.1± 1.85		8.6± 1.87		8.5± 1.8		8.3±1.62	
	<b>Obese 1</b>	8.9± 2.18		8.7±1.93		8.5± 1.79		8.5±1.62	
	<b>Obese 2</b>	8.9± 1.95		8.4± 1.73		8.6± 1.75		8.6±1.76	
	<b>Obese3</b>	8.7±1.86		8.8± 1.89		8.8± 2.08		8.9±1.75	
<b>Physical Activity</b>	<b>Very Light</b>	10.5±2.0	<b>0.01</b>	10.2±2.1	<b>0.00</b>	9.3±2.1	<b>0.05</b>	9.6±1.7	<b>0.00</b>
	<b>Light</b>	9.1±2.1		8.7±1.9		8.6±1.8		8.5±1.7	
	<b>Moderate</b>	8.7±2.1		8.3±1.8		8.2±1.7		8.0±1.6	
<b>Smoking</b>	<b>Yes</b>	9.1±2.0	<b>0.01</b>	8.7±1.9	0.14	8.5±1.9	0.32	8.4±1.8	0.31
	<b>No</b>	9.0±2.0		8.6±1.9		8.5±1.8		8.4±1.7	
	<b>Past Smoker</b>	9.6±2.2		8.9±1.8		8.8±1.8		8.7±1.7	
<b>Calories intake</b>	<b>1000</b>	9.0±2.1	0.06	8.7±1.9	0.86	8.6±1.9	0.83	8.6±1.7	0.13
	<b>1200</b>	9.3±2.0		9.0±2.2		8.8±1.9		8.6±1.5	
	<b>1400</b>	9.3±2.0		8.7±1.8		8.8±1.8		8.8±1.8	
	<b>1600</b>	8.9±2.1		8.5±2.0		8.4±1.7		8.1±1.5	
	<b>1800</b>	8.8±1.8		8.5±1.8		8.4±1.8		8.3±1.7	
	<b>2000</b>	9.3±2.1		8.7±1.8		8.5±1.8		8.3±1.4	
	<b>2200</b>	9.7±2.2		9.0±2.0		8.6±1.7		8.6±1.9	
	<b>2400</b>	10.3±3.3		8.4±2.2		8.4±1.9		8.5±1.8	

### 5.3.5 Univariate analysis for HbA1c after dividing the levels into good change (decrease in HbA1c between visits) and bad change (increase of HbA1c levels between visits)

Since there were no fixed periods between patients' visits to the clinics, we decided to determine the good change (decrease in HbA1c) and bad change (increase in HbA1c) among the four visits.

As shown in figure 5.17 the best change in HbA1c was seen between the first and fourth visit were 60.7% of the patients had developed good change in their HbA1c.

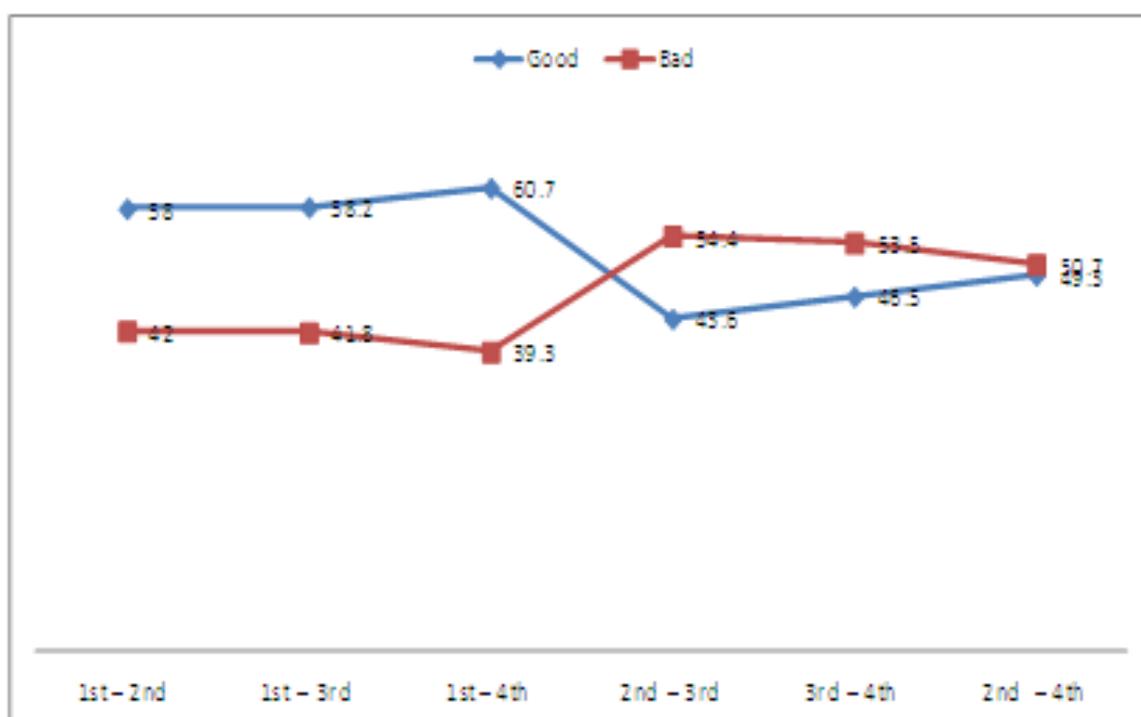


Figure 5.17 Distribution of good and bad change between visits

### 5.3.6 HbA1c change between fourth and first visit (HbA1c 4-1):

#### A- HbA1c 4-1 and demographic variables

A significant association was found between HbA1c 4-1 with the age category (41-50) years and period in study of (7 -12 months), (13-18 months) and (31-36 months) and in teaching and highly educated profession job category and MoH insurance (P <0.05), but no association was found between HbA1c 4-1 and sex, duration of diabetes, educational level, place of residency and employment (P >0.05, see table 5.4).

**Table 5.4: Distribution of HbA1c 4-1 change with various demographic variables**

Variable		Total N=746(%)	Bad HbA1c N= 293 (%)	Good HbA1c N= 453 (%)	P value	Odds ratio(CI)
Age	≤40	35 (4.69)	13 (37.1)	22 (62.9)	1	1 (0.48- 2.07)
	41-50	143 (19.2)	68 (47.6)	75 (52.4)	<b>0.04</b>	0.65 (0.43- 0.98)
	51-60	296 (40)	111(37.5)	185(62.5)	0.93	0.98 (0.7-1.38)
	> 60	272(36.46)	101(37.1)	171(62.9)		1
Sex	Male	349(46.78)	124(35.5)	225(64.5)	0.05	0.74 (0.55- 1)
	Female	397(53.21)	169(42.6)	228(57.4)		
Period in study ( months)	≤6	40 (5.3)	14 (35)	26 (65)	0.13	1.71 (0.85- 3.45)
	7-12	91 (12.19)	29 (31.9)	62 (68.1)	<b>0.01</b>	1.97 (1.18- 3.29)
	13- 18	50 (6.7)	15 (30)	35 (70)	<b>0.02</b>	2.15 (1.11- 4.16)
	19- 24	107 (14.3)	44 (41.1)	63 (58.9)	0.25	1.32 (0.83- 2.12)
	25- 30	74 (9.91)	26 (35.1)	48 (64.9)	0.06	1.7 (0.99- 2.94)
	31- 36	165 (22.1)	60 (36.4)	105(63.6)	<b>0.02</b>	1.61 (1.07- 2.44)
	> 36	219(29.35)	105(47.9)	114(52.1)		1
Duration of Diabetes (years)	≤5	211(28.28)	100(47.4)	111(52.6)	0.07	0.56 (0.3- 1.04)
	6-10	228(30.56)	95 (41.7)	133(58.3)	0.26	0.7 (0.38- 1.31)
	11-15	160 (21.4)	53 (33.1)	107(66.9)	0.98	1.01 (0.53- 1.94)
	16-20	93 (12.46)	27 (29)	66 (71)	0.59	1.22 (0.59- 2.52)
	> 20	54 (7.23)	18 (33.3)	36 (66.7)		1
Place of residency	Middle	332(31.09)	140(42.2)	192(57.8)	0.15	0.79 (0.57- 1.09)
	North	131(17.56)	50 (38.2)	81 (61.8)	0.73	0.93 (0.6- 1.42)
	South	283(37.93)	103(36.4)	180(63.6)		1

Continues in the next page

Variable		Total N=746	Bad HbA1c N= 293	Good HbA1c N= 453	P value	Odds ratio(CI)
Education level	Illiterate	109(14.61)	36 (33)	73 (67)	0.19	1.44 (0.84- 2.5)
	School	385 (51.6)	156(40.5)	229(59.5)	0.84	1.05 (0.68- 1.6)
	High school	139(18.63)	54 (38.8)	85 (61.2)	0.66	1.12 (0.68- 1.86)
	University	113(15.14)	47 (41.6)	66 (58.4)		1
Profession Total N=203	Worker	138(67.98)	51 (37)	87 (63)	0.05	3.98 (0.99- 16.08)
	Highly educated	55 (27.09)	18 (32.7)	37 (67.3)	<b>0.04</b>	4.8 (1.11- 20.76)
	Health sector	10 (4.92)	7 (70)	3 (30)		1
Employed	Yes	195(26.13)	76 (39)	119 (61)	0.92	0.98 (0.7- 1.37)
	No	551(73.85)	217(39.4)	334(60.6)		
Smoking	Yes	119(15.95)	48 (40.3)	71 (59.7)	0.21	0.71 (0.42- 1.2)
	No	501(67.15)	204(40.7)	297(59.3)	0.09	0.7 (0.47- 1.06)
	Past smoker	126(16.89)	41 (32.5)	85 (67.5)		1
Insurance	MOH	427 (57.2)	148(34.7)	279(65.3)	<b>0.03</b>	1.55 (1.06- 2.28)
	UNRWA	175 (23.45)	80 (45.7)	95 (54.3)	0.92	0.98 (0.63- 1.52)
	Others	144 (19.3)	65 (45.1)	79 (54.9)		1
Marital Status	Singe	14 (1.87)	4 (28.6)	10 (71.4)	0.35	1.8 (0.52- 6.2)
	Married	633(84.85)	250(39.5)	383(60.5)	0.67	1.1 (0.7- 1.74)
	Divorced	13 (1.74)	3 (23.1)	10 (76.9)	0.21	2.4 (0.62- 9.35)
	Widow	86 (11.52)	36 (41.9)	50 (58.1)		1

### B- HbA1c 4-1 with various follow up criteria

A significant association was found between good change in HbA1c 4-1 and good change in diastolic blood pressure 4-1( $p < 0.05$ ). No association was found between change in HbA1c 4-1 and change in MAU 4-1 and cholesterol 4-1 ( $P > 0.05$ , see table 5.5)

**Table 5.5: Distribution of HbA1c 4-1 change with various follow up criteria**

Variable	Total N=746(%)	Bad HbA1c N= 293(%)	Good HbA1c N= 453(%)	P value	Odds ratio (CI)
Good MAU*	346 (46.38)	132 (38.2)	214 (61.8)	0.56	1.09 (0.81- 1.47)
Good Cholesterol (mg/dl)	404 (54.15)	159 (39.4)	245 (60.6)	0.96	0.99 (0.74- 1.33)
Good Systolic (mmHg)*	350 (46.9)	144 (41.1)	206 (58.9)	0.33	0.86 (0.64-1.16)
Good Diastolic (mmHg)*	401 (53.7)	142 (35.4)	259 (64.6)	<b>0.02</b>	1.42 (1.06- 1.91)

\*reference category bad

### C- HbA1c 4-1 and Lifestyle behavior

No significant association was found between HbA1c 4-1 change with BMI, calorie intake and physical activity (P >0.05) (see table 5.6).

**Table 5.6: Distribution of HbA1c 4-1 with lifestyle behaviors**

Variable		Total N=746(%)	Bad HbA1c N= 421(%)	Good HbA1c N= 325(%)	P value	Odds ratio (CI)
<b>Good BMI*</b>		249 (33.37)	105 (42.2)	144 (57.8)	0.25	0.83 (0.612- 1.138)
<b>Calories</b>	<b>1000</b>	306 (41.01)	133 (43.5)	173 (56.5)	0.2	0.5 (0.174- 1.438)
	<b>1200</b>	29 (3.88)	11 (37.9)	18 (62.1)	0.48	0.629 (0.176- 2.253)
	<b>1400</b>	67 (8.98)	32 (47.8)	35 (52.2)	0.14	0.421 (0.135- 1.312)
	<b>1600</b>	104 (13.94)	39 (37.5)	65 (62.5)	0.43	0.641 (0.212- 1.936)
	<b>1800</b>	100 (13.4)	35 (35)	65 (65)	0.55	0.714 (0.235- 2.168)
	<b>2000</b>	93 (12.46)	32 (34.4)	61 (65.6)	0.59	0.733 (0.24- 2.239)
	<b>2200</b>	29 (3.88)	6 (20.7)	23 (79.3)	0.58	1.474 (0.375- 5.79)
	<b>2400</b>	18 (2.41)	5 (27.8)	13 (72.2)		1
<b>Activity level</b>	<b>Very light</b>	14 (1.87)	5 (35.7)	9 (64.3)	0.98	1.018 (0.321- 3.234)
	<b>Light</b>	613 (82.17)	245 (40)	368 (60)	0.43	0.85 (0.565- 1.277)
	<b>Moderate</b>	119 (15.9)	43 (36.1)	76 (63.9)		1

\*reference category bad

#### 5.4 Multivariate analysis

Table 5.7 shows the Multivariate analysis for HbA1c change with the different variables among the four visits.

Between the 1<sup>st</sup> and 2<sup>nd</sup> visit HbA1c was significantly determined by period being registered in the center, patients who had their visits within(7-12) months had 4 times better change in HbA1c compared with patients who had their four visits within >36 months. HbA1c between this visit was inversely associated with good change in diastolic blood pressure (AOR= 0.7(CI=0.5-0.9)) and good change in MAU (AOR= 0.6(CI=0.4 - 0.9)).

Between the 2<sup>nd</sup> and 3<sup>rd</sup> visit HbA1c change was significantly associated with period being registered in the center, patients who were registered in the center for 31-36 month had 1.5 times better change in HbA1c compared to patients who had their four visits >36 month.

Between the 1<sup>st</sup> and 4<sup>th</sup> visit HbA1c change was significantly associated with period being registered in the center, patients having their 4 visits within 7-12 months (AOR=1.94(CI=1.10-3.44)) or 13-18 months (AOR=2.33(CI=1.13-4.79) showed a better change in their HbA1c by 2 folds when compared to those spending longer time (>36 months). HbA1c change was inversely associated by change in diastolic blood pressure.

Between the 2<sup>nd</sup> and 4<sup>th</sup> visit HbA1c change was inversely associated with duration of diabetes <5 years (AOR=0.35(CI=0.18-0.69)).

Between the 3<sup>rd</sup> and 4<sup>th</sup> visit HbA1c change was inversely associated with Systolic blood pressure (AOR= 0.71(CI=0.51-0.98)).

Between the 1<sup>st</sup> and 3<sup>rd</sup> HbA1c change was inversely associated with change in MAU (AOR=0.62(CI=0.44-0.87)).

No significant association was found between HbA1c change with age, gender, employment, marital status, smoking, BMI, insurance, cholesterol level, residency and caloric intake among the four visits in the study.

**Table 5.7: Multivariate analysis for HbA1c change with the different variables among the four visits.**

		<b>HbA1c 2-1</b>	<b>HbA1c 3-2</b>	<b>HbA1c 4-1</b>	<b>HbA1c 4-2</b>	<b>HbA1c 4-3</b>	<b>HbA1c 3-1</b>
<b>Variable</b>		<b>AOR (CI)</b>					
<b>Age</b>	<b>≤40</b>	1.5(0.7-3.5)	1.2(0.5-3.0)	1.1(0.5-2.6)	1.2(0.6-2.8)	1.7(0.7-3.7)	0.9(0.4-2.1)
	<b>41-50</b>	0.8(0.5-1.3)	0.7(0.4-1.1)	0.7(0.4-1.1)	0.9(0.6-1.4)	0.95(0.6-1.5)	0.8(0.5-1.2)
	<b>51-60</b>	1.4(0.9-2.0)	0.9(0.6-1.3)	1(0.7-1.5)	0.9(0.6-1.4)	0.96(0.7-1.4)	0.9(0.6-1.3)
	<b>&gt; 60</b>	1	1	1	1	1	1
<b>Period in study (months)</b>	<b>7-12</b>	4.0 (2.2-7.3)	1.5(0.9-2.7)	1.9(1.1-3.4)	0.9(0.5-1.6)	0.9(0.5-1.5)	4.8(2.6-8.8)
	<b>13- 18</b>	2.9(1.4-5.9)	1.3(0.6-2.5)	2.3(1.1-4.8)	1.5(0.8-2.9)	1.0(0.5-1.97)	4.2(1.96-8.9)
	<b>19- 24</b>	1.7(1.-2.9)	1.7(0.98-2.8)	1.3(0.8-2.2)	1.1(0.7-1.8)	0.6(0.4-1.1)	2.7(1.6-4.7)
	<b>25- 30</b>	2.5(1.4-4.6)	1.1(0.6-1.95)	1.9(1.0-3.4)	1.1(0.6-1.97)	0.7(0.4-1.3)	3.3(1.8-6.0)
	<b>31- 36</b>	1.9(1.3-3.0)	1.6(1.0-2.5)	1.7(1.1-2.7)	1.1(0.7-1.7)	0.7(0.4-1.0)	2.3(1.5-3.5)
	<b>&gt; 36</b>	1	1	1	1	1	1
<b>Duration of Diabetes (years)</b>	<b>≤5</b>	1.3(0.7-2.5)	0.6(0.3-1.2)	0.5(0.3-1.0)	0.3(0.2-0.6)	0.4 (0.2-0.7)	0.70(0.4-1.4)
	<b>6-10</b>	1.6(0.8-3)	0.7(0.4-1.3)	0.8(0.4-1.5)	0.5(0.3-0.9)	0.7(0.34-1.2)	1.0(0.5-1.95)
	<b>11-15</b>	1.5(0.8-2.8)	1.2(0.6-2.4)	1.0(0.5-1.99)	0.8(0.4-1.6)	0.6(0.3-1.2)	1.4(0.7-2.8)
	<b>16-20</b>	1.9( 0.9-4.0)	1.2(0.6-2.6)	1.2(0.6-2.5)	0.5(0.2-1.0)	0.5(0.3-1.1)	1.97(0.9-4.2)
	<b>&gt; 20</b>	1	1	1	1	1	1
<b>Sex ***</b>	-	1.1(0.5- 2.3)	0.9 (0.4-2.1)	0.9(0.4-2.0)	0.5 (0.2-1.0)	0.8 (0.4-1.6)	0.8(0.4-1.7)
<b>Work**</b>		1.1(0.7-1.7)	1.7(1.1-2.7)	0.9(0.6-1.4)	0.9(0.6-1.3)	0.7(0.5-1.1)	1.2(0.7-1.8)
<b>Marital status</b>	<b>Single</b>	2.3(0.6-8.6)	4.3(1.2-15.0)	2.4(0.7-9.1)	1.8(0.5-5.8)	0.4(0.1-1.3)	3.96(1.1-14.7)
	<b>Married</b>	1.0(0.6-1.7)	1.5(0.8-2.5)	1.1(0.7-1.9)	1.2(0.7-2.1)	0.8(0.5-1.3)	1.8(1.1-3.1)
	<b>Divorced</b>	0.5 (0.2-1.9)	4.1(1.2-14.8)	2.97(0.7-12.5)	5.1(1.2-21.4)	0.96(0.3-3.4)	3.2(0.8-12.4)
	<b>Widow</b>	1	1	1	1	1	1
<b>Smoking</b>	<b>Yes</b>	1.2(0.7-2.1)	0.84(0.5-1.5)	0.8(0.5-1.4)	0.7(0.4-1.2)	0.9(0.54-1.6)	1.3(0.7-2.2)
	<b>No</b>	1.2(0.7-1.9)	0.8(0.5-1.2)	0.98(0.6-1.6)	0.6 (0.4-1.0)	0.9(0.5-1.4)	1.2(0.7-1.96)
	<b>Past smoker</b>	1	1	1	1	1	1

Continue in the next page

		<b>HbA1c 2-1</b>	<b>HbA1c 3-2</b>	<b>HbA1c 4-1</b>	<b>HbA1c 4-2</b>	<b>HbA1c 4-3</b>	<b>HbA1c 3-1</b>
<b>Variable</b>		<b>AOR <sup>3</sup>(CI)</b>	<b>AOR (CI)</b>				
<b>Insurance</b>	<b>MoH</b>	1.1(0.7-1.6)	1.2(0.8-1.8)	1.4(0.9-2.1)	0.99(0.7-1.5)	0.95(0.6-1.4)	1.1(0.7-1.7)
	<b>UNRWA</b>	0.8(0.5-1.4)	1.3(0.8-2.2)	0.8(0.5-1.3)	0.7(0.4-1.1)	0.7(0.4-1.2)	0.8(0.5-1.4)
	<b>Others</b>	1	1	1	1	1	1
<b>Cholesterol (mg/dl)*</b>		0.99(0.7-1.4)	1.0(0.7-1.5)	1.0(0.7-1.4)	1(0.7-1.4)	0.8(0.6-1.1)	0.7(0.5-1.0)
<b>MAU (*</b>	-	0.6(0.4-0.9)	0.5(0.3-0.7)	0.8(0.6-1.1)	0.9(0.6-1.2)	0.95(0.7-1.3)	0.6(0.4-0.9)
<b>Systolic (mmHg)*</b>	-	1.1(0.8-1.6)	1.2(0.9-1.7)	1.4(0.98-1.9)	0.8(0.6-1.1)	0.7(0.5-0.98)	1.2(0.8-1.6)
<b>Diastolic (mmHg) *</b>	-	0.7(0.5-0.9)	0.5(0.4-0.7)	0.7(0.5-0.9)	0.9(0.6-1.2)	0.98(0.7-1.4)	0.8(0.5-1.1)
<b>Residency</b>	<b>Middle</b>	1.0 (0.7-1.5)	0.9(0.6-1.3)	0.8(0.5-1.1)	0.7(0.5-1.0)	1.2(0.9-1.7)	0.8(0.5-1.1)
	<b>North</b>	0.7(0.4-1.1)	1.0(0.7-1.7)	0.9(0.6-1.4)	1.1(0.7-1.8)	1.3(0.9-2.1)	0.9(0.5-1.4)
	<b>South</b>	1	1	1	1	1	1
<b>BMI *</b>	-	1.0(0.7-1.4)	0.8(0.6-1.2)	1.1(0.8-1.5)	0.8(0.6-1.0)	0.8(0.6-1.0)	1.0(0.7-1.5)
<b>Calorie Intake</b>	<b>1000</b>	0.6(0.2-2.5)	2.0(0.6-7.4)	0.5 (0.1-1.8)	1.1(0.3-4.2)	0.5(0.1-1.6)	0.3(0.1-1.3)
	<b>1200</b>	0.8(0.2-3.8)	1.4(0.3-6.4)	0.5(0.1-2.3)	0.7(0.2-3.3)	0.5(0.1-2.2)	0.3(0.1-1.8)
	<b>1400</b>	0.6(0.2-2.5)	1.1(0.3-3.96)	0.4(0.1-1.4)	0.7(0.2-2.6)	0.6(0.2-1.8)	0.2(0.1-1.1)
	<b>1600</b>	0.5(0.2-1.9)	1.7(0.5-5.2)	0.7(0.2-2.2)	2.6(0.8-7.97)	0.7(0.3-2.1)	0.4(0.1-1.4)
	<b>1800</b>	0.5(0.2-1.8)	1.4(0.5-4.4)	0.7(0.2-2.4)	1.98(0.7-6.0)	0.8(0.3-2.2)	0.3(0.1-1.3)
	<b>2000</b>	0.8(0.2-2.7)	1.3(0.4-3.97)	0.8(0.2-2.4)	2.5(0.8-7.6)	0.98(0.4-2.8)	0.5(0.1-1.8)
	<b>2200</b>	0.6(0.2-2.6)	1.2(0.3-4.5)	1.4(0.3-5.9)	2.4(0.7-8.8)	0.8(0.2-2.6)	0.5(0.1-2.3)
	<b>2400</b>	1	1	1	1	1	1

\*reference category bad; \*\* reference category No;\*\*\*Reference category males

<sup>3</sup> AOR: Adjusted Odds Ratio

## **Discussion and Conclusion**

### **6.1 Introduction**

In this chapter, major study results are summarized and compared to other studies results worldwide. Also, these results will be discussed and interpreted. In the final part of the chapter study conclusions and recommendations are presented.

### **6.2 Summary of study findings**

The distinguishing feature of this study is that it is the first to evaluate the diabetes and dietary program held at the Diabetes Care Center at Augusta Victoria Hospital since year 2005. Also this study provides a baseline for further studies to improve dietary programs and comprehensive services in diabetes care.

The major study finding showed that, as reported in the medical files and upon patient registration in the center, 53.1% of the patients had peripheral neuropathy, 38.1% had hypertension, 20.8% with heart problems, 31% had dyslipidemia, and 70.5% were treated for diabetes by oral hypoglycemic agents.

Multivariate analysis was carried out on 746 patients who had their four visits within 4 years with irregular period between each visit (page 74 & 75).

Only 34% (n=255) of the sample had their four visits in two year, with at most 6 months between each 2 successive visits .Multivariate analysis was done on this subsample to see if the regular short period between visits shows different results and associations with the same variables included in the study ( see annex 6 ).

The results for the multivariate analysis for HbA1c change in table 5.7, showed that between visits, age, residency, type of insurance, smoking, good change in BMI, good change in cholesterol level and diet program did not show any significant associations with good change in HbA1c among the four visits. The models for change in HbA1c each between two visits were as follows

- Between the 1<sup>st</sup> and 2<sup>nd</sup> visit, the only variable associated with good change of HbA1c was numbers of years (period) visiting the clinic, but was inversely associated with good change in diastolic blood pressure and good change in MAU.

- Between the 2<sup>nd</sup> and 3<sup>rd</sup> visit, being single or married, and being employed determined the good change in HbA1c, but was inversely associated with good change in diastolic blood pressure and good change in MAU.
- Between the 1<sup>st</sup> and 3<sup>rd</sup> visit, numbers of years (period) visiting the clinic and being married or single were associated with good change in HbA1c, but was inversely associated with good change in MAU.
- Between 3<sup>rd</sup> visit and 4<sup>th</sup> visit having diabetes for  $\leq 5$  years was associated with good change in HbA1c, but was inversely associated with good change in systolic blood pressure.
- Between 2<sup>nd</sup> and 4<sup>th</sup> visit, being divorced was associated with good change in HbA1c, but was inversely associated with having diabetes for less than 10 years.
- Between the 1<sup>st</sup> and 4<sup>th</sup> visit the only variable associated with good change was numbers of years (period) visiting the clinic, but was inversely associated with good change in diastolic blood pressure and good change in MAU.

### **6.3 HbA1c levels and change before and after intervention**

In this study, the mean HbA1c (n=746) in the 1<sup>st</sup> visit was 9.1% (SD $\pm$  2.1) and in the 4<sup>th</sup> visit was 8.5% (SD $\pm$  1.7). In the 1<sup>st</sup> visit percent of our patients with controlled HbA1c ( $\leq 7$ ) was 19.2% (n=143) and increased in the 4<sup>th</sup> visit to 22.1% (n= 164). We carried another analysis on the 34% patients (n=255) of the total sample (n=746) who had their four visits done regularly within 2 years (Annex 6 &7). The repeated measures analysis showed that in this subsample (n=255 patients) the mean HbA1c for the 1<sup>st</sup> visit was 9.31 (SD=2.22) and the mean HbA1c for the 4<sup>th</sup> visit was 8.53 (SD=1.79). Also, there was good change in HbA1c levels between the 1<sup>st</sup> and 4<sup>th</sup> visit as the mean difference was 0.78 (p=0.00) (see Annex7). Comparing the findings with studies carried out in developed countries at various levels of healthcare, our results were consistent with a number of their findings. In Emirates, mean HbA1c for diabetic patients with type 2 diabetes in primary health care was 8.3%, but only 38% of patients had good glycemic control (HbA1c< 7.0%) (Juma Al-Kaabi et al, 2008). In Amman-Jordan the percentage of patients with optimal control (HbA1c  $\leq 7\%$ ) increased from 25.4% at the first visit to 27.5% at 12-month follow-up (M. Adham et al , 2010). In Al-Ain, UAE the mean HbA1c declined from 8.5% 2008 to 7.5% in

2010.(Layla Alhyas et al, 2012) . In Iraq the mean HbA1c levels at the start of the study was  $9.8 \pm 1.9$  % and after 3 years it was  $8.1 \pm 1.6$  % (Mansour et al, 2011). In Saudi Arabia 27% of the patients reached target level of glycemic control (Akbar, 2001). In Kuwait, only 17.6% of patients had achieved the goal of HbA1c < 7% In Trinidad, 15% had HbA1c $\leq$  7% (Ezenwaka & Offiah, 2001). Baseline data of newly diagnosed patients enrolled to the Korea National Diabetes Program (KNDP) cohort study conducted in Korea showed that mean HbA1c was  $8.2 \pm 2.4$ %. ( Choi et al, 2011) In Sweden a survey revealed that from type 2 diabetes patients only 34% had good glycemic control (Holmström IM et al, 2005). In Finland, only 25% of a study group had HbA1c < 7.3%. (Valle T et al., 1999). The Authors concluded that it's difficult to obtain optimal glycemic control (HbA1c  $\square$  7) due to the effects of rapid modernization, increased food consumption and obesity, and concomitant adoption of sedentary lifestyle.

This shows that our study population has much higher mean of HbA1c before using this intervention program compared to other Arab populations. Diabetic patients attending the educational sessions at the Diabetes Care Center Contribute this high mean to many factors regarding lifestyle, eating pattern, financial issues, political situation, social and psychosocial factors, and unavailability of medications, poor eating habits, poor compliance with medication and the use of inappropriate herbal medicines. In our study, comparing the reduction in the HbA1c level in the 4<sup>th</sup> visit with the baseline data from the 1<sup>st</sup> visit, a substantial improvement was found (9.1% dropped to 8.5%). For HbA1c control, as seen only 22.1% of the total number of participants reached the required target control level at the 4<sup>th</sup> visit, compared with 19.2% at the 1<sup>st</sup> visit. But compared to any other populations this is similar to many countries and many intervention programs. A meta-analysis that evaluated educational interventions in adult outpatients with diabetes before and after the intervention and at  $\geq 12$  weeks after the intervention showed that the net glycemic change was 0.32% lower in the intervention group than in the control group. (Ellis et al, 2004). In clinical practice, optimal glycemic control is difficult to obtain on a long-term basis because the reasons for poor glycemic control in Type 2 diabetes are complex (Wallace , 2000). Both patient- and health care provider related factors may contribute to poor glycemic control (Rhee et al., 2005; Wallace, 2000). The U.S. Department of Veterans Affairs and the U.S. Department of Defense (2010) stratify glycemic goals

based on co morbidity and life expectancy<sup>4</sup> (VA/DoD, 2010). This shows that the target level for HbA1c depends on the case of the patients. Therefore, in our nutrition program in AVH we aimed to lower the HbA1c level of the patients through the consultations and the diet program the patients receive throughout their visits.

### **Determinants for HbA1c levels:**

#### **Patients' gender and HbA1c**

In our study we carried out a test of significance (T-test) to assess the difference in means between the four clinic visits during the follow-up intervals. Our findings showed that males had significantly lower mean HbA1c levels than females in the 3<sup>rd</sup> and 4<sup>th</sup> visit. This could be related to the social norms of women in some conservative villages which limit their ability to take up exercise outside the home, another reason is that females usually report during the educational session that they don't have enough time during the day to care for themselves due to their huge household responsibilities, and that they usually miss their appointment or clinic because of their children who they can't leave alone at home. Similar findings were reported from Saudi Arabia (Akbar DH, 2001), Jordan (Adham et al., 2010) and Finland (Valle T et al., 1999). Other study revealed that there was no significant relationships between the level of HbA1c with gender (p=0.655) (Ismail et al., 2011).

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<sup>4</sup> The guidelines have three categories: (VA/DoD, 2010).

- 1) The patient with either none or very mild micro vascular complications of diabetes, who is free of major concurrent illnesses and who has a life expectancy of at least 10–15 years, should have HbA1c target of ,7%, if it can be achieved without risk.
- 2) The patient with longer-duration diabetes (more than 10 years) or with co morbid conditions and who requires a combination medication regimen including insulin should have an HbA1c target of 8%.
- 3) The patient with advanced micro vascular complications and/or major co morbid illness and/or a life expectancy of less than 5 years is unlikely to benefit from aggressive glucose-lowering management and should have an HbA1c target of 8–9%.

### **Patients' educational level and HbA1c**

Patients with higher educational degree had better mean HbA1c among all the four visits compared to illiterate patients ( $p \leq 0.05$ ). In the 1<sup>st</sup> visit patients who were illiterate had mean HbA1c  $9.5 \pm 2.1$ , and patients who had less than high school degree had mean HbA1c  $9.1 \pm 2.2$  compared to mean HbA1c  $8.7 \pm 2$  for patients who had university degree. In the fourth visits the illiterate patients had mean HbA1c  $8.7 \pm 1.7$  and the patients with less than high school degree had mean HbA1c of  $8.6 \pm 1.8$  compared to mean HbA1c  $8.2 \pm 1.4$  for patients with university degree ( $p \leq 0.05$ ). People with lower educational level have in general a lower satisfaction with life and are less satisfied with diabetes treatment, as well as having worse metabolic control (Biderman A. Et al, 2009).

Findings from a cohort study demonstrate that having less than a high school education was associated with a twofold higher mortality from diabetes compared with adults with a college degree or higher education level. (Saydah et al., 2009). Lower educational level was independently associated with poor levels of HbA1c (Alex N et al., 2003). But a study from Malaysia revealed that, there was no significant relationships between the level of HbA1c with education levels ( $p = 0.087$ ) (Ismail et al., 2011). Self-management in practice is complex and difficult since it should include meal planning, being physically active, skin care, taking medicines, foot care, avoiding smoking and tobacco, and other health monitoring tasks (Ahmed, 2006). Knowledge about diabetes and understanding treatment aims contribute to patients' active participation in the treatment and it will help the team responsible for the diabetes management programs to teach the patients ways of controlling diabetes such as the carbohydrate counting with insulin and medication which needs special calculations.

Traditional patient education relies heavily on written material about disease processes, medical management, and self-care instructions. Despite the availability of extensive health education materials with relatively consistent content, many are written at too high a level for low-literate patients to comprehend essential points (Davis, 1990). Thus, patients with inadequate literacy may not benefit from such educational efforts. This may explain why some patient education programs have been unsuccessful (Mulrow et al, 1987). The results of some studies confirm that the low-literate patient cannot fully comprehend medical advice using standard patient education methods. Direct involvement of patients in developing educational materials

may empower them to improve their health while ensuring that the content effectively educates them (Rudd, 1994).

### **Employment and HbA1c**

Patients who were employed had significantly lower mean HbA1c than patients who were not. Patients who were employed had mean HbA1c in the first visit  $8.8 \pm 2.1$  and improved to be  $8.1\% \pm 1.6$  in the fourth visit compared to patients who were unemployed and had mean HbA1c  $9.2\% \pm 2.1$  in the first visit and  $8.6\% \pm 1.7$  in the fourth visit. Other study findings showed that the level of control of diabetes was not statistically significantly with employment (Trief et al., 1999; Kurowska et al., 2010). In our study, both the employed and the unemployed had improved their mean HbA1c in their fourth visit. But the employed patients had better mean HbA1c through all visits compared to unemployed patients and this may be attributed to many reasons. We contribute the reason of this to the stress caused from being unemployed especially for men, then the financial burden caused by unemployment will prevent some of the patients from following up regularly in the center because of the cost of transportation, medication etc. Even some patients can't afford the high cost of living and buying whole grains, fruit, vegetables, low fat dairy products which are usually advised in the healthy diet. Another reason is that usually employed persons tend to be more active than unemployed persons. However other few studies showed that poor glycemic control is also affected by work factors for employed diabetics. Individuals working long hours are less likely to be able to properly manage their diabetes due to the lack of time to check their blood glucose levels, inject insulin, take oral agents when necessary, or eat well-balanced meals at regular time intervals, all factors that may affect glucose levels. Furthermore, Job stress, may influence diabetes through effects on metabolic regulations. Stress activates the hypothalamic pituitary adrenal axis which increases blood glucose and abdominal accumulation of body fat that causes insulin resistance. (Kroenke C.H et al , 2007 ; Kawakami N et al , 2000)

### **Type of insurance and HbA1c**

Patients who were with private insurance or insured with Israeli sick fund had significantly lower mean HbA1c than patients insured with MoH and UNRWA among the four visits. Between the 1<sup>st</sup> and 4<sup>th</sup> visit the mean HbA1c for patients who

were insured with MoH was  $9.3\% \pm 2.1$  in the first visit and improved to become  $8.5 \pm 1.6$  compared to the mean HbA1c of the private Israeli sick fund which was  $8.5 \pm 2$  in the first visit and improved to  $8.1 \pm 1.7$  in the fourth visit. This could be related to the availability of medication and the services provided to the patients and the costs of services and types of services covered vary widely. But it is very obvious in our health system that the private insurance or Israeli sick fund insurance provide a comprehensive care for diabetes patients by holding group educational sessions and individualized nutrition counseling by a registered dietitian, eye care, and provision of self monitoring blood sugar device to every diabetic patient with minimal charge on the glucosticks. On the other hand, UNRWA system and Ministry of health have recently included in their teams a dietitian even still not appointed in every clinic. The doctor sees a huge number of diabetic patients during the day which makes it impossible for him/her to give the patient enough time and privacy for discussion. Another problem is that sometimes the medication and insulin are not available in the clinics. A study in USA suggests that a nationwide coordinated healthcare system can implement quality improvement program initiatives for chronic diseases such as diabetes and that a nationwide system of universal access to care is a viable way to deliver care for patients with chronic diseases like diabetes thereby providing adequate care to all the citizens.( Arch G Mainous III , 2006)

### **Duration of having diabetes and HbA1c**

Mean HbA1c levels increased with a longer duration of DM. Patients who had diabetes for  $\leq 5$  years had better mean HbA1c than patients who had diabetes for  $> 20$  years during the four visits , but both groups have improved their HbA1c in the fourth visit.( as seen in page# 66 )

Several studies have shown significant relationship between the controlled levels of HbA1c with duration of illness (Hudon et al., 2008; Zhaolan Liu et al., 2010 ;Khattab et al., 2003;Chan et al., 2000; Bruce et al., 2000). However, Hartz et al. (2006) and Ismail et al. (2011) and Goudswaard et al (2004) showed no significant relationship between the levels of control of HbA1c with duration of illness.

The worsening of glycaemic control over time could be explained by insulin resistance associated with the ageing process. It is known that achieving and maintaining HbA1c levels  $< 7\%$  is difficult in patients with a longer duration of DM even with the addition of medication (UKPDS, 1998). Even patients with longer duration of diabetes get bored from attending the clinic, having their medication and

even attending the educational sessions, they feel they know everything about diabetes from their long experience with the disease. Thus new activities and discussions must be held in the clinics in order to encourage those patients to attend regularly and abide to their management protocols.

#### 6.4 Change in HbA1c throughout visits

In our study, the best change in HbA1c was seen between the first and fourth visit where 60.7% of the patients had improved their HbA1c as shown in figure 6.1. This shows that as our diabetic patients stay longer in the center and are undergoing the diabetes program they will have improvement in their HbA1c levels. In the National Health and Nutrition Examination Survey the mean of HbA1c levels decreased from 7.82% in 2000 to 7.47% in 2002 and 7.18% in 2003–2004. Controlled Diabetic patients with HbA1c < 7.0% increased from 37.0% in 2000 to 49.7% in 2002 and 55.7% in 2004; this indicates corresponding betterment over time (Hoerger et al, 2007).

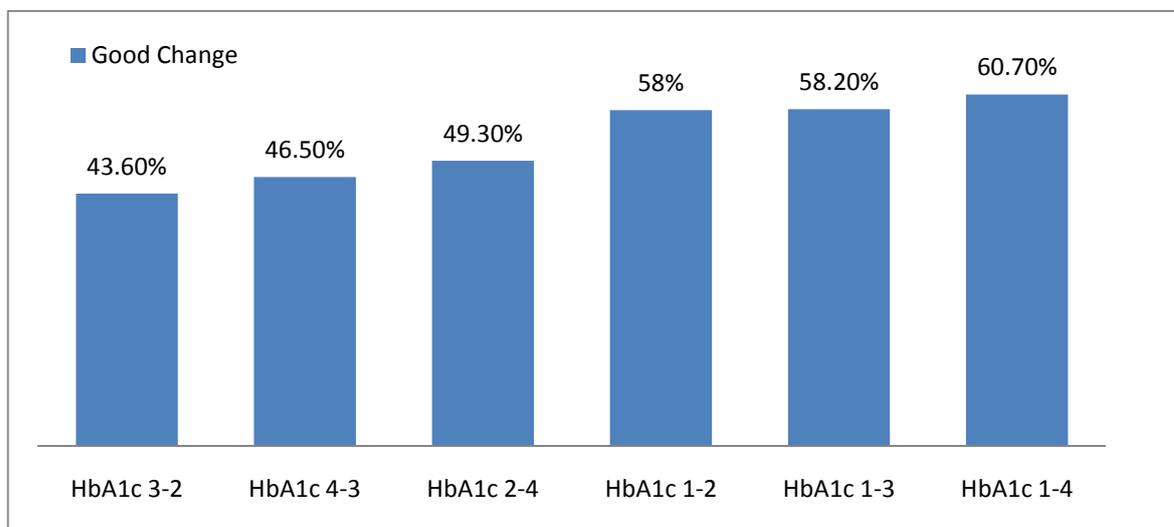


Figure 6.1: change in HbA1c between visits

Most intervention studies on diabetic patients with similar aim like our study had a planned schedule for their patients, thus patients had systematic data throughout their visits (Adham et al., 2010; ADA, 2008; Chan, 2000). But in our study the periods between the various four visits included was not systematic and varied among the patients. Thus we decided to focus on the 1<sup>st</sup> visit of the patient when the intervention

had started and the fourth visits results, which is the last one to see the impact of the program on the patients.

Glasgow et al in his study that involved 162 patients with type 2 diabetes using a multidisciplinary team showed that reduction in caloric intake and percentage of calories from fat was significantly higher in the intervention group compared to the control group. And when control group patients crossed over to the intervention group, their HbA1c levels decreased from 7.4% to 6.4% (Glasgow et al. 2001). In a prospective randomized trial, in persons newly diagnosed with or currently under treatment for type 2 diabetes, showed that with more intensive nutrition intervention programs and changes in lifestyle, HbA1c dropped by 1–2%. (Franz et al, 1995). In another 24 studies that combined physical activity advice and dietary advice in their intervention program, both factors were associated with decreased HbA1c (–0.58% to –0.43%) for intervention group as compared with control participants (Umpierre, 2011). Several studies reviewed in this meta-analysis reported a significant reduction in HbA1c of 1.0% to 2.6% with lifestyle intervention corresponding to weight loss (Norris et al, 2004). A meta-analysis study evaluated educational interventions in adult outpatients with diabetes, and reported on HbA1c concentrations before and after the intervention and at  $\geq 12$  weeks after the intervention showed that the net glycemic change was 0.32% lower in the intervention group than in the control group. (Ellis et al, 2004). In a randomized controlled trial of medical nutrition therapy at the UK Prospective Diabetes Study involved 30,444 newly diagnosed diabetic patients (type 2) at 15 centers. All groups received nutrition counseling from dieticians for three months. During the study, when the nutrition counseling was the primary intervention, “the mean HbA1c decreased by 1.9% fasting plasma glucose was reduced by 46 mg/dl, and there were average weight losses of 5 kg after 3 months (Pastors et al, 2002).

In our study and comparing the results of our program to other intervention programs (Adham et al., 2010; Wing et al., 2011, Mansour et al., 2011, Alhyas et al., 2012) we can say that the decline in the mean HbA1c between the 4<sup>th</sup> and 1<sup>st</sup> visit was 0.6 was similar to other programs in similar setups (Adham et al., 2010; Alhyas et al , 2012; ), and the 60.7% of patients who had good change in their HbA1c among this period is a quite good percent. This finding reveals that performance on process of diabetes care does not essentially translate into good metabolic control. The most important is to

implement change and any improvement and even if not reaching the optimum control level means that the program had succeeded in making a good change.

## **6.5 HbA1c change determinants between visits 1 and 4**

### **6.5.1 Association between HbA1c change and various demographic variables between visit 1 and 4**

In the multivariate model( n=746), patients' age, period being in program, duration of diabetes, sex, employment, marital status, insurance and place of residence were the main socio-demographic factors that were included in this study model.

Unexpectedly, age wasn't significantly associated with good change in HbA1c among all age groups between the 1<sup>st</sup> and 4<sup>th</sup> visit. This non significant relationship between age and poor glyceemic control in our study was not consistent with the findings of a number of studies (EL-Kebbi et al., 2003; Brenner, 2003) which reported that younger age was associated with poor glyceemic control. Several other studies also had shown that there was significant relationship between uncontrolled level of HbA1c and patient's young age (Eid et al., 2003; Suhaiza et al., 2004; Ismael et al., 2011) In the West Bank, the MOH report for year 2010 showed that the rate of diabetes varied by age which was 1.6% among age group 20-59 years and 13.6% among individuals 60 years and above (MOH report 2010).

Unlike the main sample (n=746), in the subsample of the 255 patients age between the 1<sup>st</sup> and 2<sup>nd</sup> visit had significant association with the good change in HbA1c , where patients at the age group 51-60 yrs had (2 folds) better to change their HbA1c compared to patients > 60 years ( see annex 6 table # 19) .

A possible explanation of the association between level of HbA1c and patients age could be associated with physical inactivity and poor healthy lifestyle habits at older ages. Karin in her analysis showed that increasing age was associated with physical inactivity. (Karin et. al, 2002) Another reason is that most elderly patients with diabetes may suffer from other chronic disorders and consume one or more medications that may increase glycosylation of hemoglobin thus increase HbA1c.

In our study, the period patients spent in visiting the clinic at AVH to get dietary consultation was a major determinant for HbA1c good change between the 1<sup>st</sup> and 4<sup>th</sup> visit. In the multivariate model patients having their 4 visits within 7-12 months or even within one and half year significantly showed a better change in their HbA1c by

2 folds compared to those spending longer time (>36 months). This change became less if they spend longer period which is up to 36 months and had only these 4 visits in it. The period being in the study for 19-24 months was not associated with good change in HbA1c between the 1<sup>st</sup> and 4<sup>th</sup> visit (AOR=1.29(CI=0.77-2.17)). We also noted this among the other visits where patients HbA1c between the 1<sup>st</sup> and 2<sup>nd</sup> visit and between the 1<sup>st</sup> and 3<sup>rd</sup> visit who have their HbA1c results within one year significantly showed a better change in their HbA1c by 4 and 5 times respectively when compared to those who spent longer times (36 months).

Other studies declare that routine visits to the diabetes therapist are vital in order to adapt and improve the treatment, and the steps of a successful medical nutrition therapy include assessment, individualization and regular follow up. Sustained improvements in HbA1c at 12 months and longer was seen among those consulting with registered dietitian that provided follow-up visits ranging from monthly to three sessions per year. HbA1c have decreased by 1-2% in type 2 diabetes. . (Anderson et al., 2003; ADA, 2008; Campbell et al, 2009). A meta analysis of 31 studies showed that self management education decreased HbA1c by 0.76%. HbA1c decreased more with additional contact time between participant and educator; a decrease of 1% was noted for every additional 23.6 hour of contact. (Norris et al., 2002).

This is an important finding and a good indicator for the success of the diabetes intervention program and it gives the implication that as patients being followed more frequently within regular times at the center, they will have better improve their HbA1c.

Duration of Diabetes showed no significant association with HbA1c between the 1<sup>st</sup> and 4<sup>th</sup> visit. Among the various visits the only association was found between 2<sup>nd</sup> and 4<sup>th</sup> visit where an inverse association was seen (the longer the period you had diabetes, the less good change in HbA1c was seen). Franz et al showed in his study that the average duration of diabetes for all subjects involved in the study was 4 years and the decrease in HbA1c was 0.9% (from 8.3 to 7.4%) and in the subgroup of subjects with duration of diabetes 1 year, the decrease in HbA1c was 1.9% (Franz et al, 1995). Other studies also showed that longer duration of DM was related to more difficulty in maintaining the glycaemic control (UKPDS,1998; Valle T et al., 1999; El Kebbi et al., 2003). The worsening of glycaemic control over time could be explained

by a reduction in pancreatic beta cell function and an increased fat mass, particularly visceral adiposity, leading to greater insulin resistance associated with the ageing process. It is known that achieving and maintaining HbA1c levels < 7% is difficult in patients with a longer duration of DM even with the addition of a third oral hypoglycaemic drug (UKPDS, 1998)

In the subsample analysis on the 255 patients who had their 4 visits in 2 years period, duration of diabetes was also significantly strongly associated with HbA1c change between the 1<sup>st</sup> and 2<sup>nd</sup> visit among those patients who were diagnosed with diabetes for 11-15 year significantly showed a better change in their HbA1c by 4 times when compared to those having diabetes for >20years, AOR=4.3(CI=1.14-15.99). Also between the 1<sup>st</sup> and 3<sup>rd</sup> visit the duration of diabetes was associated with the good change in HbA1c , patients who were diagnosed for 16-20 years had 6 folds to better change their HbA1c compared to those who were diagnosed for >20 years (see Annex 6) . Unlike the previous results in the main sample (n=746) that showed that duration of diabetes between the 2<sup>nd</sup> and 4<sup>th</sup> result are less likely for better change OR<1.

The Jordanian study showed that shorter duration of diabetes were related to reductions in HbA1c between the first and 12-month visits. (Adham et al, 2010) Khattab et al. in her study showed that increased duration of diabetes (N7 years vs. ≤7years) (OR=1.99, P≤.0005) was significantly associated with increased odds of poor glycemic control. (Khattab et al., 2011).

Marital status results showed that no significant association with HbA1c good change between the 1<sup>st</sup> and 4<sup>th</sup> visit. Among the other visits the association was found among the single and divorced patients between the 3<sup>rd</sup> and 2<sup>nd</sup> visit where AOR (single) = 4.28(CI=1.22-15.02) and AOR (divorced) =4.14(CI=1.16-14.77), both have around 4 times to develop the good change in HbA1c than the widow. Between the 3<sup>rd</sup> and 1<sup>st</sup> result also the single patient has 4 times to better change their HbA1c than the widow AOR= 3.96(CI=1.06-3.13). Between the 4<sup>th</sup> and 2<sup>nd</sup> visit AOR for divorced is 5.14(CI=1.23-21.42) to develop good change than the widow. Several studies had indicated that, there was no significant relationship between the level of HbA1c for patients with type 2 diabetes and marital status (Suhaiza et al., 2004; Ismail et al., 2000 , Ismail et al., 2011).

We might justify this result by the fact that it is common for marriage to affect the lifestyle of married couples as they become less active after marriage and likely reinforce increased food intake—so leading to the increased body weight. Previous work has suggested that widowhood increases risk of premature mortality and cardiovascular disease and has important implications for metabolic functioning and greater attention to the cardio metabolic health of this population is needed. (Cornelis et al., 2012)

Other factors in the model i.e. gender, employment, education level and the various types of insurance and place of residence did not show any significant association with good change in HbA1c in any of the four visits. Even with the sub sample analysis on the 255 patients with more regular visit to the clinic, the multivariate analysis for the four HbA1c period results period in study, duration of diabetes, insurance, marital status, place of residence, level of education did not show any significant effect.

## **6.5.2 Lifestyle factors associated with HbA1c change between the 1<sup>st</sup> and 4<sup>th</sup> visit**

### **6.5.2.1 Association between HbA1c and caloric intake**

Our study results showed that 41% of the patients were on 1000 Cal, 3.9% on 1200 Cal, 9% on 1400 Cal, 13.9% on 1600 Cal, 13.4% on 1800 Cal, 12.5% on 2000 Cal, 3.9% on 2200 and 2.4% on 2400 Cal among all study visits. Mean Calorie intake given to males was 1800 Cal. Compared to 1000 Cal mean calorie diets that were given to females ( $p=0.000$ ). These percentages haven't changed during the 4 years study period; all patients had the same calorie intake among the four visits of the study they were supposed to have to change their HbA1c and BMI. This was because every patient was given an individualized diet according to his assessment and needs to control diabetes and to reduce the body weight, but as the patients in every visit hadn't or had slight change in BMI thus the diet program was kept the same.

No significant association was found between the calorie intake in all groups (1000, 1200, 1400, 1600, 1800, 2000, 2200, 2400 Cal) with good change in HbA1c between the 1<sup>st</sup> and 4<sup>th</sup> visit.

After controlling for the confounding variables(Age , sex, employments , marital satatus and smoking ) the only association found in the multivariate analysis was in the

subsample sample(n=255) who followed regularly for four visits within two years and was between the 2<sup>nd</sup> and 4<sup>th</sup> visits for patients who were given 1000 calories and 1600 calories. Patients who were given 1000 calories have better change in HbA1c by 15 times compared to patients who were on diets with higher amounts of calories (2400 calories). Also patients who were on 1600 calories had better change their HbA1c by 21 folds compared to patients on 2400 calories. (AOR=14.9(CI=1.7-130.8), AOR=21.3(CI= 2.1-219.7) respectively) (See table 19 in Annex 6).

However in other studies conducted showed that sustained improvements in HbA1c at 12 months and longer was seen among those consulting with registered dietitian that provided follow-up visits ranging from monthly to three sessions per year where HbA1c have decreased by 1-2% in type 2 diabetes (ADA, 2008). In a meta-analysis to study the efficacy of low glycemic index diets in people with type 1 and type 2 diabetes, data for six trials measuring HbA1c showed a mean reduction of 0.5% for patients on low glycemic index diets compared to patients with higher glycemic index diets (Thomas et al, 2009). In a prospective randomized trial in USA, that used two levels of MNT on metabolic control in persons newly diagnosed with or currently under treatment for type 2 diabetes patients fasting plasma glucose level decreased by 50–100 mg/dl and the HbA1c dropped by 1–2% (Franz et al, 1995). In a study to determine factors associated with poor glycemic control for patients with type 2 diabetes showed that not following eating plan as recommended by dietitians (OR=2.98, P≤.0005), and increased barriers to adherence scale scores were significantly associated with increased odds of poor glycemic control. (Khattab et al., 2011)

Increased food intake is part of the socialization process and is a ritual based on large gatherings, where meals consisting of rice (high carbohydrates) and meat (high fat) are shared.

In our study the non-significant association between the caloric intake and the good change in HbA1c may be due to several reasons:

- The patients were not followed up regularly, the HbA1c results were taken in four years which make the period between the follow up visit for some patients far apart from other.
- Almost every patient was given the same amount of calories during his/her visits.
- No data documented in the patient file prove that the patient was abiding to the diet

- The diet given to the patients may need some modification regarding the amount of calories , traditional foods etc
- No evaluation was done on the diet program along this four years period of time.

### 6.5.2.2 Association between HbA1c change and Body mass index (BMI)

Our study shows that the mean body mass index (BMI) in the 1<sup>st</sup> visit was 31.3(SD±5.3) and in the 4<sup>th</sup> visit was increased to 31.9 (SD±5.3). This may reflect the increase of obesity in the Palestinian population as a result of urbanization, lifestyle shifting toward physical inactivity and increased food consumption.

As shown in figure 6.2, between the 1<sup>st</sup> and 4<sup>th</sup> visit only 33.4% had good change in their BMI. The best period where the largest number of patients had good change in BMI was between the 3<sup>rd</sup> and 4<sup>th</sup> visit where 46.6% of the patients had good change in BMI.

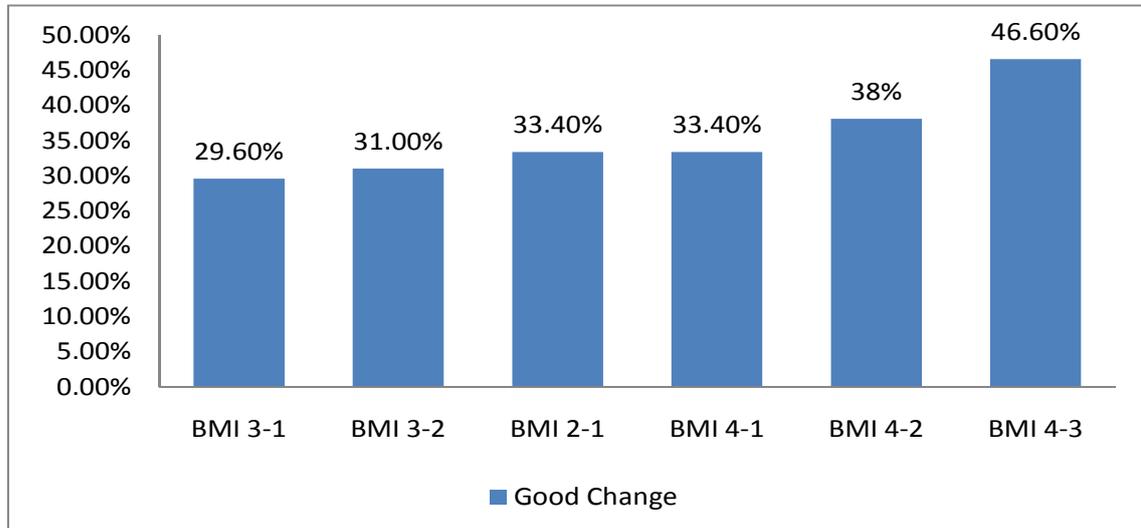


Figure 6.2: change in BMI between visits

Unlike what was expected in our study, the results of multivariate analysis revealed that there was no significant association between the good changes in BMI with the good change in HbA1c between the 1<sup>st</sup> and 4<sup>th</sup> visit. Even in the sub sample (n=255) no association was found between the change in HbA1c level and the BMI among all study visits. Similar results were found in other studies that showed there was no

significant relationship between the levels of HbA1c with BMI. (Hartz et al., 2006; Ismail et al, 2011; Ghazanfari et al, 2010)

However other studies showed the opposite. In a study after 4 years results showed that the participants assigned to the Mediterranean-style diet had lost more weight and had more improvement in some measures of glycemic control and coronary risk than had participants consuming the low-fat diet. (Esposito et al, 2009).

In another study in which type 2 diabetic patients were treated in a behavioral weight control program and followed up for one year showed that weight loss was significantly correlated with improvements in HbA1c. Patients who lost more than 6.9 kg or had more than 5% reduction in body weight had significant improvements in HbA1c values at one year (Wing, 1987). Several studies reviewed in this meta-analysis reported a significant reduction in HbA1c of 1.0% to 2.6% with lifestyle intervention corresponding to weight loss (Norris et al, 2004). In the UKPDS, the degree of weight loss required to normalize the fasting blood glucose was 10 kg (16% of initial body weight) if the initial value was 6-8mmol/L versus 22 kg (35%) if the initial value was 12-14 mmol/L (NHS, 2008). In a randomized control trial weight loss of 8.5% through an intensive education and support program decreased HbA1c by 0.64% (Pi-Sunyer, 2007). The United Kingdom Prospective Diabetic Study also showed that the level of blood glucose was greatly improved in type 2 diabetic patients who achieved weight reduction (UKPDS, 1998). In a study that examined the association between the magnitude of weight loss and changes in CVD risk factors at 1 year showed that weight loss was strongly associated with improvements in glycemia, blood pressure, triglycerides, and HDL cholesterol. Also when compared with weight-stable participants, those who lost 5 kilograms or less than 10% of their body weight had increased odds of achieving a 0.5% point reduction in HbA1c (Wing et. al, 2011).

A possible explanation of our study result could be as Watts et al. showed in his study moderate weight loss may not improve glycaemic control in all obese patients who have diabetes because there is a possibility that patients with longstanding disease or severe pancreatic  $\beta$ -cell dysfunction are not as responsive to weight loss as those with less extensive disease (Watts et al, 1990). Weight loss as an intervention is very challenging as there are so many factors that make it difficult to achieve. Follow up

with the dietitian was not upon regular basis, central obesity may be a better indicator to be used rather than BMI.

### **6.5.2.3 Association between HbA1c change and Physical activity**

The diabetes patients following up at the Diabetes Care Center were categorized according to the Diabetes Center definition of the physical activity to patients who were with very light physical activity and those are patients who were extremely inactive; patients with light physical activity and those are patients who do the routine daily work with little or no physical exercise ;and patients with moderate activity and those are patients who walk or exercise 150 minute per week (3 times a week).

In our study 20.8% of the patients as reported by medical files were doing physical exercise. In the four visits included in the study the Mean HbA1c in the 1<sup>st</sup> visit was  $8.7 \pm 2.1$  and in the fourth visit decreased to  $8.0 \pm 1.6$ . In multivariate analysis physical activity had no significant association with the good change of HbA1c between the 1<sup>st</sup> and fourth visit, and among all other visits in our study population.

Other studies showed the opposite; Castaneda et al showed in her study that sixteen weeks of (three times per week) resulted in reduced HbA1c levels (from 8.7 to 7.6), and reduced the dose of prescribed diabetes medication in 72% of exercisers compared with the control group,  $P = 0.004-0.05$ . Control subjects showed no change in HbA1c, and a 42% increase in diabetes medications (Castaneda et al 2002). Another Meta analysis study evaluated the effect of exercise interventions (duration  $\leq$  8 weeks) in adults with type 2 diabetes (11 randomized and 3 non-randomized) using controlled trials. The mean HbA1c post physical exercise intervention was lower in the exercise groups compared with the control groups (7.65% versus 8.31) (Boule et. al, 2001).

The increased availability of cars, greater use of mechanized home appliances, widespread use of computers, televisions and electronic gaming devices has created an environment that encourages sedentary lifestyles , Cultural barriers and limited access to sporting facilities are significant factors to low physical activity levels of the patients.

A possible explanation for our study results regarding physical activity might be due to:

- The patients were reporting their activity level and not evaluated by physical activity trainer.
- No physical activity level or PT trainer is available in the center to evaluate the accurate level of the patients
- Physical activity program is not included within the comprehensive care diabetes center.

### 6.5.3 Association between HbA1c change with MAU

The % of diabetic patients who had normal levels of Micro albumin urea (MAU) was 52% at the 1<sup>st</sup> visit and after being involved in the intervention program the % of patients with MAU increased to 54.3%. The highest percent of patients who developed good change in MAU was between the 1<sup>st</sup> and 4<sup>th</sup> visit as shown in figure 6.3.

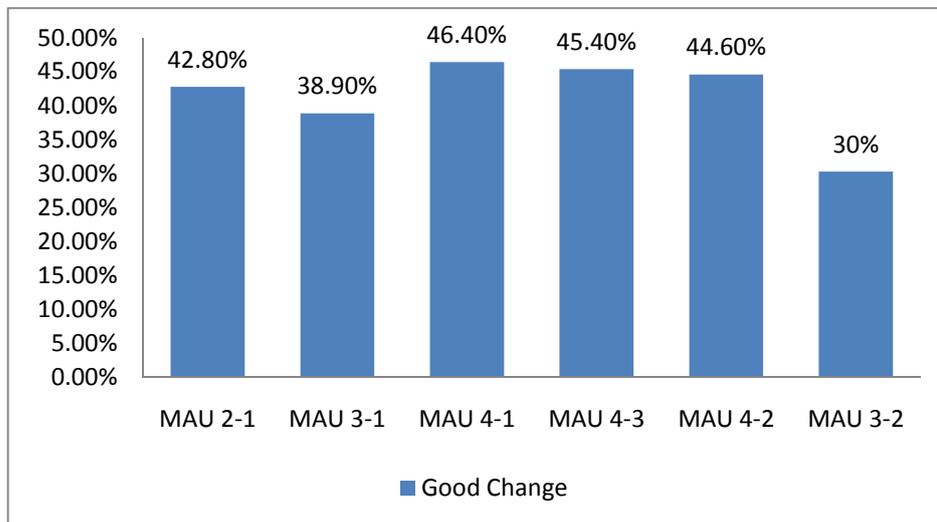


Figure 6.3: change in MAU between visits

There was no significant association between the good change in MAU and the good change in HbA1c between the 1<sup>st</sup> and 4<sup>th</sup> visit. But we find interesting results upon the other visits where there was a significant inverse association between MAU with HbA1c change between the 1<sup>st</sup> and 2<sup>nd</sup> visit. In the multivariate analysis for the subsample MAU was significantly inversely associated with HbA1c between the 1<sup>st</sup> and 2<sup>nd</sup> visit (AOR= 0.51(CI=0.28-0.94)).

A study found that microalbuminuria had a highly significant correlation with HbA1c ( $p < 0.05$ ) and an early onset of microalbuminuria could be due to poor glycaemic control (high HbA1c  $> 7\%$ ). (Sheikh et al., 2009) Another cross sectional study found that there was no statistically significant correlation between microalbuminuria and glycosylated hemoglobin (HbA1c). (M. Afkhami-Ardekani et al., 2008)

#### 6.5.4 Association between HbA1c change with cholesterol level

The mean cholesterol level at the 1<sup>st</sup> visit was 207.9 mg/dl and in the 4<sup>th</sup> visit after undergoing the intervention program was 194.9 mg/dl.

As shown in figure 6.4 the highest percent of patients with good change was seen between the 1<sup>st</sup> and 4<sup>th</sup> visit where 54.2% of the patients developed good change in cholesterol.

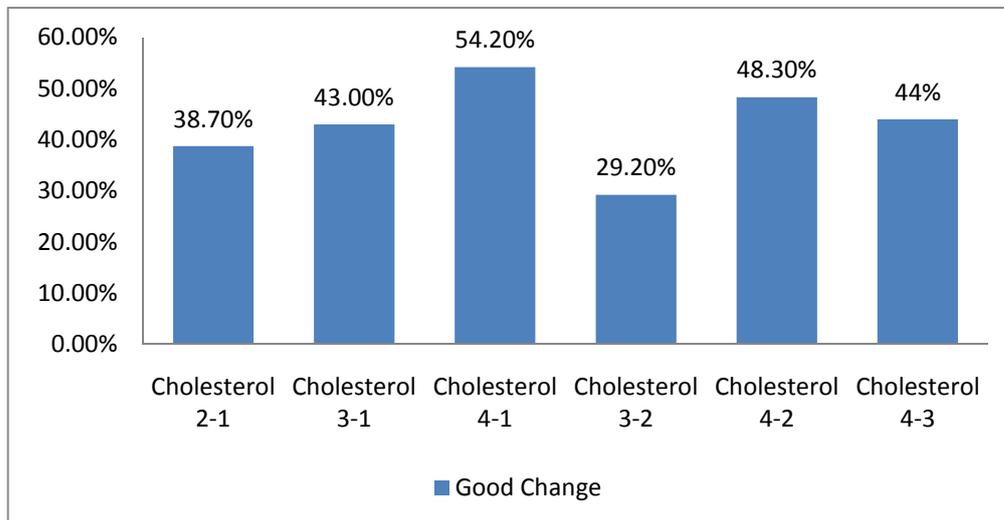


Figure 6.4: change in cholesterol between visits

Elevated cholesterol level is known to be one of the factors associated with uncontrolled type 2 diabetes mellitus. Several studies had indicated significant relationship between control of type 2 diabetes mellitus with high cholesterol level (Eid et al., 2003; Coro et al., 2004; Charumathi et al., 2009). But in our study no association was found between changes in HbA1c and change in cholesterol level between the 1<sup>st</sup> and 4<sup>th</sup> results and between the other visits ( $p > 0.05$ ). In a study to find the association between glycemic control and lipid profile HbA1c exhibited direct correlations with cholesterol. There was a linear relationship between HbA1c and dyslipidemia. The levels of serum cholesterol was significantly higher among patients with worse glycemic control as compared to patients with good glycemic control. The

findings of this study clearly indicate that HbA1c is a good predictor of lipid profile. (Khan HA et al.,2007)

## **6.6 Conclusion**

This study described, for the first time in the diabetes center, the determinants for the Change in HbA1c during the intervention program within year 2005-2009. Results from this study are comparable with other studies elsewhere; however, there is still scope for further improvement.

We found that between the 1<sup>st</sup> and 4<sup>th</sup> visit 60.7% of the patients developed good change in HbA1c. From socio-demographic factors, we found that change in HbA1c between the 1<sup>st</sup> and 4<sup>th</sup> visit was affected by period being in study. Unexpectedly and unlike many studies, from lifestyle factors, we found no association between the calorie intake, BMI and physical activity with the HbA1c change between the 1<sup>st</sup> and 4<sup>th</sup> visit where the patients were undergoing the intervention program. Regarding laboratory tests, an interesting finding was found between the MAU good change and HbA1c change between the 2<sup>nd</sup> and 1<sup>st</sup> visit and between the 2<sup>nd</sup> and 3<sup>rd</sup> visit and between the 1<sup>st</sup> and 3<sup>rd</sup> visit Where AOR was less than one. No association was found between the 1<sup>st</sup> and 4<sup>th</sup> visit.

Since the period was long and the follow – up visits were not systematic, we took a subsample from the study population where the visits were regular within 2 years time period but the results didn't show any much difference (Annex 6), period of study was the only demographic factor that determined the change in HbA1c between the 1<sup>st</sup> and 4<sup>th</sup> visit. But interestingly in the subsample we observed strong association between caloric intake (1000 cal and 1600 cal) with the HbA1c change between the 2<sup>nd</sup> and 4<sup>th</sup> visit.

Results were not as we expected due to the long period of the study without regular follow-up and evaluation program during this period that requires an evaluation of the dietary program of the diabetic patients after a particular period of intervention to evaluate the effectiveness of the education they received concerning dietary therapy and to determine the extent of the patients compliance. Detailed data about some aspects of patient management at baseline were not available in this study. Such as changes in drug management and compliance of patients with the treatment protocol,

could account for the improvements in HbA1c levels and likely influence glycaemic control

But still this study demonstrates that there is encouraging progress in the diabetes care reflected by the overall improvement in the mean of HbA1c, MAU, cholesterol and even the slight increment in the number of people reaching the target of HbA1c control. However, the results have shown that there is scope for further improvement, especially for a better glycaemia control. Findings from this study can help healthcare professionals, policy-makers and planners in the Diabetes Care Center at AVH in comparing performance and planning for quality improvement initiatives within the program. Results showed the problems in the system of follow up and appointment of the patients in the center, this will help the team of the center to look up for the reasons of the irregular period between visits for many patients which is supposed to be 3 months and to communicate with patients to find better solutions. Also to increase the number of visits of the patients to the center to participate in individual and group sessions and, this was shown to be effective and caused good change in HbA1c levels.

Regarding the dietary program, there was no enough data about the adherence of patients to the healthy diet given by the dietitians of the center, the diet was changed annually for the patients and nearly all patients had the same diet and calorie content throughout the four years period of study, interviews with patients must be done regularly to assess their needs, follow up and compliance with the diet program, this need new modifications and intervention strategies.

## **6.7 Recommendations:**

### **Recommendations for the Diabetes Center team at Augusta Victoria:**

- Continuous monitoring and evaluating the diabetes care provided are highly recommended to tackle any variance in care to improve and promote the quality of diabetes.
- There is a need for regular follow- up on patients treated in the center. This could be achieved by, using different methods of telecommunication , home visits, mobile clinic.

- Division of patients to two groups, a group of controlled patients ( $HbA1c \leq 7$ ) and another group of uncontrolled groups ( $HbA1c > 7$ ). Uncontrolled patients should undergo intensive diabetes intervention program with more frequent visits, intensive education, frequent individual dietary counseling and examining for detection of early complications.
- Use new strategies in the dietary program that include involving of the patients in education through peer discussions, practical implementation such as cooking healthy food, carbohydrate counting and sharing healthy recipes.
- Survey patient satisfactions on services provided, and work to improve quality of care accordingly.
- Assign one of the members of the team to act as a quality officer during the clinic day to check the files of the patients and assure that patients have been examined by doctor, dietitian and specialized nurses upon the protocol of the center and that all needed information is documented in the file and appointment given for next visit.
- Establish total quality system that continuously work to improve quality and safety of care provided at the center through computerized system.
- Team discussion by the end of each clinic to discuss cases of patients and prepare plans for the next time visit to improve their health conditions.
- Capacity building for the team working in the AVH Diabetes Center through conferences, training programs and motivation of self-learning, skills in research writing and data collection, analysis and interpretation.
- Add detailed data items collected in the patient file about some aspects of patient financial issues, self-management, medication and compliance this would be useful in future studies.
- Compare the current AVH nutrition program with similar other national, regional and international programs.
- To modify patients' files to include more information regarding patients' socioeconomic status and health condition such as complications, method of follow up, date of diagnosis of complications, etc...repeated up, also merge
- Conduct analysis and encourage studies using the huge database available in the Centre.
- Introduce attractive diabetes health education methods such as audio-visual aids, leaflets, role plays

## **Recommendations for health care providers in Palestine**

- Link clinical practice and data with academic institutions for more evidence based interventions and scientific researches
- Integrate diabetes guidelines into existing local public health and related programs, including emphasis on treatment and follow up the diabetes complications for patients with previous adverse outcomes.
- Maximize public health surveillance and related research mechanisms to monitor improvements and weakness of the diabetes programs at national level
- Enhance collaboration between the various health care providers to set up a unified national care Strategy for Type two diabetes mellitus
- National information system to track diabetic and chronic patients
- To have a national advocacy for applying the diabetes guidelines by all health care providers, in particular by those working in the private sector.
- To have an action plan for having a well-trained specialized teams (doctors, nurses, dietitians etc.) in diabetes care.
- To conduct training sessions for all health care provider staff on diabetes management guidelines.
- To introduce the necessary lab tests, such as: LDL, HDL, urine for microalbumin and HbA1c test as the main lab tests to be done for every diabetic patient upon protocol.
- To set up national monitoring and surveillance plans for the "proper" diabetes management.
- To increase awareness programs amongst patients about HbA1c (value and utility), thereby empowering them to take appropriate action when their diabetes is poorly controlled.
- To work with people with Type 2 diabetes to bridge the information gap to eliminate misunderstanding and improve patient outcomes.

### **Recommendations for patients with type 2 diabetes:**

- To engage with the health professionals directly, informing them of their status and empowering them to choose to control their diabetes and providing practical, realistic vehicles to achieve this.
- To form a special society for diabetes patients, to gather, meet, cook healthy food, do physical activity to discuss their conditions, needs, share experiences
- There is clearly a need for patients to have their diabetes reviewed regularly, and if current treatments provide inadequate control they should explore more effective disease management options with their healthcare professional
- To cooperate with the health care professionals , to follow the medical advices adhere to healthy lifestyle
- To share with health providers experiences and provide practical intervention strategies which enable them to change behavior – for example, weight loss.

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# Annex:

## Annex (1): Diabetes Care Center File

### Summary sheet

Date	B.P	Wt.	HbA1c	MAU	Choles.	Hypo.	Medical Requirements	Sig.

**Identification Data:**

Date: ..... / ..... / .....

- File Number: ..... Interview done by:.....
- Hospital Number: ..... ID. #:.....
- Patient Name:..... Preferred name:..... Sex:.....
- Place of birth: ..... Date of birth:..... Residency.....
- District:..... Telephone number: ..... Fax #:.....
- Insurance: (1 no (2 yes Type of insurance:..... Number: .....
- Marital status:..... Age of spouse:.....

===== **Subjective Data:** =====

Patient **Education:** ..... Current **work:** 1) yes 2) no 3) retired.

**Type of work:**..... **Years at the last work:**.....

**Social support** system: 1) live alone 2) within a family 3) others; specify.....

If live within a **family** then:

Total number of **family members** living with patient in the same house:.....

Family member who mostly **takes care** of the patient:.....

Patient relation to family:.....

**Educational background of family members:**

Husband: 1).....2) NA

Wife: 1).....2) NA (mention if more than one wife).

Sons: .....(mention all living with patient).

Daughters:.....(mention all living with patient).

Others:.....specify:.....

**Any family member has:**

- Diabetes: 1) No 2) Yes If yes: Type of diabetes:..... Relation to patient:.....

- Hypertension: 1) No 2) Yes Relation to patient:.....

- Cardiovascular: 1) No 2) Yes Relation to patient:.....Specify the disease:.....

- Renal failure 1) No 2) Yes Relation to patient:.....

- Others: 1) No 2) Yes Specify:.....

**Patient health information:**

**Type of diabetes:** ..... **Date of diagnosis:** ..... **Diagnosed by:** .....

In your opinion, main **causes** of your diabetes are: .....

**Treatment** based on: 1) Diet only                      2) Oral preparations                      3) Insulin  
4) Oral preparations and insulin together.                      5) Others: .....

If patient on **insulin**, who is giving the injection: .....

Any **teaching** done regarding the injection of insulin: .....

If patient on **diet**: diet regime prescribed by: .....

Do you follow the prescribed diet: .....

Beside your normal daily activities, do you **exercise** regularly: .....

If yes: Type of exercise: ..... Frequency and Duration: .....

Have there been changes in your **weight** in the past: .....

If yes: Increased ..... Kgs,                      or                      Decreased ..... Kgs.

Have there been changes in your **weight** recently: .....

If yes: Increased ..... Kgs,                      or                      Decreased ..... Kgs.

Do you **smoke**: 1) Yes                      2) No                      3) Past smoker.

If yes, kind of smoking: 1) Cigarettes    2) Nargila    3) Both

Number of packets: ..... # of years being smoking: .....

If past smoker, years smoked: .....

Do you have **allergy** to: Food: 1) No    2) Yes if yes what types of food: .....

Medication: 1) No 2) Yes, Type of medications: .....

Others specify: .....

Any kind of food not preferred: 1) No 2) Yes. Type of food: .....

Do you have **Hypertension**: ....., Since .....

Do you have **Heart Problems**: ....., Type: ..... Since: .....

Do you ever had a **Stroke**: ....., How many times: ..... When: .....

Do you have **Peripheral Neuropathy**: ..... Since: .....

Do you have **Feet Problems**: ....., Type: ..... Since: .....

Do you have **Kidney Problems**: ....., Type: ..... Since: .....

Do You have **Eye Problems**: ....., Type: ..... Since: .....

Do you have increased **Cholesterol**: 1) Yes 2) No 3) Unknown, if yes, Since: .....

Other **Related Complications**: 1) Yes 2) No Type, and Year Diagnosed .....

Other health problems: 1) Yes 2) No Specify ..... years .....

Previous **admissions** to the hospital after diagnosed with diabetes.....

How many times:..... Reasons for admission: .....

Outcome of that admission: .....

Any **operations** done after diagnosed with diabetes .....

Type of operation:..... year.....

**For women:** History of Gestational Diabetes (if any):.....

**venue for health education** do you prefer?

- 1) Individual education                      2) Group education with other patients
- 3) Education within family context   4) Others, Specify.....

Additional **comments** from patients regarding his/her condition.....

.....

===== **Objective Data:** =====

Patient weight:..... Kgs,    Height:..... cm,    BMI:.....,    WHR:.....

Wrist Circumference:.....    Frame Size:.....    IBW:.....Kgs.    Kcal:.....

Baseline **vital signs:** **BP:**.....mmHg    **Pulse:**.....bpm.

Visual Acuity: Rt eye:..... corrected:..... corrected by:.....

Lt eye:.....corrected:.....corrected by:.....

Last blood sugar result (F R PP).....mg/dl

Dental problems:.....Specify:..... year.....

Hearing problems:..... Specify:..... year.....

Foot inspection: Findings: **Color:** (Rt.....Lt.....), **Skin integrity** (Rt.....Lt.....)

**Ulcers:** (Rt.....Lt.....), **Pulses** (Rt.....Lt.....), Others:.....

**Baseline Laboratory Investigations:**

**Glucose:** (F R PP).....mg/dl    **HbA1c:**.....%    **Microalbuminuria:**(Ratio).....

**Total Cholesterol**..... **Triglycerides**..... **LDL**..... **HDL**.....

**Creatinin** ..... **Urea** .....

**U.A:** (Glucose..... Ketone..... Protein.....)

Others.....

**Medications** taken by the patient:

	Medication	Dose	Route	Frequency	Start date	Prescribed by
1						
2						
3						
4						
5						
6						
7						

### Follow-up Sheet

Date	BMI	T.Calories Given	Activity Level	Dilated eye exam	Feet Exam	Labs required and Results

## Annex 2 : Diets

### 1800 سعر حراري

الفتور	وجبة خفيفة	الغذاء	وجبة خفيفة	العشاء	وجبة خفيفة
رغيف خبز أسمر + ملعقتين لبننة صغيرة + ملعقة زيت صغيرة + خضار	2 حبة خضار + حبة فواكه	120 غم سمك مشوي + صحن سلطة خضار +2 حبة خضار مشوية +2 حبة بطاطا مشوية	حبة خضار + حبة فاكهة	رغيف خبز أسمر + 2 ملعقة حمص صغيرة + حبة خضار	حبة فواكه + حبة خضار + كأس حليب قليل الدسم
رغيف خبز أسمر + بيضة مسلوقة + حبة خضار + 2 ملعقة لبننة	حبة فواكه + حبة خضار	كأس مجردة برغل + سلطة + ½ كأس لبن + 7 حبات زيتون	حبة فاكهة + حبة خضار	رغيف خبز أسمر + 2 ملعقة صغيرة لبننة قليلة الدسم + ملعقة زيت صغيرة + بندورة	حبة فاكهة + كأس حليب قليل الدسم
رغيف خبز أسمر + قطعة جبنة بيضاء قليلة الدسم و غير مالحة + خضار + كأس حليب قليل الدسم	2 حبة خضار + حبة فاكهة	كأس فريكة مطبوخ + كأس سلطة + صدر دجاج بدون جلده + ½ كأس لبن	حبة فاكهة + ملعقتين مكسرات	ملعقتين صغيرة حمص + ملعقة زيت زيتون + رغيف خبز أسمر + حبة خضار	حبة فاكهة + 2 حبة خضار
ملعقتين حمص + رغيف خبز أسمر + خضار	خضار + حبة فواكه +	كأس خضار مطبوخة + قطعة صغيرة لحمة عجل بدون دهون + كأس أرز مطبوخ + سلطة	حبة فواكه + حبة فواكه	رغيف خبز أسمر + 2 خضار + لبننة	كأس حليب قليل الدسم + حبة فواكه

**بدائل الخبز:** ¼ رغيف خبز، أو ½ شطيرة همبرغر، أو ½ كأس أرز مسلوق، أو ½ كأس برغل مسلوق، أو ½ كأس ذرة، أو ½ كأس معكرونة مسلوقة، أو حبة بطاطا مسلوقة متوسطة الحجم، ½ كأس كورن فليكس قمح

**بدائل الحليب:** كأس حليب قليل الدسم، أو كأس لبن قليل الدسم، أو 2 ملعقة لبننة قليلة الدسم، أو قطعة جبنة بيضاء قليلة الدسم

**بدائل الفاكهة:** ½ موزة كبيرة، أو حبة تفاح، أو 10 – 15 حبات عنب، أو (2-3) حبة مشمش، أو (1-2) حبة تين، حبة تين مجفف، أو ½ جريب فروت، أو حبة أجاص صغيرة، حبة جوافة، أو (1-2) حبة كيوي، أو حبة برتقال، أو حبة خوخ صغيرة، أو ¼ - ½ حبة مانغا، 2 حبة صبر صغيرة، أو كأس شرائح بطيخ، كأس شرائح شمام، أو حبتين برقوق، ¼ حبة أناناس أو قطعة صغيرة أناناس مجفف، كأس توت أرضي، 2 حبة تمر، 4 حبات اسكدنيا، ½ حبة رمان، 2 حبة كلمنتينا، ملعقة زبيب، ½ حبة بوملة صغيرة، أو ½ كأس عصير طبيعي

**بدائل الخضار:** كأس خضار طازج (كأس سلطة)، أو حبة خضار (حبة خيار، حبة فلفل، حبة بندورة، ..) ½ كأس خضار مطبوخة (كوسا، سبانخ، ملوخية، ملفوف، بادنجان...)، أو ½ كأس عصير خضار (عصير جزر، عصير بندورة، ...)

**بدائل اللحم:** قطعة صغيرة 60-90 غم من اللحم، دجاج، سمك، أو ½ كأس مطبوخ من البقوليات (حمص، فول، عدس)، أو 2 ملعقة كبيرة مكسرات، أو 2 ملعقة صغيرة من زبدة الفول السوداني، أو بيضة واحدة، 2 ملعقة حمص كبيرة، 2 قطعة حبش، 60-90 غم طن

**بدائل الدهون:** ملعقة زيت (زيتون، ذرة، عباد الشمس، زيت سمسم صغيرة)، ملعقة طحينية صغيرة، ملعقة مرجرين صغيرة، 5-10 حبات زيتون

وجبة خفيفة	عشاء	وجبة خفيفة	غذاء	وجبة خفيفة	الإفطار
كأس حليب+ حبة فواكه+ خضار	رغيف خبز أسمر + زيت و زعتر + حبة خضار	حبة فاكهة + ملعقتين مكسرات + 2 حبة خضار	كأس فريكة مطبوخة بدون دهون + كأس سلطة خضار طازجة + صدر دجاج مشوي بدون جلدة	حبة فاكهة+ خضار+ ½ رغيف خبز أسمر مع لبننة	رغيف خبز أسمر + خضار + لبننة و زيت زيتون
كأس حليب+ حبة فواكه+ خضار	رغيف خبز+ 2 ملعقة حمص صغيرة+حبة خضار + حبة فاكهة	حبة فواكه + 2 خضار	كأس لبن قليل الدسم+كأس برغل أو أرز بني مطبوخ + كأس يخني خضار مطبوخة+ لحمة عجل بدون دهون	حبة فاكهة + كأس سلطة + ½ رغيف خبز + مرتديلا حبش	كأس حليب قليل الدسم+ رغيف خبز أسمر + خضار + زيت و زعتر
كأس حليب+ حبة فواكه+ خضار	رغيف خبز أسمر+ بيضة مسلوقة + حبة خضار	حبة فاكهة + 2 خضار	كأس خضار مطبوخة+ قطعة سمك مشوي + 2 حبة بطاطا مشوية	حبة خضار + حبة فاكهة + ½ رغيف خبز + جبنة بيضاء	رغيف خبز أسمر+ قطعة جبنة بيضاء قليلة الدسم غير مالحة+ خضار

**بدائل الخبز:** ¼ رغيف خبز، أو ½ شطيرة همبرغر، أو ½ كأس أرز مسلوقة، أو ½ كأس برغل مسلوقة، أو ½ كأس ذرة، أو ½ كأس معكرونة مسلوقة، أو حبة بطاطا مسلوقة متوسطة الحجم، ½ كأس كورن فليكس قمح

**بدائل الحليب:** كأس حليب قليل الدسم، أو كأس لبن قليل الدسم، أو 2 ملعقة لبننة قليلة الدسم، أو قطعة جبنة بيضاء قليلة الدسم

**بدائل الفاكهة:** ½ موزة كبيرة، أو حبة تفاح، أو 10 حبات عنب، أو (2-3) حبة مشمش، أو (1-2) حبة تين، حبة تين مجفف، أو ½ جريب فروت، أو حبة أجاص صغيرة، حبة جوافة، أو (1-2) حبة كيوي، أو حبة برتقال، أو حبة خوخ صغيرة، أو ¼ - 2/1 حبة مانغا، 2 حبة صبر صغيرة، أو كأس شرائح بطيخ، كأس شرائح شمام، أو حبتين برقوق، ¼ حبة أناناس أو قطعة صغيرة أناناس مجفف، كأس توت أرضي، 2 حبة تمر، 4 حبات اسكندنيا، 3 حبات لوز، 2/1 حبة رمان، 2 حبة كلمنتينا، ملعقة زبيب، ½ حبة بوملة صغيرة، أو ½ كأس عصير طبيعي

**بدائل الخضار:** كأس خضار طازج (كأس سلطة)، أو حبة خضار (حبة خيار، حبة فلفل، حبة بندورة،...) ½ كأس خضار مطبوخة (كوسا، سبانخ، ملوخية، ملفوف، باذنجان...)، أو ½ كأس عصير خضار (عصير جزر، عصير بندورة،...)

**بدائل اللحمة:** 60-90 قطعة صغيرة غم من اللحوم، دجاج، سمك، أو ½ كأس مطبوخ من البقوليات (حمص، فول، عدس)، أو 2 ملعقة كبيرة مكسرات، أو 2 ملعقة صغيرة من زبدة الفول السوداني، أو بيضة واحدة، 2 ملعقة حمص كبيرة، 2 قطعة حبش، 60 غم طن

**بدائل الدهون:** ملعقة زيت (زيتون، ذرة، عباد الشمس، زيت سمس صغيرة)، ملعقة طحينية صغيرة، ملعقة مرجرين صغيرة

## 1000 سعر حراري

وجبة خفيفة	العشاء	وجبة خفيفة	الغذاء	وجبة خفيفة	الفتور
حبة فاكهة + حبة خضار	½ رغيف خبز أسمر + زيت و زعتر + خضار	كأس لبن + حبة فواكه	كأس فريكة أو أرز مطبوخ + صحن سلطة + ½ صدر دجاج مشوي أو لحمة عجل بدون دهون + كأس يخني خضار مطبوخ	حبة خضار + حبة فاكهة	كأس حليب قليل الدسم + ½ رغيف خبز أسمر + لبننة + ملعقة زيت زيتون + حبة خضار
حبة فاكهة + حبة خضار	½ رغيف خبز أسمر + قطعة جبنة بيضاء قليلة الملح + حبة خضار	حبة فواكه + حبة خضار	كأس مجرة برغل + سلطة خضار + كأس لبن	حبة خضار + حبة فاكهة	كأس حليب قليل الدسم + ½ رغيف خبز أسمر + بيضنة مسلوقة + خضار
حبة فواكه + كأس حليب قليل الدسم	½ رغيف خبز أسمر + ملعقة حمص + خضار	حبة فواكه + حبة خضار	سمك مشوي + 2 خضار مشوية + 2 حبة بطاطا صغيرة مشوية + سلطة خضار	حبة فواكه + 2 حبة خضار	½ رغيف خبز أسمر + لبننة و زيت زيتون + خضار

يمكن استبدال الاغذية بأخرى من نفس المجموعة و بنفس الكمية التي تعادلها من البدائل:

**بدائل الخبز:** ¼ رغيف خبز، أو شريحة توست، أو ½ كأس كورن فليكس قمح أو قطعة قرشلة، أو ½ كأس أرز مسلووق، أو ½ كأس برغل مسلووق، أو ½ كأس ذرة، أو ½ كأس معكرونة مسلووقة، أو حبة بطاطا مسلووقة متوسطة الحجم،

**بدائل الحليب:** كأس حليب قليل الدسم، أو كأس لبن قليل الدسم، أو 2 ملعقة لبننة قليلة الدسم، أو قطعة جبنة بيضاء قليلة الدسم

**بدائل الفاكهة:** ½ موزة كبيرة، أو حبة تفاح، أو 10 حبات عنب، أو (2-3) حبة مشمش، أو (1-2) حبة تين، حبة تين مجفف، أو ½ جريب فروت، أو حبة أجاص صغيرة، حبة جوافة، أو (1-2) حبة كيوي، أو حبة برتقال، أو حبة خوخ صغيرة، أو 4/1 – 2/1 حبة مانغا، 2 حبة صبر صغيرة، أو كأس شرائح بطيخ، كأس شرائح شمام، أو حبتين برقوق، ¼ حبة أناناس أو قطعة صغيرة أناناس مجفف، كأس توت أرضي، 2 حبة تمر، 4 حبات اسكدنيا، 3 حبات لوز، 2/1 حبة رمان، 2 حبة كلمنتينا، ملعقة زبيب، ½ حبة بوملة صغيرة، أو ½ كأس عصير طبيعي

**بدائل الخضار:** كأس خضار طازج (كأس سلطة)، أو حبة خضار (حبة خيار، حبة فلفل، حبة بندورة...)، ½ كأس خضار مطبوخة (كوسا، سبانخ، ملوخية، ملفوف، بادنجان...)، أو ½ كأس عصير خضار (عصير جزر، عصير بندورة...)،

**بدائل اللحمية:** قطعة صغيرة 60-90 غم من اللحوم، دجاج، سمك، أو ½ كأس مطبوخ من البقوليات (حمص، فول، عدس)، أو 2 ملعقة كبيرة مكسرات، أو 2 ملعقة صغيرة من زبدة الفول السوداني، أو بيضنة واحدة، 2 ملعقة حمص كبيرة، 2 قطعة حبش، 60 غم طن

**بدائل الدهون:** ملعقة زيت (زيتون، ذرة، عباد الشمس، زيت سمسم صغيرة، صويا)، ملعقة طحينية صغيرة، ملعقة مرجرين صغيرة

الفطور	وجبة خفيفة	الغذاء	وجبة خفيفة	العشاء	وجبة خفيفة
½ رغيف خبز أسمر + قطعة جبنة بيضاء قليلة الدسم + حبة خضار	حبة خضار + حبة فاكهة + ½ رغيف جيز أسمر مع لبنة	كأس فريكة مطبوخة + كأس سلطة + صدر دجاج مشوي + كأس خضار مطبوخة	حبة خضار + حبة فاكهة	½ رغيف خبز أسمر + 2 ملعقة صغيرة لبنة + 2 حبة خضار	حبة فاكهة + حبة خضار + كأس حليب قليل الدسم
كأس حليب قليل الدسم + ½ رغيف خبز أسمر + معلقتين لبنة + خضار	حبة خضار + حبة فاكهة + كأس لبن	120 غم سمك مشوي + حبة بطاطا (وسط) مشوية + 2 حبة خضار مشوية	حبة فاكهة + حبة خضار	½ رغيف خبز أسمر + قطعة جبنة بيضاء قليلة الدسم + 2 حبة خضار 2 ملعقة لبنة	حبة فاكهة + كأس سلطة + ½ رغيف خبز أسمر
½ رغيف خبز أسمر + زيت زيتون مع زعتر + خضار	حبة خضار + كأس لبن + ¼ رغيف خبز	كأس أرز مطبوخ + كأس يخني خضار + قطعة لحمة عجل يدون دهون	حبة خضار + حبة فاكهة	½ رغيف خبز أسمر + معلقتين صغيرتين حمص + خضار	حبة خضار + حبة فواكه +
½ رغيف خبز أسمر + بيضة مسلوقة + 2 حبة خضار	حبة فواكه + حبة خضار + كأس لبن	كأس مجدرة برغل + سلطة + 5 حبات زيتون	+ حبة فواكه + حبة بطاطا مسلوقة	شورية خضار + ½ رغيف خبز أسمر + حبة خضار	حبة فواكه + كأس حليب قليل الدسم

**بدائل الخبز:** ¼ رغيف خبز، أو ½ شطيرة همبرغر، أو ½ كأس أرز مسلوقة، أو ½ كأس برغل مسلوقة، أو ½ كأس ذرة، أو ½ كأس معكرونة مسلوقة، أو حبة بطاطا مسلوقة متوسطة الحجم، ½ كأس كورن فليكس قمح

**بدائل الحليب:** كأس حليب قليل الدسم، أو كأس لبن قليل الدسم، أو 2 ملعقة لبنة قليلة الدسم، أو قطعة جبنة بيضاء قليلة الدسم

**بدائل الفاكهة:** ½ موزة كبيرة، أو حبة تفاح، أو 10 حبات عنب، أو (2-3) حبة مشمش، أو (1-2) حبة تين، حبة تين مجفف، أو ½ جريب فروت، أو حبة أجاص صغيرة، حبة جوافة، أو (1-2) حبة كيوي، أو حبة برتقال، أو حبة خوخ صغيرة، أو 4/1 - 2/1 حبة مانغا، 2 حبة صبر صغيرة، أو كأس شرائح بطيخ، كأس شرائح شمام، أو حبتين برقوق، ¼ حبة أناناس أو قطعة صغيرة أناناس مجفف، كأس توت أرضي، 2 حبة تمر، 4 حبات اسكندنيا، 3 حبات لوز، 2/1 حبة رمان، 2 حبة كلمنتينا، ملعقة زبيب، ½ حبة بوملة صغيرة، أو ½ كأس عصير طبيعي

**بدائل الخضار:** كأس خضار طازج (كأس سلطة)، أو حبة خضار (حبة خيار، حبة فلفل، حبة بندورة، ..) ½ كأس خضار مطبوخة (كوسا، سبانخ، ملوخية، ملفوف، باذنجان...)، أو ½ كأس عصير خضار (عصير جزر، عصير بندورة، ...)

**بدائل اللحم:** قطعة صغيرة 60-90 غم من اللحم، دجاج، سمك، أو ½ كأس مطبوخ من البقوليات (حمص، فول، عدس)، أو 2 ملعقة كبيرة مكسرات، أو 2 ملعقة صغيرة من زبدة الفول السوداني، أو بيضة واحدة، 2 ملعقة حمص كبيرة، 2 قطعة حبش، 60 غم طن

**بدائل الدهون:** ملعقة زيت (زيتون، ذرة، عباد الشمس، زيت سمسم صغيرة)، ملعقة طحينة صغيرة، ملعقة مرجرين صغيرة

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الفطور	وجبة خفيفة	الغذاء	وجبة خفيفة	العشاء	وجبة خفيفة
كأس حليب قليل الدسم+ رغيف خبز أسمر+ 2 ملعقة لبننة صغيرة+ 2 حبة خضار	1/2 رغيف خبز أسمر+ حبة فاكهة +قشرة جبنة بيضاء قليلة الدسم	كأس لبن قليل الدسم + كأس يخني خضار مطبوخة +كأس فريكة مطبوخة+ صدر دجاج بدون جلدة	2 حبة خضار +حبة فاكهة	رغيف خبز أسمر+ 2 ملعقة لبننة صغيرة+ حبة بندورة+ حبة خضار	1/2 رغيف خبز أسمر + معلقة زيت و زعتر+ خيار
كأس حليب قليل الدسم+ رغيف خبز أسمر+ قطعة جبنة بيضاء+ 2 حبة خضار	حبة خضار+ معلقة حمص + 1/2 رغيف خبز أسمر + حبة فواكه	2 حبة بطاطا صغيرة مشوية+ 120 غم سمك مشوي + سلطة خضار طازجة	حبة خضار+ حبة فاكهة	كأس حليب + رغيف خبز أسمر + بيضة مسلوقة+ حبة خضار	1/2 رغيف خبز أسمر +قشرة جبنة بيضاء+ حبة خضار
كأس حليب قليل الدسم + رغيف خبز أسمر + شرحة مرتديلا حبش + 2 حبة خضار+ حبة فاكهة	حبة خضار+ 2 ملعقة لبننة صغيرة قليلة الدسم + 1/2 رغيف خبز أسمر	كأس برغل مطبوخ+ لحمة عجل بدون دهون مشوية + كأس سلطة+ كأس لبن + 1/2 كأس عصير طبيعي	حبة خضار+ حبة فاكهة	كأس حليب+ رغيف خبز أسمر+ حبة خضار + 2 ملعقة لبننة صغيرة	1/2 رغيف خبز أسمر + معلقة زيت و زعتر+ حبة خضار

**بدائل الخبز:** 1/4 رغيف خبز، أو 1/2 شطيرة همبرغر، أو 1/2 كأس أرز مسلووق، أو 1/2 كأس برغل مسلووق، أو 1/2 كأس ذرة، أو 1/2 كأس معكرونة مسلووقة، أو حبة بطاطا مسلووقة متوسطة الحجم، 1/2 كأس كورن فليكس قمح

**بدائل الحليب:** كأس حليب قليل الدسم، أو كأس لبن قليل الدسم، أو 2 ملعقة لبننة قليلة الدسم، أو قشرة جبنة بيضاء قليلة الدسم

**بدائل الفاكهة:** 1/2 موزة كبيرة، أو حبة تفاح، أو 10 حبات عنب، أو (2-3) حبة مشمش، أو (1-2) حبة تين، حبة تين مجفف، أو 1/2 جريب فروت، أو حبة أجاص صغيرة، حبة جوافة، أو (1-2) حبة كيوي، أو حبة برتقال، أو حبة خوخ صغيرة، أو 1/4 - 2/1 حبة مانغا، 2 حبة صبر صغيرة، أو كأس شرائح بطيخ، كأس شرائح شمام، أو حبتين برقوق، 1/4 حبة أناناس أو قطعة صغيرة أناناس مجفف، كأس توت أرضي، 2 حبة تمر، 4 حبات اسكندنيا، 3 حبات لوز، 2/1 حبة رمان، 2 حبة كلمنتينا، ملعقة زبيب، 1/2 حبة بوملة صغيرة، 3 حبات لوز، أو 1/2 كأس عصير طبيعي

**بدائل الخضار:** كأس خضار طازج (كأس سلطة)، أو حبة خضار (حبة خيار، حبة فلفل، حبة بندورة..) 1/2 كأس خضار مطبوخة (كوسا، سبانخ، ملوخية، ملفوف، باذنجان،....)، أو 1/2 كأس عصير خضار (عصير جزر، عصير بندورة،....)

**بدائل اللحم:** قطعة صغيرة 60-90 غم من اللحوم، دجاج، سمك، أو 1/2 كأس مطبوخ من البقوليات (حمص، فول، عدس)، أو 2 ملعقة كبيرة من المكسرات، أو 2 ملعقة صغيرة من زبدة الفول السوداني، أو بيضة واحدة، 2 ملعقة حمص كبيرة، 2 قطعة حبش

الإفطار	وجبة خفيفة	غذاء	وجبة خفيفة	عشاء	وجبة خفيفة
4 توست أسمر + حبة فاكهة + حبة خضار + لبننة قليلة الدهن + كأس حليب قليل الدهن	حبة فاكهة + حبة خضار +	كأس و نصف أرز مطبوخ بدون دهون + صحن سلطة خضار طازجة + صدر دجاج مشوي بدون جلد + كأس يخني خضار مطبوخ	حبة فاكهة + حبة خضار	4 توست أسمر + زيت و زعترا + خضار	حبة فواكه + حبة خضار
كأس حليب قليل الدهن + 4 توست أسمر + خضار + 2 بياض بيض	حبة فاكهة + سلطة	كأس لبن قليل الدهن + كأس و نصف مجردة برغل أو أرز بني مطبوخ + كأس يخني خضار مطبوخة + سلطة	حبة فواكه + خضار	4 توست أسمر + جبنة بياض قليلة الملح + خضار	حبة فواكه + خضار
كأس حليب قليلة الدهن + كأس bran flakes	حبة خضار + 4 توست أسمر + لبننة قليلة الدهن	شوربة خضار + خضار مشوية + سمك مشوي + سلطة خضار	حبة فاكهة + حبة خضار	2 توست أسمر + جبنة بياض قليلة الدهن + خضار	حبة فاكهة + حبة بطاطا مسلوقة

**بدائل الخبز:** ¼ رغيف خبز، أو ½ شطيرة همبرغر، أو ½ كأس أرز مسلوقة، أو ½ كأس برغل مسلوقة، أو ½ كأس ذرة، أو ½ كأس معكرونة مسلوقة، أو حبة بطاطا مسلوقة متوسطة الحجم، أو ½ كأس كورن فليكس قمح

**بدائل الحليب:** كأس حليب قليل الدهن، أو كأس لبن قليل الدهن، أو 2 ملعقة لبننة قليلة الدهن، أو قطعة جبنة بياض قليلة الدهن

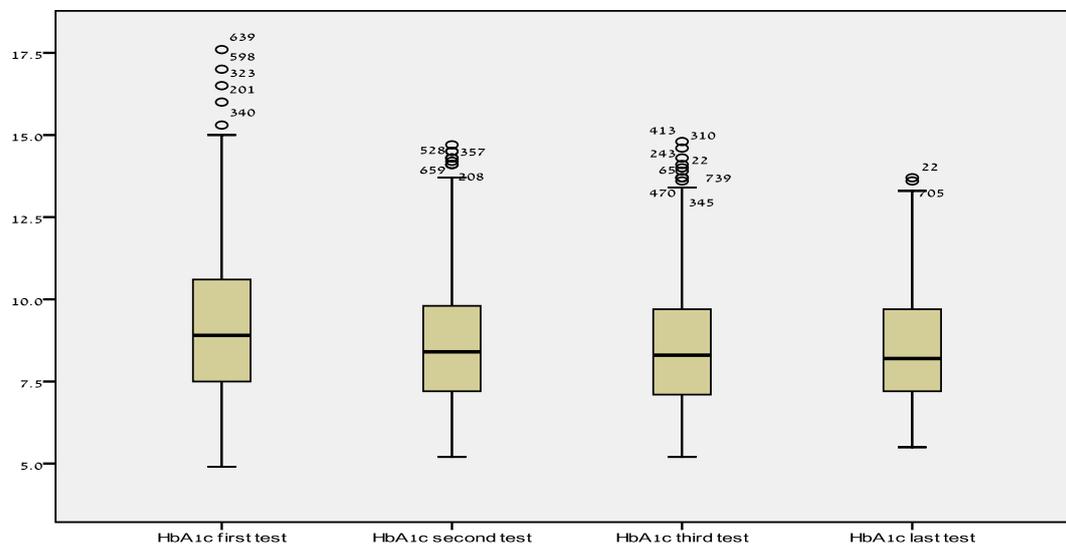
**بدائل الفاكهة:** ½ موزة كبيرة، أو حبة تفاح، أو 10 حبات عنب، أو (2-3) حبة مشمش، أو (1-2) حبة تين، حبة تين مجفف، أو ½ جريب فروت، أو حبة أجاص صغيرة، حبة جوافة، أو (1-2) حبة كيوي، أو حبة برتقال، أو حبة خوخ صغيرة، أو ¼ - 2/1 حبة مانغا، 2 حبة صبر صغيرة، أو كأس شرائح بطيخ، كأس شرائح شمام، أو حبتين برقوق، ¼ حبة أناناس أو قطعة صغيرة أناناس مجفف، كأس توت أرضي، 2 حبة تمر، 4 حبات اسكندنيا، 3 حبات لوز، 2/1 حبة رمان، 2 حبة كلمنتينا، ملعقة زبيب، ½ حبة بوملة صغيرة، أو ½ كأس عصير طبيعي

**بدائل الخضار:** كأس خضار طازج (كأس سلطة)، أو حبة خضار (حبة خيار، حبة فلفل، حبة بندورة،...) ½ كأس خضار مطبوخة (كوسا، سبانخ، ملوخية، ملفوف، بادنجان...)، أو ½ كأس عصير خضار (عصير جزر، عصير بندورة،...)

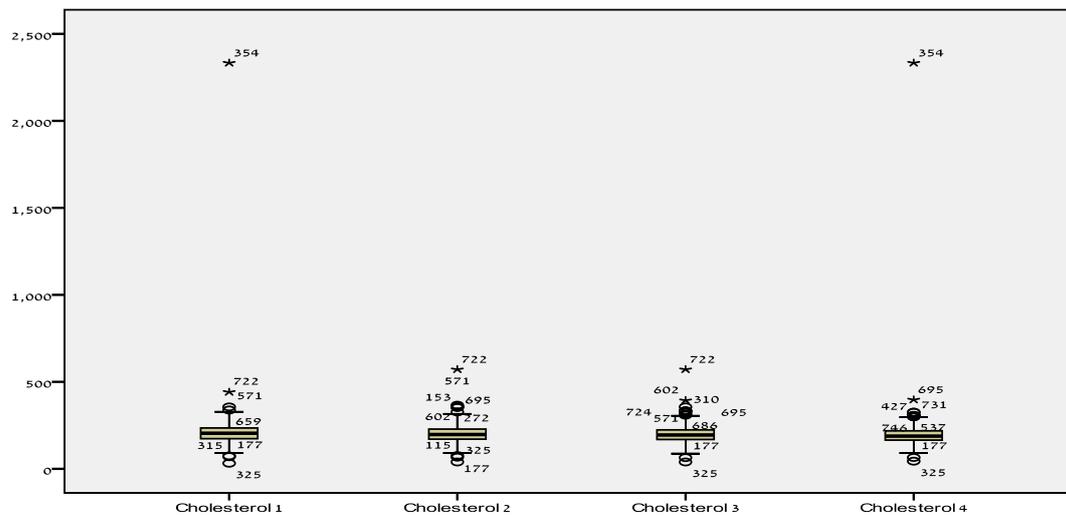
**بدائل اللحم:** 60-90 قطعة صغيرة غم من اللحوم، دجاج، سمك، أو ½ كأس مطبوخ من البقوليات (حمص، فول، عدس)، أو 2 ملعقة كبيرة مكسرات، أو 2 ملعقة صغيرة من زبدة الفول السوداني، أو بيضة واحدة، 2 ملعقة حمص كبيرة، 2 قطعة حبش، 60 غم طن

**بدائل الدهون:** ملعقة زيت (زيتون، ذرة، عباد الشمس، زيت سمسم صغيرة)، ملعقة طحينية صغيرة، ملعقة مرجرين صغيرة

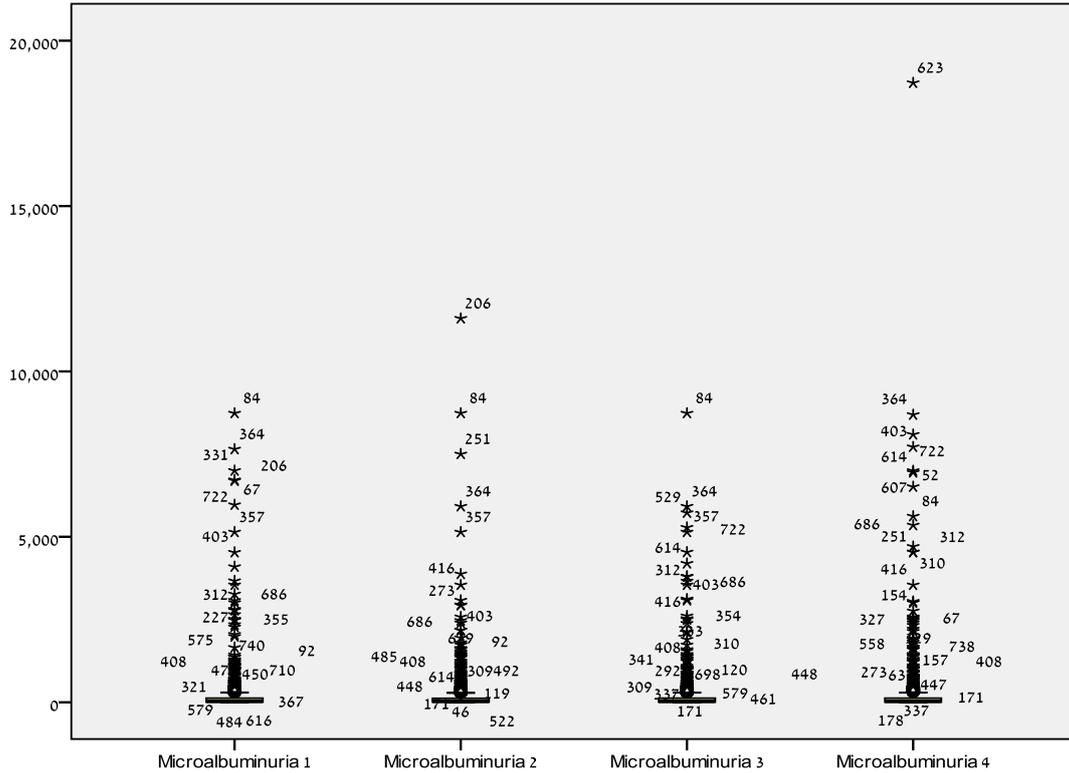
### Annex 3: box plots



### Distribution of HbA1c in patients in the four visits

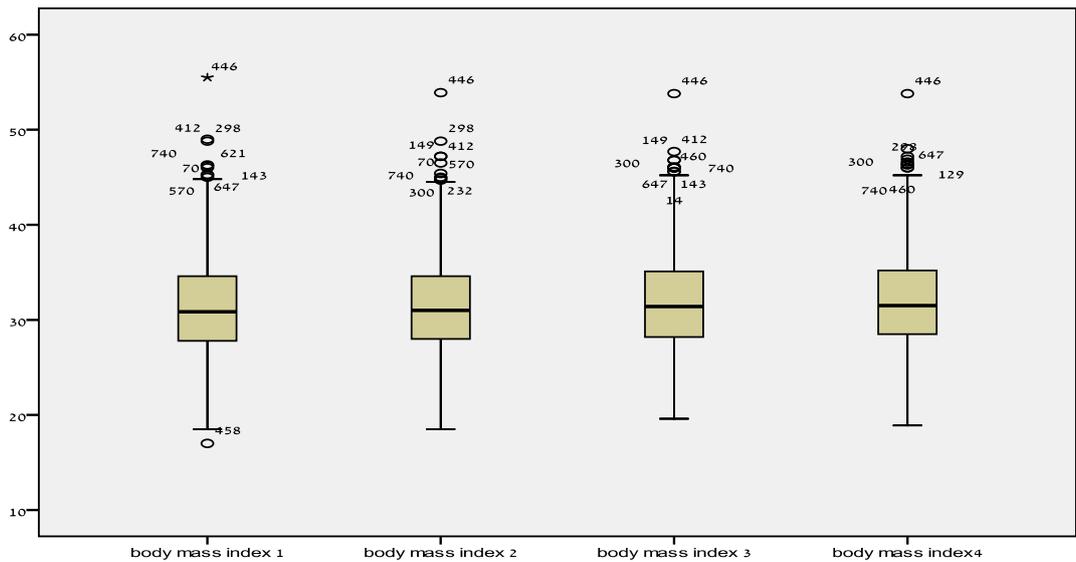


### Distribution of cholesterol in patients in the four visits



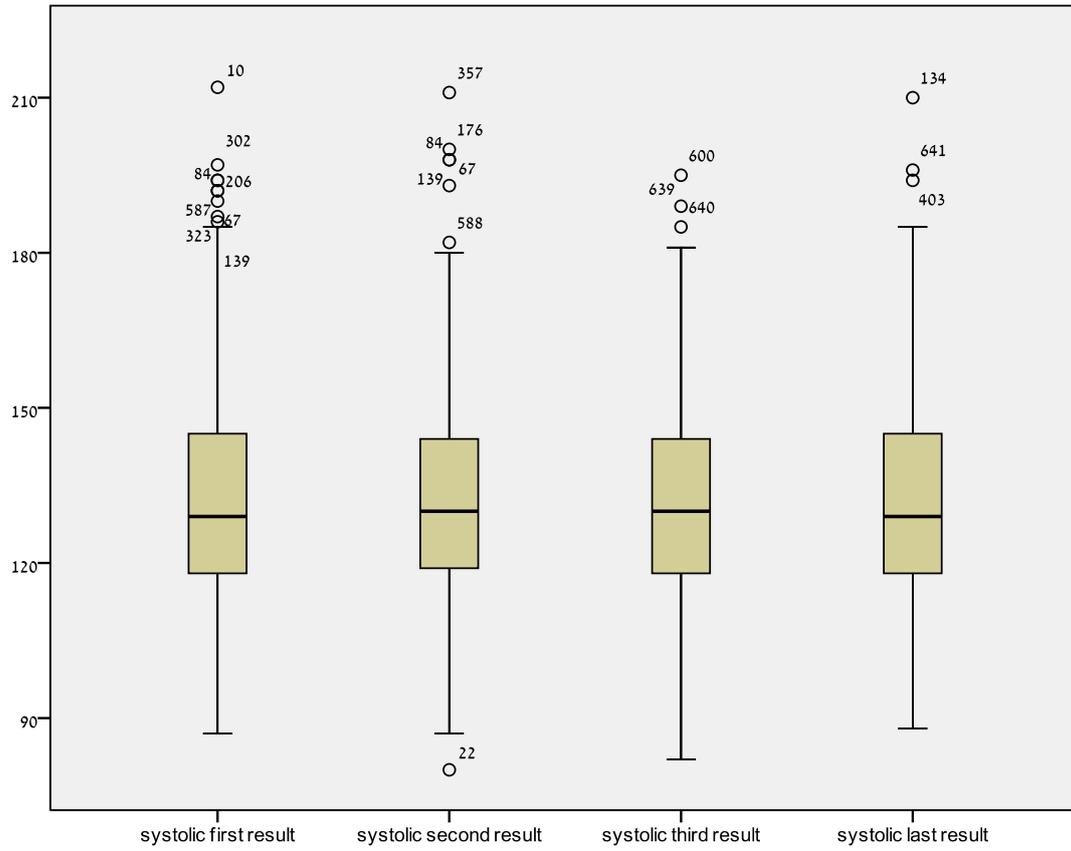
**Distribution of Albumin levels in patients in the four visits**

- Normal albuminuria less than 30 mg/dl
- Microalbuminuria 30-300 mg/dl
- Macroalbuminuria more than 300 mg/dl



**Data shows that mean BMI in the four visits**

- *\*Underweight: BMI < 18.5, normal: 18.5-24.99, overweight: ≥ 25, pre-obese: 25-29.99, Obese class 1: 30 - 34.99, Obese class 2: 35.00 - 39.99, Obese class 3: ≥40.00*



**Systolic results of the patients at the four follow up period.**

## Annex 4:

### Descriptive analysis for the four visit for HbA1c, BMI, MAU, Cholesterol, Systolic and Diastolic Blood Pressure

	Mean	Median	SD	SE	Min	Max
HbA1c 1 <sup>st</sup> visit	9.1	8.9	2.1	0.1	4.9	17.6
HbA1c 2 <sup>nd</sup> visit	8.7	8.4	1.9	0.1	5.2	14.7
HbA1c 3 <sup>rd</sup> visit	8.6	8.3	1.8	0.1	5.2	14.8
HbA1c 4 <sup>th</sup> visit	8.5	8.2	1.7	0.1	5.5	13.7
BMI 1 <sup>st</sup> visit	31.3	30.9	5.3	0.2	17.0	55.5
BMI 2 <sup>nd</sup> visit	31.5	31.0	5.2	0.2	18.5	53.9
BMI 3 <sup>rd</sup> visit	31.8	31.4	5.2	0.2	19.6	53.8
BMI 4 <sup>th</sup> visit	31.9	31.5	5.3	0.2	18.9	53.8
Microalbuminuria 1 <sup>st</sup> visit	247.4	27.6	814	29.8	0.0	8735
Microalbuminuria 2 <sup>nd</sup> visit	223.9	29.0	775	28.4	0.0	11600
Microalbuminuria 3 <sup>rd</sup> visit	223.4	28.8	701.1	25.7	0.0	8735
Microalbuminuria 4 <sup>th</sup> visit	302.1	25.7	1109	40.6	0.0	18723
Cholesterol levels 1 <sup>st</sup> visit	208	204	90.0	3.3	32	441
Cholesterol levels 2 <sup>nd</sup> visit	199.2	197	45.7	1.7	39	571
Cholesterol levels 3 <sup>rd</sup> visit	196.8	194	45.2	1.7	39	571
Cholesterol levels 4 <sup>th</sup> visit	195	188	88.8	3.3	44	397
Systolic 1 <sup>st</sup> visit	132	129	20.0	1.0	87	212
Systolic 2 <sup>nd</sup> visit	132	130	20.0	1.0	80	211
Systolic 3 <sup>rd</sup> visit	131	130	19.0	1.0	82	195
Systolic 4 <sup>th</sup> result	131	129	19.0	1.0	88	210
Diastolic 1 <sup>st</sup> visit	83.0	82.0	11.0	0.0	51	135
Diastolic 2 <sup>nd</sup> visit	82.0	82.0	11.0	0.0	50	125
Diastolic 3 <sup>rd</sup> visit	81.0	81.0	11.0	0.0	50	133
Diastolic 4 <sup>th</sup> visit	81.0	80.0	10.0	0.0	51	113

## Annex 5: Univariate analysis among the various visits

### HbA1c change between Second and first visit (HbA1c 2-1):

#### A-HbA1c 2-1 and demographic factors

A significant association was found between HbA1c 2-1 with age category (50-61 years), and with 16 – 20 years duration of diabetes, and with period being in study ( $p < 0.05$ ) except the period (19-24 months where  $p > 0.05$ ). No association was found between HbA1c 2-1 and gender, residency and marital status ( $p > 0.05$ ) (see table 1).

Table 1: the distribution between HbA1c 2-1 with various demographic variables

Variable		Total N=746	Bad N= 313	Good N= 433	P value	Odds ratio(CI)
Age	≤40	35 (4.7)	13 (37)	22 (63)	0.33	1.44 (0.7 - 3.0)
	41-50	143 (19.2)	69 (48.3)	74 (51.7)	0.66	0.91 (0.61- 1.37)
	51-60	296 (40)	106 (35.8)	190 (64.2)	<b>0.01</b>	1.52 (1.09- 2.13)
	> 60	272 (36.5)	125 (46)	147 (54)		1
Sex	Male	349 (46.8)	142 (40.7)	207 (59.3)	0.51	0.91 (0.68- 1.21)
	Female	397 (53.2)	171 (43.1)	226 (56.9)		
Period in study Months	≤6	40 (5.3)	27 (67.5)	13 (32.5)	0.08	0.53 (0.26- 1.09)
	7-12	91 (12.2)	23 (25.3)	68 (74.7)	<b>0.00</b>	3.27 (1.9- 5.62)
	13- 18	50 (6.7)	15 (30)	35 (70)	<b>0.01</b>	2.58 (1.33- 5.0)
	19- 24	107 (14.3)	44 (41.1)	63 (58.9)	0.05	1.58 (0.99- 2.53)
	25- 30	74 (9.9)	26 (35.1)	48 (64.9)	<b>0.01</b>	2.04 (1.18- 3.52)
	31- 36	165 (22.1)	63 (38.2)	102 (61.8)	<b>0.01</b>	1.79 (1.19- 2.7)
	> 36	219 (29.4)	115 (52.5)	104 (47.5)		1
Duration of Diabetes Years	≤5	211 (28.3)	93 (44.1)	118 (55.9)	0.21	1.47 (0.81- 2.68)
	6-10	228 (30.6)	96 (42.1)	132 (57.9)	0.13	1.6 (0.88- 2.9)
	11-15	160 (21.4)	65 (40.6)	95 (59.4)	0.1	1.7 (0.91- 3.16)
	16-20	93 (12.5)	30 (32.3)	63 (67.7)	<b>0.01</b>	2.44 (1.22- 4.85)
	> 20	54 (7.2)	29 (53.7)	25 (46.3)		1
Education level	Illiterate	109 (14.6)	46 (42.2)	63 (57.8)	0.37	0.78 (0.46- 1.34)
	School	385 (51.6)	163 (42.3)	222 (57.7)	0.25	0.78 (0.5- 1.2)
	High school	139 (18.6)	63 (45.3)	76 (54.7)	0.15	0.69 (0.41- 1.14)
	University	113 (15.1)	41 (36.3)	72 (63.7)		1
Profession Total N=203	Worker	138 (68)	57 (41.3)	81 (58.7)	0.59	1.42 (0.39- 5.14)
	Highly educated	55 (27.1)	21 (38.2)	34 (61.8)	0.49	1.62 (0.42- 6.27)
	Health sector	10 (4.9)	5 (50)	5 (50)		1
Employed	Yes	195 (26.1)	78 (40)	117 (60)	0.52	0.9 (0.64- 1.25)
	No	551 (73.9)	235 (42.6)	316 (47.4)		
Smoking	Yes	119 (16)	47 (39.5)	72 (60.5)	0.59	1.15 (0.69- 1.91)
	No	501 (67.15)	212 (42.3)	289 (57.7)	0.91	1.02 (0.69- 1.52)
	Past smoker	126 (16.89)	54 (42.9)	72 (57.1)		1
Insurance	MOH	427 (57.2)	172 (40.3)	255 (59.7)	1	1 (0.68- 1.48)
	UNRWA	175 (23.45)	81 (46.3)	94 (53.7)	0.29	0.78 (0.5- 1.23)
	Others					
Marital Status	Single	14 (1.87)	4 (28.6)	10 (71.4)	0.31	1.9 (0.55- 6.5)
	Married	633 (84.85)	265 (41.9)	368 (58.1)	0.84	1.05 (0.67- 1.65)
	Divorced	13 (1.74)	7 (53.8)	6 (46.2)	0.47	0.65 (0.2- 2.09)
	Widow	86 (11.52)	37 (43)	49 (57)		1

**B-HbA1c 2-1 with various follow up criteria (MAU, cholesterol, systolic and diastolic blood pressure)**

HbA1c 2-1 was significantly associated with MAU 2-1 and diastolic blood pressure ( $p < 0.05$ ), while, no significant association was found between HbA1c 2-1 with cholesterol and with Systolic blood pressure ( $P > 0.05$ , see table 2).

**Table 2: Associations between HbA1c 2-1 change with change in cholesterol, MAU, and blood pressure**

Variable	Total N=746	Bad N= 313	Good N= 433	P value	Odds ratio (CI)
Good MAU*	319 (42.7)	118 (37)	201 (63)	<b>0.02</b>	1.43 (1.06- 1.93)
Good cholesterol*	289 (38.7)	122 (42.2)	167 (57.8)	0.91	0.98 (0.73- 1.33)
Good Systolic*	359 (48.12)	148 (41.2)	211 (58.8)	0.7	1.06 (0.79- 1.42)
Good Diastolic*	381 (51.1)	138 (36.2)	243 (63.8)	<b>0.00</b>	1.62 (1.21- 2.17)

\*reference category bad

**C –HbA1c 2-1 with lifestyle behaviors**

No significant association was found between HbA1c 2-1 and BMI, Calories intake and activity level ( $P > 0.05$  see table 3)

**Table 3: Associations between HbA1c 2-1 change with BMI, caloric intake and physical activity**

Variable	Total N=746	Bad N= 313	Good N= 433	P value	Odds ratio (CI)	
Good BMI*	249 (33.37)	105 (42.2)	144 (57.8)	0.93	0.99 (0.73- 1.34)	
Calories	<b>1000</b>	306 (41.01)	132 (43.1)	174 (56.9)	0.09	0.38 (0.12- 1.17)
	<b>1200</b>	29 (3.88)	11 (37.9)	18 (62.1)	0.27	0.47 (0.12- 1.79)
	<b>1400</b>	67 (8.98)	31 (46.3)	36 (53.7)	0.07	0.33 (0.1- 1.11)
	<b>1600</b>	104 (13.94)	47 (45.2)	57 (54.8)	0.08	0.35 (0.11- 1.12)
	<b>1800</b>	100 (13.4)	43 (43)	57 (57)	0.11	0.38 (0.12- 1.23)
	<b>2000</b>	93 (12.46)	34 (36.3)	59 (63.4)	0.25	0.5 (0.15- 1.62)
	<b>2200</b>	29 (3.88)	11 (37.9)	18 (62.1)	0.27	0.47 (0.12- 1.78)
Activity level	<b>2400</b>	18 (2.41)	4 (22.2)	14 (77.8)		1
	<b>Very light</b>	14 (1.87)	5 (35.7)	9 (64.3)	0.65	1.3 (0.41- 4.13)
	<b>Light</b>	613 (82.17)	258 (42.1)	355 (57.9)	0.99	0.99 (0.67- 1.48)
	<b>Moderate</b>	119 (15.9)	50 (42)	69 ( 58)		1

\*reference bad BMI

### 3. HbA1c change between Third and Second visit (HbA1c 3-2):

#### A. HbA1c 3-2 and demographic variables

For the demographic factors, only significant difference was found between the frequency of HbA1c 3-2 with the period being in the study ( $P < 0.05$ ). No association was found between the HbA1c 3-2 change with Age, Sex, duration of diabetes, place of residency, education level, type of profession, employment, insurance and marital status ( $P > 0.05$ , see table 4).

**Table 4: the distribution between HbA1c 3-2 with demographic variables.**

		Total N=746	Bad N= 421	Good N= 325	P value	Odds ratio (CI)
<b>Age</b>	≤40	35 (4.69)	20 (57.1)	15 (42.9)	0.79	0.91 (0.45- 1.85)
	41-50	143 (19.2)	89 (62.2)	54 (37.8)	0.15	0.74 (0.49- 1.11)
	51-60	296 (40)	163 (55.1)	133 (44.9)	0.95	0.99 (0.71- 1.38)
	> 60	272 (36.46)	149 (54.8)	123 (45.2)		1
<b>Sex</b>	Male	349 (46.78)	195 (55.9)	154 (44.1)	0.77	0.96 (0.72- 1.28)
	Female	397 (53.2)	226 (56.9)	171 (43.1)		
<b>Period in study</b>	≤6	40 (5.3)	40 (100)	0 (0)	0.99	0.00 (0.00)
	7-12	91 (12.19)	49 (53.8)	42 (46.2)	0.37	1.25 (0.77- 2.05)
	13- 18	50 (6.7)	29 (58)	21 (42)	0.86	1.06 (0.57- 1.97)
	19- 24	107 (14.3)	52 (48.6)	55 (51.4)	0.07	1.55 (0.97- 2.46)
	25- 30	74 (9.91)	43 (58.1)	31 (41.9)	0.85	1.05 (0.62- 1.8)
	31- 36	165 (22.1)	78 (47.3)	87 (52.7)	<b>0.02</b>	1.63 (1.08- 2.45)
	> 36	219 (29.35)	130 (59.4)	89 (40.6)		1
<b>Duration of Diabetes</b>	≤5	211 (28.28)	132 (37.4)	79 (37.4)	0.15	0.65 (0.35- 1.18)
	6-10	228 (30.56)	138 (60.5)	90 (39.5)	0.25	0.7 (0.39- 1.27)
	11-15	160 (21.4)	76 (47.5)	84 (52.5)	0.58	1.19 (0.64- 2.21)
	16-20	93 (12.46)	47 (50.5)	46 (49.5)	0.88	1.05 (0.54- 2.06)
	> 20	54 (7.23)	28 (51.9)	26 (48.1)		1
<b>Place of residency</b>	Middle	332 (44.5)	196 (59)	136 (41)	0.25	0.83 (0.60- 1.14)
	North	131 (17.5)	71 (54.2)	60 (45.8)	0.97	1.01 (0.67- 1.53)
	South	283 (38)	154 (54.4)	129 (45.6)		1
<b>Education level</b>	Illiterate	109 (14)	65 (59.6)	44 (40.4)	0.33	0.77 (0.45- 1.3)
	School	385 (51)	217 (56.4)	168 (43.6)	0.54	0.88 (0.58- 1.34)
	High school	139 (18.63)	79 (56.8)	60 (43.2)	0.55	0.86 (0.52- 1.42)
	University	113 (15.14)	60 (53.1)	53 (46.9)		1
<b>Profession Total N=203</b>	Worker	138 (67.98)	76 (55.1)	62 (44.9)	0.76	1.22 (0.33- 4.53)
	Highly educated	55 (27.09)	27 (49.1)	28 (50.9)	0.53	1.56 (0.4- 6.13)
	Health Sector	10 (4.92)	6 (60)	4 (40)		1
<b>Employed</b>	Yes	195 (26.13)	104 (53.3)	91 (46.7)	0.31	0.84 (0.61- 1.17)
	No	551 (73.85)	317 (57.5)	234 (42.5)		
<b>Smoking</b>	Yes	119 (15.95)	66 (55.5)	53 (44.5)	0.72	0.91 (0.55- 1.51)
	No	501 (67.15)	288 (57.5)	213 (42.5)	0.38	0.84 (0.57- 1.24)
	Past smoker	126 (16.89)	67 (53.2)	59 (46.8)		1
<b>Insurance</b>	MOH	427 (57.2)	239 (56.0)	188 (44.0)	0.35	1.2 (0.82- 1.76)
	UNRWA	175 (23.45)	95 (54.3)	80 (45.7)	0.271	1.29 (0.82-2.01)
	Others	144 (19.3)	87 (60.4)	57 (39.6)		1
<b>Marital Status</b>	Single	14 (1.87)	5 (35.7)	9 (64.3)	0.05	3.19 (0.98- 10.38)
	Marrried	633 (84.85)	356 (56.2)	277 (43.8)	0.18	1.38 (0.87- 2.2)
	Divorced	13 (1.74)	5 (38.5)	8 (61.5)	0.09	2.84 (0.85- 9.43)
	Widow	86 (11.52)	55 (64.0)	31 (36.0)		1

### B- HbA1c 3-2 with various follow up criteria

A significant difference was found between change in HbA1c 3-2 with MAU 3-2 and diastolic blood pressure 3-2 ( $P < 0.05$ ). No association was found between cholesterol, systolic blood pressure with HbA1c 3-2 ( $p < 0.05$ ) (see table 5).

**Table 5: The distribution of HbA1c 3-2 with various follow up criteria**

Variable	Total N=746	Bad N= 421	Good N= 325	P value	Odds ratio (CI)
Good MAU*	226 (30.2)	99 (43.8)	127 (56.2)	<b>0.00</b>	2.09 (1.52- 2.86)
Good cholesterol*	218 (29.2)	114 (52.3)	104 (47.7)	0.14	1.27 (0.92- 1.74)
Good Systolic*	338 (45.3)	182 (53.8)	156 (46.2)	0.19	1.21 (0.91- 1.62)
Good Diastolic*	340 (45.5)	162 (47.6)	178 (52.4)	<b>0.00</b>	1.94 (1.44- 2.6)

\*reference category bad

### C- HbA1c 3-2 and lifestyle behavior

No association was found between Change in HbA1c 3-2 , BMI 3-2 and amount of Calories intake and activity level(see table 6).

**Table 6: The distribution of HbA1c 3-2 with lifestyle behaviors**

Variable	Total N=746	Bad N= 421	Good N= 325	P value	Odds ratio (CI)	
Good BMI	231 (30.96)	119 (51.5)	112 (48.5)	0.07	1.33 (0.98- 1.82)	
Calories	1000	306 (41.01)	170 (55.6)	136 (44.4)	0.65	1.26 (0.48- 3.33)
	1200	29 (3.88)	18 (62.1)	11 (37.9)	0.95	0.96 (0.29- 3.22)
	1400	67 (8.98)	42 (62.7)	25 (37.3)	0.9	0.94 (0.32- 2.73)
	1600	104 (13.94)	53 (51)	51 (49)	0.43	1.51 (0.54- 4.21)
	1800	100 (13.4)	56 (56)	44 (44)	0.69	1.24 (0.44- 3.45)
	2000	93 (12.46)	53 (57)	40 (43)	0.75	1.19 (0.42- 3.33)
	2200	29 (3.88)	18 (62.1)	11 (37.9)	0.95	0.96 (0.29- 3.22)
	2400	18 (2.41)	11 (61.1)	7 (38.9)		1
Activity level	Very light	14 (1.87)	6 (42.9)	8 (57.1)	0.41	1.61 (0.53- 4.91)
	Light	613 (82.17)	350 (57.1)	263 (42.9)	0.62	0.9 (0.61- 1.34)
	Moderate	119 (15.9)	65 (54.6)	54 (45.4)		1

#### 4. HbA1c change between Fourth and Third visit (HbA1c 4-3):

##### A- HbA1c 4-3 and demographic factors

Table 7 presents the association between HbA1c 4-3 with demographic variables, A significant association was found with age (41-50) years, period in study (31-36 months), duration of diabetes  $\leq 5$  years ( $p < 0.05$ ), no association was found with age category, Gender, place of residency and job category ( $p > 0.05$ ).

**Table 7: The distribution of HbA1c 4-3 with various demographic variables.**

Variable		Total N=746	Bad N= 399	Good N= 347	P value	Odds ratio (CI)
Age	$\leq 40$	35 (4.69)	18 (51.4)	17 (48.6)	1	1 (0.48- 2.07)
	41-50	143(19.2)	82 (57.3)	61 (42.7)	<b>0.04</b>	0.65 (0.43- 0.98)
	51-60	296 (40)	164(55.4)	132(44.6)	0.93	0.98 (0.7- 1.38)
	> 60	272(36.46)	135(49.6)	137(50.4)		1
Sex	Male	349(46.78)	181(51.9)	168(48.1)	0.41	0.89 (0.66- 1.18)
	Female	397 (53.2)	218(54.9)	179(45.1)		
Period in study	$\leq 6$	40 (5.3)	22 (55)	18 (45)	0.36	0.73 (0.37- 1.43)
	7-12	91 (12.19)	49 (53.8)	42 (46.2)	0.28	0.76 (0.47- 1.24)
	13- 18	50 (6.7)	26 (52)	24 (48)	0.53	0.82 (0.44- 1.52)
	19- 24	107 (14.3)	62 (57.9)	45 (42.1)	0.07	0.64 (0.4- 1.03)
	25- 30	74 (9.91)	41 (55.4)	33 (44.6)	0.21	0.72 (0.42- 1.21)
	31- 36	165 (22.1)	96 (58.2)	69 (41.8)	<b>0.03</b>	0.64 (0.43- 0.96)
	> 36	219(29.35)	103 (47)	116 (53)		1
Duration of Diabetes	$\leq 5$	211(28.28)	134(63.5)	77 (36.5)	<b>0.00</b>	0.37 (0.2- 0.68)
	6-10	228(30.56)	113(49.6)	115(50.4)	0.16	0.65 (0.35 - 1.19)
	11-15	160 (21.4)	81 (50.6)	79 (49.4)	0.14	0.62 (0.33 - 1.16)
	16-20	93 (12.46)	50 (53.8)	43 (46.2)	0.08	0.55 (0.28- 1.08)
	> 20	54 (7.23)	21 (38.9)	33 (61.1)		1
District	Middle	332(31.09)	171(51.5)	161(48.5)	0.25	1.21 (0.88-1.66)
	North	131(17.56)	69 (52.7)	62 (47.3)	0.5	1.15 (0.76- 1.75)
	South	283(37.93)	159(56.2)	124(43.8)		1
Education level	Illiterate	109(14.61)	54 (49.5)	55 (50.5)	0.35	1.28 (0.76 - 2.18)
	School	385 (51.6)	218(56.6)	167(43.4)	0.87	0.97 (0.63 - 1.47)
	High school	139(18.63)	64 (46.0)	75 (54.0)	0.13	1.48 (0.9 - 2.43)
	University (Ref.)	113(15.14)	63 (55.8)	50 (44.2)		1
Profession Total N=203	Worker	138(67.98)	76 (55.1)	62 (44.9)	0.76	1.22 (0.33- 4.53)
	Highly educated	55 (27.09)	30 (54.5)	25 (45.5)	0.75	1.25 (0.32 - 4.93)
	Health sector	10 (4.92)	6 (60.0)	4 (40.0)		1
Employed	Yes	195(26.13)	111(56.9)	84 (43.1)	0.26	1.21 (0.87- 1.68)
	No	551(73.85)	288(52.3)	263(47.7)		
Smoking	Yes	119(15.95)	62 (52.1)	57 (47.9)	0.65	0.89 (0.54- 1.47)
	No	501(67.15)	275(54.9)	226(45.1)	0.25	0.8 (0.54- 1.18)
	Past smoker	126(16.89)	62 (49.2)	64 (50.8)		1
Insurance	MOH	427 (57.2)	221(51.8)	206(48.2)	0.95	1.01 (0.69- 1.48)
	UNRWA	17523.45	103(58.9)	72 (41.1)	0.23	0.76 (0.49- 1.18)
	Others	144 (19.3)	75 (52.1)	69 (47.9)		1
Marital Status	Single	14 (1.87)	10 (71.4)	4 (28.6)	0.13	0.38 (0.11- 1.31)
	Married	633(84.85)	341(53.9)	292(46.1)	0.38	0.82 (0.52- 1.28)
	Divorced	13 (1.74)	6 (46.2)	7 (53.8)	0.86	1.11 (0.35- 3.59)
	Widow	86 (11.52)	42 (48.8)	44 (51.2)		1

### B-HbA1c 4-3 with various follow up criteria

A significant association was found between HbA1c 4-3 and systolic blood pressure ( $p < 0.05$ ). HbA1c 4-3 was not associated with MAU 4-3 and cholesterol and diastolic blood pressure 4-3 ( $P > 0.05$ , see table 8).

**Table 8: The distribution of HbA1C 4-3 with various follow up criteria for 746 diabetic patient**

Variable	Total N=746	Bad N= 399	Good N= 347	P value	Odds ratio (CI)
Good MAU*	339(45.44)	178 (52.5)	161 (47.5)	0.63	1.08 (0.81- 1.44)
Good cholesterol*	328 (43.9)	165 (50.3)	163 (49.7)	0.12	1.26 (0.94- 1.68)
Good Systolic*	354(47.4)	174 (49.2)	180 (50.8)	<b>0.02</b>	1.39 (1.04- 1.86)
Good Diastolic*	372(49.8)	194 (52.2)	178 (47.8)	0.47	1.11 (0.84- 1.48)

\*reference category bad

### C –HbA1c 4-3 with lifestyle behaviors

No association was found between the frequency of HbA1c 4-3 and BMI, Calories intake and activity level ( $P > 0.05$  see table 9)

**Table 9: The distribution of Hba1c 4-3 with lifestyle behaviors**

Variable	Total N=746	Bad N= 399	Good N= 347	P value	Odds ratio (CI)	
Good BMI*	348(46.64)	174 (50)	174 (50)	0.07	1.3 (0.97- 1.74)	
Calories	1000	306(41.01)	173 (56.5)	133 (43.5)	0.59	0.77 (0.3-1.99)
	1200	29 (3.88)	15 (51.7)	14 (48.3)	0.91	0.93 (0.29- 3.03)
	1400	67 (8.98)	35 (52.2)	32 (47.8)	0.87	0.91 (0.32- 2.59)
	1600	104(13.94)	54 (51.9)	50 (48.1)	0.88	0.93 (0.34- 2.52)
	1800	100 (13.4)	54 (54)	46 (46)	0.75	0.85 (0.31- 2.33)
	2000	93 (12.46)	44 (47.3)	49 (52.7)	0.83	1.11 (0.41- 3.06)
	2200	29 (3.88)	15 (51.7)	14 (48.3)	0.91	0.93 (0.29 -3.03)
	2400	18 (2.41)	9 (50.0)	9 (50)		1
Activity level	Very light	14 (1.87)	10 (71.4)	4 (28.6)	0.1	0.36 (0.11- 1.2)
	Light	613(82.17)	333 (54.3)	280 (45.7)	0.15	0.75 (0.5- 1.11)
	Moderate	119 (15.9)	56 (47.1)	63 (52.9)		1

\*reference bad BMI

## 5 HbA1c change between fourth and second visit (HbA1c 4-2)

### A- HbA1c 4-2 and demographic factors

A significant association was found between HbA1c 4-2 and duration of diabetes  $\leq 5$  years, smoking and marital status ( $p < 0.05$ ). No association was found in age, sex, period in study, education level, type of profession, residency, employment and insurance ( $p > 0.05$ ) (see table 10).

**Table 10: the distribution of HbA1c 4-2 with various demographic variables.**

Variable		Total N=746	Bad N= 378	Good N= 368	P value	Odds ratio (CI)
Age	$\leq 40$	35 (4.69)	18 (51.4)	17 (48.6)	0.66	0.85 (0.42- 1.72)
	41-50	143 (19.2)	78 (54.5)	65 (45.5)	0.17	0.75 (0.5-1.13)
	51-60	296 (40)	153 (51.7)	143 (48.3)	0.31	0.84 (0.61- 1.17)
	> 60	272(36.46)	129 (47.4)	143 (52.6)		1
Sex	Male	349(46.78)	173 (49.6)	176 (50.4)	0.57	0.92 (0.69- 1.23)
	Female	397 (53.2)	205 (51.6)	192 (48.4)		
Period in study	$\leq 6$	40 (5.3)	22 (55.0)	18 (45.0)	0.65	0.86 (0.44-1.69)
	7-12	91 (12.19)	48 (52.7)	43 (47.3)	0.8	0.94 (0.58- 1.53)
	13- 18	50 (6.7)	23 (46.0)	27 (54.0)	0.51	1.23 (0.66- 2.28)
	19- 24	107 (14.3)	54 (50.5)	53 (49.5)	0.91	1.03 (0.65- 1.63)
	25- 30	74 (9.91)	36 (48.6)	38 (51.4)	0.71	1.11 (0.65- 1.87)
	31- 36	165 (22.1)	83 (50.3)	82 (49.7)	0.87	1.03 (0.69- 1.55)
	> 36	219(29.35)	112 (51.1)	107 (48.9)		1
Duration of Diabetes	$\leq 5$	211(28.28)	130 (61.6)	81 (38.4)	<b>0.00</b>	0.37 (0.2- 0.68)
	6-10	228(30.56)	117 (51.3)	111 (48.7)	0.06	0.56 (0.3- 1.03)
	11-15	160 (21.4)	63 (39.4)	97 (60.6)	0.76	0.91 (0.48- 1.71)
	16-20	93 (12.46)	48 (51.6)	45 (48.4)	0.09	0.55 (0.28- 1.1)
	> 20	54 (7.23)	20 (37.0)	34 (63.0)		1
District	Middle	332(31.09)	181(54.5)	151 (45.5)	0.11	0.77 (0.56-1.06)
	North	131(17.56)	61 (46.6)	70 (53.4)	0.78	1.06 (0.7-1.61)
	South	283(37.93)	136 (48.1)	147 (51.9)		1
Education level	Illiterate	109(14.61)	47 (43.1)	62 (56.9)	0.14	1.49 (0.88- 2.54)
	School	385 (51.6)	208 (54.0)	177 (46.0)	0.86	0.96 (0.63- 1.47)
	High school	139(18.63)	63 (45.3)	76 (54.7)	0.22	1.37 (0.83- 2.25)
	University	113(15.14)	60 (53.1)	53 (46.9)		1
Profession Total N=203	Worker	138(67.98)	75 (54.3)	63 (45.7)	0.73	1.26 (0.34- 4.66)
	Highly educated	55 (27.09)	24 (43.6)	31 (56.4)	0.35	1.94 (0.49- 7.65)
	Health sector	10 (4.92)	6 (60.0)	4 (40.0)		1
Employed	Yes	195(26.13)	103 (52.8)	92 (47.2)	0.49	1.12 (0.81- 1.56)
	No	551(73.85)	275 (49.9)	276 (50.1)		
Smoking	Yes	119(15.95)	61 (51.3)	58 (48.7)	0.12	0.67 (0.4- 1.11)
	No	501(67.15)	265 (52.9)	236 (47.1)	<b>0.02</b>	0.63 (0.42-0.93)
	Past smoker	126(16.89)	52 (41.3)	74 (58.7)		1
Insurance	MOH	427 (57.2)	208 (48.7)	219 (51.3)	0.58	1.11 (0.76- 1.62)
	UNRWA	175(23.45)	96 (54.9)	79 (45.1)	0.54	0.87 (0.56-1.35)
	Others	144(18.63)	74 (51.4)	70 (48.6)		1
Marital Status	Single	14 (1.87)	6 (42.9)	8 (57.1)	0.42	1.61 (0.51- 5.03)
	Married	633(84.85)	322 (50.9)	311 (49.1)	0.51	1.16 (0.74- 1.83)
	Divorced	13 (1.74)	3 (23.1)	10 (76.9)	<b>0.04</b>	4.02 (1.03- 15.62)
	Widow	86(11.52)	47 (54.7)	39 (45.3)		1

**B-HbA1c 4-2 with various follow up criteria (MAU, cholesterol, systolic and diastolic blood pressure)**

HbA1c 4-2 was not associated with MAU 4-2 and cholesterol, systolic and diastolic blood pressure (P >0.05, see table 11).

**Table 11: The distribution of HbA1C 4-2 with various follow up criteria**

Variable	Total N=746	Bad N= 378	Good N= 368	P value	Odds ratio (CI)
Good MAU*	333(44.6)	164 (49.2)	169 (50.8)	0.49	1.11 (0.83- 1.48)
Good cholesterol*	360(48.25)	181 (50.3)	179 (49.7)	0.84	1.03 (0.77- 1.37)
Good Systolic*	352 (47.18)	169 (48.0)	183 (52.0)	0.17	1.22 (0.92- 1.63)
Good Diastolic*	397 (53.2)	193 (48.6)	204 (51.4)	0.23	1.19 (0.89- 1.59)

\*reference category bad

**C –HbA1c 4-2 with lifestyle behaviors**

No association was found between the frequency of HbA1c 4-2 and BMI, Calories intake and activity level (P >0.05, see table 12)

**Table 12: The distribution of HbA1c 4-2 with lifestyle behaviors**

Variable	Total N=746	Bad N= 378	Good N= 368	P value	Odds ratio (CI)	
Good BMI	284(38.06)	131(46.1)	153(53.9)	0.05	1.34 (1- 1.8)	
Calories	1000	306(41.01)	159 (52.0)	147 (48.0)	0.59	0.77 (0.3- 2)
	1200	29 (3.88)	16 (55.2)	13 (44.8)	0.91	0.93 (0.3- 3.0)
	1400	67 (8.98)	42 (62.7)	25 (37.3)	0.87	0.91 (0.3- 2.6)
	1600	104 (13.94)	44 (42.3)	60 (57.7)	0.88	0.93 (0.3- 2.5)
	1800	100 (13.4)	51 (51.0)	49 (49.0)	0.75	0.85 (0.3- 2.3)
	2000	93 (12.46)	40 (43.0)	53 (57.0)	0.83	1.11 (0.4- 3.0)
	2200	29 (3.88)	14 (48.3)	15 (51.7)	0.91	0.93 (0.3- 3.0)
	2400	18 (2.41)	12 (66.7)	6 (33.3)		1
Activity level	Very light	14 (1.87)	7 (50.0)	7 (50.0)	0.1	0.36 (0.1- 1.2)
	Light	613 (82.17)	318 (51.9)	295 (48.1)	0.15	0.75 (0.5- 1.1)
	Moderate	119 (15.9)	53 (44.5)	66 (55.5)		1

\*reference category bad

## 6 HbA1c change between Third and first visit (HbA1c 3-1):

### A- HbA1c 3-1 and demographic factors

Table 13 presents the association between HbA1c 3-1 with various demographic variables, a significant association was found with period in study, duration of diabetes (16-20years), place of residency ( $p < 0.05$ ). No association was found between HbA1c 3-1 and Age, Gender, education level, employment, insurance, marital status and type of profession ( $p > 0.05$ )

**Table 13: The association between HbA1c 3-1 with demographic variables.**

Variable		Total N=746	Bad N= 312	Good N= 434	P value	Odds ratio (CI)
Age	≤40	35 (4.69)	15 (42.9)	20 (57.1)	0.95	0.98 (0.48- 1.99)
	41-50	143(19.2)	66 (46.2)	77 (53.8)	0.45	0.86 (0.57- 1.28)
	51-60	296 (40)	116 (39.2)	180 (60.8)	0.45	1.14 (0.81-1.59)
	> 60	272(36.46)	115 (42.3)	157 (57.7)		1
Sex	Male	349(46.78)	137 (39.3)	212 (60.7)	0.18	0.82 (0.61- 1.1)
	Female	397 (53.2)	175 (44.1)	222 (55.9)		
Period in study	≤6	40 (5.3)	27 (67.5)	13 (32.5)	0.17	0.61 (0.3- 1.24)
	7-12	91 (12.19)	23 (25.3)	68 (74.7)	<b>0.00</b>	3.72 (2.16- 6.4)
	13- 18	50 (6.7)	14 (28.0)	36 (72.0)	<b>0.00</b>	3.23 (1.65- 6.34)
	19- 24	107 (14.3)	37 (34.6)	70 (65.4)	<b>0.00</b>	2.38 (1.47- 3.84)
	25- 30	74 (9.91)	25 (33.8)	49 (66.2)	<b>0.00</b>	2.47 (1.42- 4.28)
	31- 36	165 (22.1)	64 (38.8)	101 (61.2)	<b>0.00</b>	1.99 (1.32- 3)
	> 36	219(29.35)	122 (55.7)	97 (44.3)		1
Duration of Diabetes	≤5	211(28.28)	104 (49.3)	107 (50.7)	0.7	0.89 (0.49- 1.61)
	6-10	228(30.56)	102 (44.7)	126 (55.3)	0.84	1.07 (0.59- 1.93)
	11-15	160 (21.4)	56 (35.0)	104 (65.0)	0.14	1.6 (0.86- 2.99)
	16-20	93 (12.46)	25 (26.9)	68 (73.1)	<b>0.02</b>	2.35 (1.16- 4.74)
	> 20	54 (7.23)	25 (46.3)	29 (53.7)		1
Place of residency	Middle	332(31.09)	154 (46.4)	178 (53.6)	<b>0.03</b>	0.69 (0.5- 0.96)
	North	131(17.56)	52 (39.7)	79 (60.3)	0.66	0.91 (0.6- 1.39)
	South	283(37.93)	106 (37.5)	177 (62.5)		1
Education level	Illiterate	109(14.61)	47 (43.1)	62 (56.9)	0.44	0.81 (0.47- 1.39)
	School	385 (51.6)	163 (42.3)	222 (57.7)	0.42	0.84 (0.54- 1.29)
	High school	139(18.63)	59 (42.4)	80 (57.6)	0.48	0.83 (0.5- 1.38)
	University (Ref.)	113(15.14)	43 (38.1)	70 (61.9)		1
Profession Total N=203	Worker	138(67.98)	51 (37.0)	87 (63.0)	0.16	2.56 (0.69- 9.5)
	Highly educated	55 (27.09)	21 (38.2)	34 (61.8)	0.21	2.43 (0.61- 9.63)
	Health background(Ref.)	10 (4.92)	6 (60.0)	4 (40.0)		1
Employed	Yes	195(26.13)	78 (40.0)	117 (60.0)	0.55	0.9 (0.65- 1.26)
	No	551(73.85)	234 (42.5)	317 (57.5)		
Smoking	Yes	119(15.95)	46 (38.7)	73 (61.3)	0.68	1.12 (0.67- 1.86)
	No	501(67.15)	214 (42.7)	287 (57.3)	0.77	0.94 (0.63- 1.4)
	Past smoker	126(16.89)	52 (41.3)	74 (58.7)		1
Insurance	MOH	427(57.2)	171 (40.0)	256 (60.0)	0.35	1.2 (0.82- 1.75)
	UNRWA	175(23.45)	77 (44.0)	98 (56.0)	0.94	1.02 (0.65- 1.59)
	Others	144(19.63)	64 (44.4)	80 (55.6)		1
Marital Status	Single	14 (1.87)	4 (28.6)	10 (71.4)	0.15	2.5 (0.73- 8.59)
	Married	633(84.85)	261 (41.2)	372 (58.8)	0.12	1.43 (0.91- 2.24)
	Divorced	13 (1.74)	4 (30.8)	9 (69.2)	0.2	2.25 (0.64- 7.86)
	Widow	86 (11.52)	43 (50.0)	43 (50.0)		1

### B-HbA1c 3-1 with various follow up criteria

HbA1c 3-1 was significantly associated with MAU 3-1( $p<0.05$ ) and diastolic blood pressure. While, no significant association was found between HbA1c 3-1 with cholesterol and diastolic pressure ( $P >0.05$ , see table 14).

**Table 14: The distribution of HbA1c 3-1 with various follow up criteria**

Variable	Total N=746	Bad N= 312	Good N= 434	P value	Odds ratio (CI)
Good MAU*	290(38.8)	108 (37.2)	182 (62.8)	<b>0.04</b>	1.36 (1.01- 1.84)
Good cholesterol*	321 (43)	128 (39.9)	193 (60.1)	0.35	1.15 (0.86- 1.55)
Good Systolic*	357(47.8)	149 (41.7)	208 (58.3)	0.96	1.01 (0.75-1.35)
Good Diastolic*	382(51.2)	144 (37.7)	238 (62.3)	<b>0.02</b>	1.42 (1.06- 1.9)

\*reference category bad

### C –Hba1c 3-1 with lifestyle behaviors

Inverse association was found between HbA1c 3-1 and the Calories intake (1000, 1400 calories) ( $p<0.05$ ,  $OR<1$ ).No association was found between the frequency of HbA1c 3-1 and BMI 3-1, and activity level ( $P >0.05$ ) (see table 15).

**Table 15: The distribution of HbA1C 3-1 with lifestyle behavior**

Variable	Total N=746	Bad N= 312	Good N= 434	P value	Odds ratio (CI)	
Good BMI	221(29.6)	96 (43.4)	125 (56.6)	0.56	0.91 (0.66- 1.25)	
Calories	1000	306(41.01)	137 (44.8)	169 (55.2)	<b>0.03</b>	0.25 (0.07- 0.87)
	1200	29 (3.88)	11 (37.9)	18 (62.1)	0.13	0.33 (0.08- 1.39)
	1400	67 (8.98)	33 (49.3)	34 (50.7)	<b>0.02</b>	0.21 (0.06- 0.78)
	1600	104(13.94)	44 (42.3)	60 (57.7)	0.05	0.27 (0.074- 1)
	1800	100 (13.4)	41 (41.0)	59 (59.0)	0.06	0.29 (0.08- 1.06)
	2000	93 (12.46)	33 (35.5)	60 (64.5)	0.13	0.36 (0.1- 1.35)
	2200	29 (3.88)	10 (34.5)	19 (65.5)	0.19	0.38 (0.09- 1.63)
	2400	18 (2.41)	3 (16.7)	15 (83.3)		1
Activity level	Very light	14 (1.87)	4 (28.6)	10 (71.4)	0.46	1.58 (0.47- 5.32)
	Light	613(82.17)	262 (42.7)	351 (57.3)	0.41	0.84 (0.57- 1.26)
	Moderate	119 (15.9)	46 (38.7)	73 (61.3)		1

## Annex 6: Univariate and multivariate analysis of the subsample (n=255)

### HbA1c change between Second and first visit (HbA1c 2-1):

#### A-HbA1c 2-1 and demographic factors

**Table 1: the association between HbA1c 2-1 with various demographic variables.**

Variable		Total N=255	Bad N= 86	Good N=169	P value	Odds ratio(CI)
Age	≤40	15(5.88)	4 (26.7)	11(73.3)	0.18	2.3(0.68-7.77)
	41-50	42(16.47)	14(33.3)	28(66.7)	0.19	1.67(0.78-3.59)
	51-60	108(42.35)	27(25)	81(75)	<b>0.00</b>	2.51(1.38-4.58)
	> 60	90(35.29)	41(45.6)	49(54.4)		
Sex	Male	117(45.88)	36(30.8)	81(69.2)	0.36	0.78(0.46-1.32)
	Female	138(54.12)	50(36.2)	88(63.8)		
Period in study Months	≤6	1(0.39)	0 (0)	1(100)	1	1.281E9(0.00)
	7-12	37(14.5)	7(18.9)	30(81.1)	<b>0.02</b>	3.4(1.27-9.13)
	13- 18	25(9.8)	8(32)	17(68)	0.31	1.69(0.62-4.59)
	19- 24	71(27.8)	26(36.6)	45(63.4)	0.4	1.37(0.66-2.85)
	25- 30	21(8.23)	5(23.8)	16(76.2)	0.11	2.54(0.81-7.96)
	31- 36	48(18.82)	17(35.4)	31(64.6)	0.37	1.45(0.65-3.24)
	> 36	52(20.39)	23(44.2)	29(55.8)		1
Duration of Diabetes Years	≤5	70(27.45)	24(34.3)	46(65.7)	<b>0.03</b>	3.83(1.18-12.49)
	6-10	65(25.4)	21(32.3)	44(67.7)	<b>0.02</b>	4.19(1.27-13.81)
	11-15	56(21.96)	14(25)	42(75)	<b>0.00</b>	6.00(1.75-20.57)
	16-20	49(19.22)	17(34.7)	32(65.3)	<b>0.03</b>	3.77(1.11-12.80)
	> 20	15(5.88)	10(66.7)	5(33.30)		1
Regions	Middle	100 (39.22)	40 (40)	60(60)	<b>0.048</b>	0.56(0.32-0.99)
	North	41(16.08)	15(36.6)	26(63.4)	0.26	0.65(0.3-1.38)
	South	114(44.71)	31(27.2)	83(72.8)		1
Education level	Illiterate	55 (21.57)	23 (41.8)	32(58.2)	<b>0.04</b>	0.37(0.14- 0.96)
	School	124 (48.63)	41 (33.1)	83(66.9)	0.16	0.54 (0.23-1.28)
	High school	38 (14.9)	14(36.8)	24(63.2)	0.13	0.46(0.17-1.27)
	University	38 (14.9)	8(21.1)	30(78.9)		1
Employed	Yes	65(25.49)	20 (30.8)	45 (69.2)	0.56	0.84 (0.46-1.53)
	No	190(74.51)	66 (34.7)	124 (65.3)		
Smoking	Yes	36(14.12)	11(30.6)	25(69.4)	0.28	1.66 (0.66-4.18)
	No	174(68.24)	56(32.2)	118(67.8)	0.21	1.54(0.79-3.01)
	Past smoker	45(17.65)	19(42.2)	26(57.8)		1
Insurance	MOH	140 (54.9)	53 (37.9)	87(62.1)	0.07	0.52 (0.26- 1.06)
	UNRWA	61 (23.92)	20 (32.8)	41(67.2)	0.3	0.65(0.29-1.48)
	Others	54 (21.18)	13(24.1)	41(75.9)		1
Marital Status	Single	4 (1.57)	1 (25)	3(75)	0.46	2.43 (0.23-25.51)
	Married	209 (81.96)	66 (31.6)	143(68.4)	0.12	1.75 (0.87-3.54)
	Divorced	4 (1.57)	2 (50)	2(50)	0.84	0.81 (0.1-6.36)
	Widow	38 (14.9)	17(44.7)	21(55.3)		1

## B-HbA1c 2-1 and lab tests

**Table 2: Associations between HbA1c 2-1 change with change in cholesterol, MAU, and blood pressure**

Variable	Total N=255	Bad N= 86	Good N=169	P value	Odds ratio (CI)
Good MAU*	97 (38.09)	27(27.8)	70(72.2)	0.12	1.55(0.89-2.68)
Good cholesterol*	78(30.59)	24 (30.8)	54(69.2)	0.51	1.21 (0.69-2.15)
Good Systolic*	136 (53.3)	48(35.3)	88 (64.7)	0.57	0.86(0.51-1.45)
Good Diastolic*	138 (54.12)	37 (26.8)	101 (73.2)	<b>0.01</b>	1.97(1.16-3.33)

\*reference category bad

## C –HbA1c 2-1 with lifestyle behaviors

**Table 3: Associations between HbA1c 2-1 change with BMI, caloric intake and physical activity**

Variable	Total N=255	Bad N= 86	Good N=169	P value	Odds ratio (CI)	
Good BMI*	93 (36.47)	32 (34.4)	61(65.6)	0.86	0.95 (0.56-1.63)	
Calories	1000	103 (40.39)	38 (36.9)	65(63.1)	0.15	0.21(0.03-1.78)
	1200	13 (5.1)	6 (46.2)	7 (53.8)	0.11	0.15(0.01-1.53)
	1400	19 (7.45)	7 (36.8)	12 (63.2)	0.19	0.21(0.02-2.09)
	1600	22(8.63)	9 (40.9)	13 (59.1)	0.14	0.18(0.02-1.71)
	1800	45(17.65)	16 (35.6)	29(64.4)	0.18	0.23(0.03-1.98)
	2000	32(12.55)	6 (18.8)	26 (81.3)	0.6	0.54(0.06-5.19)
	2200	12 (4.71)	3 (25)	9(75)	0.43	0.38(0.03-4.37)
	2400	9(3.53)	1 (11.1)	8 (88.9)		1
Activity level	Very light	5 (1.96)	2(40)	3 (60)	0.5	0.52 (0.08-3.56)
	Light	211 (82.75)	74(35.1)	137(64.9)	0.26	0.64(0.3-1.38)
	Moderate	39 (15.29)	10(25.6)	29(74.4)		1

\*reference bad BMI

## HbA1c change between third and first visit (HbA1c 3-1):

### A-HbA1c 3-1 and demographic factors

**Table 4: the association between HbA1c 3-1 with various demographic variables.**

Variable		Total N=255	Bad N= 86	Good N=169	P value	Odds ratio(CI)
Age	≤40	15(5.88)	8 (53.3)	7(46.7)	0.17	0.46 (0.15-1.39)
	41-50	42(16.47)	11(26.2)	31(73.8)	0.34	1.48(0.66-3.34)
	51-60	108(42.35)	27(25)	81(75)	0.15	1.58(0.85-2.92)
	> 60	90(35.29)	31(34.4)	59(65.6)		1
Sex	Male	117(45.88)	31 (26.5)	86 (73.5)	0.24	0.72 (0.42-1.24)
	Female	138(54.12)	46 (33.3)	92 (66.7)		
Period in study Months	≤6	1(0.39)	0(0)	1(100)	1.00	1.010E9(0.00)
	7-12	37(14.5)	7(18.9)	30(81.1)	0.05	2.68 (0.99-7.24)
	13- 18	25(9.8)	7(28)	18(72)	0.37	1.61(0.57-4.53)
	19- 24	71(27.8)	19(26.8)	52 (73.2)	0.17	1.71(0.79-3.68)
	25- 30	21(8.23)	7(33.3)	14 (66.7)	0.68	1.25(0.43-3.63)
	31- 36	48(18.82)	17 (35.4)	31 (64.6)	0.75	1.14(0.51-2.57)
	> 36	52(20.39)	20(38.5)	32(61.5)		1
Duration of Diabetes Years	≤5	70(27.45)	25(35.7)	45(64.3)	0.09	2.7(0.86-8.47)
	6-10	65(25.4)	20(30.8)	45(69.2)	<b>0.04</b>	3.38(1.06-10.76)
	11-15	56(21.96)	12(21.4)	44(78.6)	<b>0.01</b>	5.5(1.63-18.52)
	16-20	49(19.22)	11(22.4)	38(77.6)	<b>0.01</b>	5.18(1.51-17.76)
	> 20	15(5.88)	9(60)	6(40)		1
Regions	Middle	100 (39.22)	36(36)	64(64)	0.13	0.64(0.35-1.14)
	North	41(16.08)	11(26.8)	30(73.2)	0.95	0.97(0.44-2.18)
	South	114(44.71)	30(26.3)	84(73.7)		1
Education level	Illiterate	55 (21.57)	18(32.7)	37(67.3)	0.22	0.55(0.21-1.43)
	School	124 (48.63)	43(34.7)	81(65.3)	0.12	0.5(0.21-1.19)
	High school	38 (14.9)	8(21.1)	30(78.9)	1	1(0.33-3.01)
	University	38 (14.9)	8(21.1)	30(78.9)		1
Employed	Yes	65(25.49)	20(30.8)	45 (69.2)	0.91	1.04(0.56-1.91)
	No	190(74.51)	57(30)	133(70)		
Smoking	Yes	36(14.12)	11(30.6)	25(69.4)	0.64	1.25(0.49-3.2)
	No	174(68.24)	50(28.7)	124(71.3)	0.38	1.37(0.68-2.74)
	Past smoker	45(17.65)	16(35.6)	29(64.4)		1
Insurance	MOH	140 (54.9)	44(31.4)	96(68.6)	0.99	1(0.51- 1.97)
	UNRWA	61 (23.92)	16(26.2)	45(73.8)	0.54	1.29(0.58-2.9)
	Others	54 (21.18)	17(31.5)	37(68.5)		1
Marital Status	Single	4 (1.57)	1(25)	3(75)	0.46	2.43(0.23-25.51)
	Married	209 (81.96)	58(27.8)	151(72.2)	<b>0.04</b>	2.11(1.04-4.28)
	Divorced	4 (1.57)	1(25)	3(75)	0.46	2.43(0.23-25.51)
	Widow	38 (14.9)	17(44.7)	21(55.3)		1

## B-HbA1c 3-1 and lab tests

**Table 5 :Associations between HbA1c 3-1 change with change in cholesterol, MAU, and blood pressure**

Variable	Total N=255	Bad N= 77	Good N=178	P value	Odds ratio (CI)
Good MAU*	85( 33.3)	19(22.4)	66(77.6)	0.5	1.8 (0.99-3.28)
Good cholesterol*	84(32.94)	24(28.6)	60(71.4)	0.69	1.12(0.63- 1.99)
Good Systolic*	138 (54.2)	43(31.2)	95(68.8)	0.72	0.91(0.53-1.55)
Good Diastolic*	130 (50.98)	37 (28.5)	93(71.5)	0.54	1.18(0.69-2.02)

\*reference category bad

## C –HbA1c 3-1 with lifestyle behaviors

**Table 6 :Associations between HbA1c 3-1 change with BMI, caloric intake and physical activity**

Variable	Total N=255	Bad N= 77	Good N=178	P value	Odds ratio (CI)	
Good BMI*	88 (34.51)	29(33)	59 (67)	0.49	0.82(0.47-1.43)	
Calories	1000	103 (40.39)	33(32)	70(68)	0.22	0.27(0.03-2.21)
	1200	13 (5.1)	5(38.5)	8(61.5)	0.18	0.2(.019-2.12)
	1400	19 (7.45)	6(31.6)	13(68.4)	0.26	0.27(.03-2.68)
	1600	22(8.63)	6(27.3)	16(72.7)	0.35	0.33(0.03-3.26)
	1800	45(17.65)	17(37.8)	28(62.2)	0.15	0.21(0.02-1.79)
	2000	32(12.55)	7(21.9)	25(78.1)	0.48	0.45(0.047-4.2)
	2200	12 (4.71)	2(16.7)	10(83.3)	0.72	0.63(0.048-8.2)
	2400	9(3.53)	1(11.1)	8(88.9)		1
Activity level	Very light	5 (1.96)	1(20)	4(80)	0.98	1.03 (0.1-10.56)
	Light	211 (82.75)	68(32.2)	143(67.8)	0.15	0.54 (0.24-1.24)
	Moderate	39 (15.29)	8(20.5)	31(79.5)		1

\*reference bad BMI

## HbA1c change between third and second (HbA1c 3-2):

### A-HbA1c 3-2 and demographic factors

**Table 7 : the association between HbA1c 3-2 with various demographic variables.**

Variable		Total N=255	Bad N= 127	Good N=128	P value	Odds ratio(CI)
Age	≤40	15(5.88)	8(53.3)	7 (46.7)	0.69	0.8(0.27-2.39)
	41-50	42(16.47)	25(59.5)	17(40.5)	0.21	0.62 (0.3-1.31)
	51-60	108(42.35)	51(47.2)	57(52.8)	0.94	1.02(0.58-1.79)
	> 60	90(35.29)	43(47.8)	47(52.2)		1
Sex	Male	117(45.88)	60 (51.3)	57(48.7)	0.66	1.12 (0.68- 1.83)
	Female	138(54.12)	67(48.6)	71(51.4)		
Period in study Months	≤6	1(0.39)	1(100)	0(0)	1	0.00(0.00)
	7-12	37(14.5)	17(45.9)	20(54.1)	0.58	1.27(0.55-2.96)
	13- 18	25(9.8)	12(48)	13(52)	0.75	1.17(0.45-3.04)
	19- 24	71(27.8)	30(42.3)	41(57.7)	0.29	1.48(0.72-3.03)
	25- 30	21(8.23)	15(71.4)	6(28.6)	0.13	0.43(0.15-1.29)
	31- 36	48(18.82)	25(52.1)	23(47.9)	0.99	0.99(0.45-2.18)
	> 36	52(20.39)	27(51.9)	25(48.1)		1
Duration of Diabetes Years	≤5	70(27.45)	33 (47.1)	37(52.9)	0.66	1.28(0.42-3.92)
	6-10	65(25.4)	35(53.8)	30(46.2)	0.97	0.98(0.32-3.02)
	11-15	56(21.96)	29(51.8)	27(48.2)	0.92	1.06(0.34-3.33)
	16-20	49(19.22)	22(44.9)	27(55.1)	0.57	1.4(0.44-4.48)
	> 20	15(5.88)	8(53.3)	7(46.7)		1
Regions	Middle	100 (39.22)	50(50)	50(50)	1	1 (0.58- 1.71)
	North	41(16.08)	20(48.8)	21(51.2)	0.89	1.05(0.51-2.14)
	South	114(44.71)	57(50)	57(50)		1
Education level	Illiterate	55 (21.57)	27 (49.1)	28(50.9)	0.56	1.28 (0.56-2.94)
	School	124 (48.63)	62 (50)	62(50)	0.57	1.24(0.6-2.56)
	High school	38 (14.9)	17(44.7)	21(55.3)	0.36	1.53(0.62-3.77)
	University	38 (14.9)	21(55.3)	17(44.7)		1
Employed	Yes	65(25.49)	34 (52.3)	31(47.7)	0.64	1.14 (0.65- 2.01)
	No	190(74.51)	93(48.9)	97(51.1)		
Smoking	Yes	36(14.12)	17 (47.2)	19 (52.8)	0.59	1.28 (0.53-3.07)
	No	174(68.24)	86 (49.4)	88 (50.6)	0.64	1.17(0.61-2.26)
	Past smoker	45(17.65)	24 (53.3)	21(46.7)		1
Insurance	MOH	140 (54.9)	64 (45.7)	76(54.3)	<b>0.01</b>	2.38(1.23-4.58)
	UNRWA	61 (23.92)	27(44.3)	34(55.7)	<b>0.02</b>	2.52(1.18-5.38)
	Others	54 (21.18)	36(66.7)	18(33.3)		1
Marital Status	Single	4 (1.57)	1(25)	3(75)	0.32	3.33 (0.32-34.99)
	Married	209 (81.96)	104(49.8)	105(50.2)	0.75	1.12(0.56-2.24)
	Divorced	4 (1.57)	2(50)	2(50)	0.92	1.11(0.14-8.73)
	Widow	38 (14.9)	20(52.6)	18(47.4)		1

## B-HbA1c 3-2 and lab tests

**Table 8: Associations between HbA1c 3-2 change with change in cholesterol, MAU, and blood pressure**

Variable	Total N=255	Bad N= 127	Good N=128	P value	Odds ratio (CI)
Good MAU*	60(23.53)	22(36.7)	38 (63.3)	<b>0.02</b>	2.02 (1.11- 3.66)
Good cholesterol*	36 (14.12)	17 (47.2)	19 (52.8)	0.74	1.13 (0.55-2.29)
Good Systolic*	128(50.2)	66 (51.6)	62(48.4)	0.57	0.87 (0.53- 1.42)
Good Diastolic*	130 (50.98)	58 (44.6)	72(55.4)	0.09	1.53 (0.93- 2.51)

\*reference category bad

## C –HbA1c 3-2 with lifestyle behaviors

**Table 9 :Associations between HbA1c 3-2 change with BMI, caloric intake and physical activity**

Variable	Total N=255	Bad N= 127	Good N=128	P value	Odds ratio (CI)	
Good BMI*	83 (32.5)	44 (53)	39 (47)	0.48	0.83 (0.49- 1.4)	
Calories	1000	103 (40.39)	46 (44.7)	57 (55.3)	0.22	2.48 (0.59- 10.45)
	1200	13 (5.1)	8 (61.5)	5 (38.5)	0.81	1.25 (0.21- 7.41)
	1400	19 (7.45)	10(52.6)	9 (47.4)	0.49	1.8 (0.35- 9.4)
	1600	22(8.63)	7 (31.8)	15 (68.2)	0.08	4.29 (0.82- 22.34)
	1800	45(17.65)	24(53.3)	21 (46.7)	0.47	1.75 (0.39- 7.88)
	2000	32(12.55)	20(62.5)	12 (37.5)	0.82	1.2 (0.25- 5.71)
	2200	12 (4.71)	6(50)	6 (50)	0.45	2 (0.33- 11.97)
Activity level	2400	9(3.53)	6(66.7)	3 (33.3)		1
	Very light	5 (1.96)	1 (20)	4 (80)	0.29	3.43 (0.35-33.52)
	Light	211 (82.75)	108 (51.2)	103 (48.8)	0.56	0.82 (0.41-1.62)
	Moderate	39 (15.29)	18 (46.2)	21 (53.8)		1

\*reference bad BMI

## HbA1c change between forth and second visit (HbA1c 4-2):

### A-HbA1c 4-2 and demographic factors

**Table 10 : the association between HbA1c 4-2 with various demographic variables.**

Variable	Total N=255	Bad N=130	Good N= 125	P value	Odds ratio(CI)	
Age	≤40	15(5.88)	8 (53.3)	7 (46.7)	0.81	1.14(0.38- 3.43)
	41-50	42(16.47)	25 (59.5)	17 (40.5)	0.76	0.89 (0.42-1.87)
	51-60	108(42.35)	46 (42.6)	62 (57.4)	<b>0.049</b>	1.76 (1- 3.1)
	> 60	90(35.29)	51 (56.7)	39 (43.3)		1
Sex	Male	117(45.88)	65(55.6)	52 (44.4)	0.18	1.4 (0.86- 2.3)
	Female	138(54.12)	65 (47.1)	73 (52.9)		
Period in study Months	≤6	1(0.39)	1 (100)	0 (0)	1	0.00 (0.00)
	7-12	37(14.5)	19 (51.4)	18 (48.6)	0.19	1.79 (0.76- 4.24)
	13- 18	25(9.8)	9 (36)	16(64)	<b>0.02</b>	3.36 (1.24-9.1)
	19- 24	71(27.8)	33 (46.5)	38 (53.5)	<b>0.04</b>	2.18 (1.04- 4.55)
	25- 30	21(8.23)	11(52.4)	10 (47.6)	0.3	1.72 (0.61- 4.81)
	31- 36	48(18.82)	23 (47.9)	25 (52.1)	0.08	2.05 (0.92- 4.59)
	> 36	52(20.39)	34 (65.4)	18 (34.6)		1
Duration of Diabetes Years	≤5	70(27.45)	39(55.7)	31(44.3)	0.53	0.7 (0.23-2.13)
	6-10	65(25.4)	30(46.2)	35 (53.8)	0.97	1.02 (0.33- 3.15)
	11-15	56(21.96)	27(48.2)	29 (51.8)	0.92	0.94 (0.3-2.94)
	16-20	49(19.22)	27(55.1)	22 (44.9)	0.57	0.71 (0.22-2.28)
	> 20	15(5.88)	7 (46.7)	8 (53.3)		1
Regions	Middle	100 (39.22)	57 (57)	43 (43)	0.13	0.66 (0.38-1.13)
	North	41(16.08)	20(48.8)	21(51.2)	0.8	0.91 (0.45-1.86)
	South	114(44.71)	53(46.5)	61 (53.5)		1
Education level	Illiterate	55 (21.57)	25 (45.5)	30 (54.5)	0.24	1.65 (0.72-3.8)
	School	124 (48.63)	70 (56.5)	54(43.5)	0.88	1.06 (0.51-2.21)
	High school	38 (14.9)	13 (34.2)	25(65.8)	<b>0.04</b>	2.64(1.04-6.7)
	University	38 (14.9)	22 (57.9)	16 (42.1)		1
Employed	Yes	65(25.49)	37 (56.9)	28 (43.1)	0.27	1.38 (0.78- 2.43)
	No	190(74.51)	93 (48.9)	97 (51.1)		
Smoking	Yes	36(14.12)	17 (47.2)	19 (52.8)	0.73	1.17 (0.49-2.81)
	No	174(68.24)	90 (51.7)	84 (48.3)	0.94	0.98 (0.51- 1.88)
	Past smoker	45(17.65)	23 (51.1)	22 (48.9)		1
Insurance	MOH	140 (54.9)	70 (50)	70(50)	0.64	1.16 (0.62- 2.18)
	UNRWA	61 (23.92)	31(50.8)	30(49.2)	0.76	1.12(0.54- 2.34)
	Others	54 (21.18)	29(53.7)	25(46.3)		1
Marital Status	Single	4 (1.57)	1 (25)	3 (75)	0.2	4.6 (0.44- 48.47)
	Married	209 (81.96)	104(49.8)	105(50.2)	0.22	1.55 (0.77- 3.13)
	Divorced	4 (1.57)	2(50)	2(50)	0.69	1.53 (0.19- 12.09)
	Widow	38 (14.9)	23(60.5)	15(39.5)		1

## B-HbA1c 4-2 and lab tests

**Table 11 :Associations between HbA1c 4-2 change with change in cholesterol, MAU, and blood pressure**

Variable	Total N=255	Bad N= 130	Good N= 125	P value	Odds ratio (CI)
Good MAU*	111 (43.52)	56 (50.5)	55 (49.5)	0.88	1.04 (0.63- 1.7)
Good cholesterol*	101 (39.6)	55 (54.5)	46 (45.5)	0.37	0.79 (0.48- 1.31)
Good Systolic*	125(49.02)	63 (50.4)	62 (49.6)	0.86	1.05 (0.64-1.71)
Good Diastolic*	131(51.37)	62 (47.3)	69(52.7)	0.23	1.35 (0.83- 2.21)

\*reference category bad

## C –HbA1c 4-2 with lifestyle behaviors

**Table 12: Associations between HbA1c 4-2 change with BMI, caloric intake and physical activity**

Variable	Total N=255	Bad N= 130	Good N= 125	P value	Odds ratio (CI)	
Good BMI*	103 (40.39)	49 (47.6)	54 (52.4)	0.37	1.26 (0.76- 2.08)	
Calories	<b>1000</b>	103 (40.39)	41 (39.8)	62 (60.2)	<b>0.02</b>	12.1 (1.46- 100.38)
	<b>1200</b>	13 (5.1)	9 (69.2)	4 (30.8)	0.3	3.56 (0.33- 38.78)
	<b>1400</b>	19 (7.45)	13 (68.4)	6 (31.6)	0.26	3.69 (0.37- 36.57)
	<b>1600</b>	22(8.63)	9 (40.9)	13 (59.1)	<b>0.03</b>	11.56 (1.22- 109.19)
	<b>1800</b>	45(17.65)	29 (64.4)	16 (35.6)	0.18	4.41 (0.51- 38.53)
	<b>2000</b>	32(12.55)	16 (50)	16 (50)	0.06	8 (0.89- 71.58)
	<b>2200</b>	12 (4.71)	5 (41.7)	7(58.3)	<b>0.046</b>	11.2 (1.04- 120.36)
	<b>2400</b>	9(3.53)	8 (88.9)	1 (11.1)		1
Activity level	<b>Very light</b>	5 (1.96)	2 (40)	3 (60)	0.88	1.16 (0.17- 7.73)
	<b>Light</b>	211 (82.75)	111(52.6)	100 (47.4)	0.3	0.7 (0.35- 1.39)
	<b>Moderate</b>	39 (15.29)	17 (43.6)	22 (56.4)		1

\*reference bad BMI

## HbA1c change between fourth and first visit (HbA1c 4-1):

### A-HbA1c 4-1 and demographic factors

**Table 13: the distribution between HbA1c 4-1 with various demographic variables.**

Variable		Total N=255	Bad N= 92	Good N= 163	P value	Odds ratio(CI)
Age	≤40	15(5.88)	7 (46.7)	8 (53.3)	0.81	1.14 (0.38- 3.43)
	41-50	42(16.47)	16 (38.1)	26 (61.9)	0.76	0.89 (0.42-1.87)
	51-60	108(42.35)	33 (30.6)	75 (69.4)	<b>0.049</b>	1.76 (1-3.1)
	> 60	90(35.29)	36 (40)	54 (60)		1
Sex	Male	117(45.88)	42 (35.9)	75 (64.1)	0.96	0.99 (0.59- 1.65)
	Female	138(54.12)	50 (36.2)	88 (63.8)		
Period in study Months	≤6	1(0.39)	1(100)	0 (0)	1	0.00 (0.00)
	7-12	37(14.5)	10 (27)	27(73)	0.19	1.79 (0.76- 4.24)
	13- 18	25(9.8)	8(32)	17(68)	<b>0.02</b>	3.36(1.24- 9.1)
	19- 24	71(27.8)	21(29.6)	50(70.4)	<b>0.04</b>	2.18 (1.04- 4.55)
	25- 30	21(8.23)	9(42.9)	12(57.1)	0.3	1.72 (0.61- 4.81)
	31- 36	48(18.82)	17(35.4)	31(64.6)	0.08	2.05 (0.92- 4.59)
	> 36	52(20.39)	26(50)	26(50)		1
Duration of Diabetes Years	≤5	70(27.45)	28 (40)	42 (60)	0.53	0.7 (0.23- 2.13)
	6-10	65(25.4)	24 (36.9)	41(63.1)	0.97	1.02 (0.33- 3.15)
	11-15	56(21.96)	16 (28.6)	40 (71.4)	0.92	0.94 (0.3-2.94)
	16-20	49(19.22)	16 (32.7)	33 (67.3)	0.57	0.71 (0.22- 2.28)
	> 20	15(5.88)	8 (53.3)	7 (46.7)		1
Regions	Middle	100 (39.22)	43 (43)	57(57)	0.13	0.66 (0.38- 1.13)
	North	41(16.08)	13 (31.7)	28 (68.3)	0.8	0.91 (0.45- 1.86)
	South	114(44.71)	36 (31.6)	78 (68.4)		1
Education level	Illiterate	55 (21.57)	18 (32.7)	37 (67.3)	0.24	1.65(0.72- 3.8)
	School	124 (48.63)	49(39.5)	75 (60.5)	0.88	1.06 (0.51- 2.21)
	High school	38 (14.9)	12(31.6)	26 (68.4)	<b>0.04</b>	2.64 (1.04-6.7)
	University	38 (14.9)	13 (34.2)	25(65.8)		1
Employed	Yes	65(25.49)	42 (35.9)	75 (64.1)	0.96	0.99 (0.59- 1.65)
	No	190(74.51)	50 (36.2)	88 (63.8)		
Smoking	Yes	36(14.12)	13 (36.1)	23 (63.9)	0.73	1.17 (0.49- 2.81)
	No	174(68.24)	61 (35.1)	113 (64.9)	0.94	0.98 (0.51- 1.88)
	Past smoker	45(17.65)	18(40)	27 (60)		1
Insurance	MOH	140 (54.9)	51 (36.4)	89 (63.6)	0.64	1.16 (0.62- 2.18)
	UNRWA	61 (23.92)	23 (37.7)	38 (62.3)	0.76	1.12 (0.54- 2.34)
	Others	54 (21.18)	18 (33.3)	36 (66.7)		1
Marital Status	Single	4 (1.57)	1 (25)	3 (75)	0.2	4.6 (0.44- 48.47)
	Married	209 (81.96)	72 (34.4)	137 (65.6)	0.22	1.55 (0.77- 3.13)
	Divorced	4 (1.57)	2 (50)	2 (50)	0.69	1.53 (0.19- 12.09)
	Widow	38 (14.9)	17 (44.7)	21 (55.3)		1

## B-HbA1c 4-1 and lab tests

**Table 14: Associations between HbA1c 4-1 change with change in cholesterol, MAU, and blood pressure**

Variable	Total N=255	Bad N= 92	Good N= 163	P value	Odds ratio (CI)
Good MAU*	111 (43.53)	35 (31.5)	76 (68.5)	0.18	1.42 (0.85- 2.4)
Good cholesterol*	117 (45.88)	43 (36.8)	74 (63.2)	0.84	0.95 (0.57- 1.58)
Good Systolic*	122 (47.84)	46 (37.7)	76 (62.3)	0.6	0.87(0.52- 1.46)
Good Diastolic*	118 (46.27)	37 (31.4)	81 (68.6)	0.15	1.47 (0.88- 2.46)

\*reference category bad

## C –HbA1c 4-1 with lifestyle behaviors

**Table 15: Associations between HbA1c 4-1 change with BMI, caloric intake and physical activity**

Variable		Total N=255	Bad N= 92	Good N= 163	P value	Odds ratio (CI)
Good BMI*		100 (39.22)	40 (40)	60 (60)	0.3	0.76 (0.45-1.28)
Calories	1000	103 (40.39)	35 (34)	68(66)	0.97	0.97 (0.23- 4.12)
	1200	13 (5.1)	6 (46.2)	7 (53.8)	0.55	0.58 (0.1-3.4)
	1400	19 (7.45)	9 (47.4)	10 (52.6)	0.49	0.56 (0.11-2.9)
	1600	22(8.63)	8 (36.4)	14 (63.6)	0.87	0.88(0.17- 4.49)
	1800	45(17.65)	18 (40)	27(60)	0.71	0.75 (0.17-3.39)
	2000	32(12.55)	11 (34.4)	21 (65.6)	0.95	0.96 (0.2-4.57)
	2200	12 (4.71)	2 (16.7)	10 (83.3)	0.38	2.5(0.32- 19.53)
	2400	9(3.53)	3 (33.3)	6 (66.7)		1
Activity level	Very light	5 (1.96)	2 (40)	3 (60)	0.77	0.75 (0.11- 5.06)
	Light	211 (82.75)	77 (36.5)	134 (63.5)	0.71	0.87 (0.42- 1.79)
	Moderate	39 (15.29)	13(33.3)	26 (66.7)		1

\*reference bad BMI

### HbA1c change between fourth and first visit (HbA1c 4-3):

#### A-HbA1c 4-3 and demographic factors

**Table 16 : the distribution between HbA1c 4-3 with various demographic variables.**

Variable		Total N=255	Bad N=143	Good N=112	P value	Odds ratio(CI)
Age	≤40	15(5.88)	8 (53.3)	7 (46.7)	0.63	0.76 (0.25- 2.29)
	41-50	42(16.47)	24 (57.1)	18 (42.9)	0.84	1.08 (0.51- 2.3)
	51-60	108(42.35)	57 (52.8)	51 (47.2)	0.17	1.52 (0.84- 2.73)
	> 60	90(35.29)	54 (60)	36 (40)		1
Sex	Male	117(45.88)	71 (60.7)	46 (39.3)	0.17	1.42 (0.86- 2.33)
	Female	138(54.12)	72 (52.2)	66 (47.8)		
Period in study Months	≤6	1(0.39)	1 (100)	0 (0)	1.00	0.00 (0.00)
	7-12	37(14.5)	19 (51.4)	18 (48.6)	<b>0.03</b>	2.7(1.09- 6.69)
	13- 18	25(9.8)	13 ( 52)	12 (48)	0.14	2.13 (0.78- 5.78)
	19- 24	71(27.8)	36 (50.7)	35 (49.3)	<b>0.02</b>	2.38 (1.13- 5.02)
	25- 30	21(8.23)	11 (52.4)	10 (47.6)	0.58	1.33 (0.48- 3.7)
	31- 36	48(18.82)	28 (58.3)	20 (41.7)	0.14	1.82 (0.82- 4.07)
	> 36	52(20.39)	35 (67.3)	17 (32.7)		1
Duration of Diabetes Years	≤5	70(27.45)	38 (54.3)	32 (45.7)	0.35	1.71(0.56- 5.26)
	6-10	65(25.4)	34 (52.3)	31 (47.7)	0.25	1.95 (0.63- 6.06)
	11-15	56(21.96)	36 (64.3)	20 (35.7)	0.08	2.86 (0.89- 9.19)
	16-20	49(19.22)	29 (59.2)	20 (40.8)	0.15	2.36 (0.73-7.65)
	> 20	15(5.88)	6 (40)	9 (60)		1
Regions	Middle	100 (39.22)	53 (53)	47 (47)	0.09	0.61 (0.35- 1.07)
	North	41(16.08)	21 (51.2)	20 (48.8)	0.99	0.99 (0.46- 2.14)
	South	114(44.71)	69 (60.5)	45 (39.5)		1
Education level	Illiterate	55 (21.57)	30 (54.5)	25 (45.5)	0.88	1.07 (0.45- 2.57)
	School	124 (48.63)	76 (61.3)	48(38.7)	0.56	0.8 (0.37- 1.7)
	High school	38 (14.9)	17 (44.7)	21(55.3)	0.81	1.13 (0.43- 2.94)
	University	38 (14.9)	20 (52.6)	18 (47.4)		1
Employed	Yes	65(25.49)	40 (61.5)	25 (38.5)	0.3	1.35 (0.76-2.4)
	No	190(74.51)	103 (54.2)	87 (45.8)		
Smoking	Yes	36(14.12)	18 (50)	18 (50)	0.72	1.18 (0.48 -2.91)
	No	174(68.24)	99 (56.9)	75 (43.1)	0.54	1.24 (0.63- 2.42)
	Past smoker	45(17.65)	26 (57.8)	19 (42.2)		1
Insurance	MOH	140 (54.9)	81 (57.9)	59 (42.1)	0.69	0.87 (0.45- 1.69)
	UNRWA	61 (23.92)	41 (67.2)	20 (32.8)	0.63	0.83 (0.38- 1.78)
	Others	54 (21.18)	21 (38.9)	33 (61.1)		1
Marital Status	Single	4 (1.57)	3 (75)	1 (25)	0.46	2.43 (0.23- 25.51)
	Married	209 (81.96)	118 (56.5)	91 (43.5)	0.23	1.54 (0.77- 3.1)
	Divorced	4 (1.57)	1 (25)	3 (75)	0.84	0.81 (0.1-6.36)
	Widow	38 (14.9)	21 (55.3)	17 (44.7)		1

## B-HbA1c4-3 and lab tests

**Table 17 : Associations between HbA1c 4-3 change with change in cholesterol, MAU, and blood pressure**

Variable	Total N=255	Bad N=143	Good N=112	P value	Odds ratio (CI)
Good MAU*	102 (40)	62 (60.8)	40 (39.2)	0.22	0.73 (0.44- 1.21)
Good cholesterol*	96 (37.65)	54(56.3)	42 (43.8)%	0.97	0.99 (0.59- 1.65)
Good Systolic*	115 (45.1)	62 (53.9)	53 (46.1)	0.53	1.17 (0.71-1.93)
Good Diastolic*	108 (42.35)	65 (60.2)	43 (39.8)	0.26	0.75 (0.45- 1.24)

\*reference category bad

## C –HbA1c 4-3 with lifestyle behaviors

**Table 18: Associations between HbA1c 4-3 change with BMI, caloric intake and physical activity**

Variable	Total N=255	Bad N=143	Good N=112	P value	Odds ratio (CI)	
Good BMI*	118 (46.27)	65 (55.1)	53 (44.9)	0.77	1.08 (0.66-1.77)	
Calories	1000	103 (40.39)	54 (52.4)	49 (47.6)	0.97	0.97 (0.23- 4.12)
	1200	13 (5.1)	7 (53.8)	6 (46.2)	0.55	0.58 (0.10-3.40)
	1400	19 (7.45)	13 (68.4)	6 (31.6)	0.49	0.56 (0.11- 2.90)
	1600	22(8.63)	13 (59.1)	9 (40.9)	0.87	0.88 (0.17- 4.49)
	1800	45(17.65)	27 (60)	18 (40)	0.71	0.75 (0.17-3.39)
	2000	32(12.55)	18 (56.3)	14 (43.8)	0.95	0.96 (0.20- 4.57)
	2200	12 (4.71)	5 (41.7)	7 (58.3)	0.38	2.50 (0.32-19.53)
Activity level	2400	9(3.53)	6 (66.7)	3 (33.3)		1
	Very light	5 (1.96)	4 (80)	1 (20)	0.77	0.75 (0.11- 5.06)
	Light	211 (82.75)	118 (55.9)	93 (44.1)	0.71	0.87 (0.42- 1.79)
	Moderate	39 (15.29)	21 (53.8)	18 (46.2)		1

\*reference bad BMI

**Table 19: Multivariate analysis for HbA1c change among the visits with the various variables (n=255)**

Variable		AOR (CI) 2-1	AOR (CI) 4-1	AOR(CI) 3-2	AOR (CI) 4-3	AOR(CI) 4-2	AOR (CI) 3-1
Age	≤40	2.42 (0.6-9.8)	0.7 (0.21- 2.26)	-----	-----	1.34 (0.36- 4.98)	-----
	41-50	1.54 (0.62- 3.8)	1.08 (0.48- 2.41)	-----	-----	1.02 (0.42- 2.46)	-----
	51-60	<b>2.15 (1.07- 4.32)</b>	1.69 (0.89- 3.18)	-----	-----	<b>2.35 (1.21- 4.6)</b>	-----
	> 60	1	1	-----	-----	1	-----
Period in study Months	-----	-----	-----	-----	-----	-----	-----
	7-12	<b>3.18 (1.06- 9.55)</b>	<b>2.54 (1.01- 6.43)</b>	-----	1.95 (0.82- 4.64)	2.36 (0.89- 6.28)	-----
	13- 18	1.83 (0.57- 5.92)	2.09 (0.75- 5.8)	-----	1.9 (0.72- 5.04)	<b>5.43 (1.66- 17.73)</b>	-----
	19- 24	1.61 (0.7-3.73)	<b>2.58 (1.19- 5.6)</b>	-----	2(0.95- 4.21)	<b>3.63 (1.55- 8.52)</b>	-----
	25- 30	2.33 (0.66- 8.27)	1.48 (0.51- 4.25)	-----	1.87 (0.67- 5.26)	<b>3.35 (1.02- 10.99)</b>	-----
	31- 36	1.48 (0.6-3.64)	1.78 (0.78- 4.06)	-----	1.47 (0.65- 3.32)	1.78 (0.74- 4.28)	-----
	> 36	1	1	-----	1	1	-----
Duration of Diabetes Years	≤5	2.49 (0.67- 9.23)	-----	-----	-----	-----	2.59 (0.81- 8.35)
	6-10	2.86 (0.76- 10.72)	-----	-----	-----	-----	<b>3.52 (1.08- 11.50)</b>
	11-15	4.26 (1.14- 15.99)	-----	-----	-----	-----	<b>5.52 (1.6- 19.09)</b>
	16-20	3.38 (0.9-12.7)	-----	-----	-----	-----	<b>5.66 (1.6- 19.98)</b>
	> 20	1	-----	-----	-----	-----	1
Insurance	MOH	-----	-----	-----	-----	-----	-----
	UNRWA	-----	-----	-----	-----	-----	-----
	Others	-----	-----	-----	-----	-----	-----
Marital Status	Singe	-----	-----	-----	-----	-----	3.4 (0.31- 37.66)
	Married	-----	-----	-----	-----	-----	<b>2.15 (1.04- 4.47)</b>
	Divorced	-----	-----	-----	-----	-----	4.22 (0.37- 48.4)
	Widow	-----	-----	-----	-----	-----	1
Region	Middle	0.68 (0.36- 1.29)	-----	-----	-----	-----	-----
	North	0.71 (0.29- 1.7)	-----	-----	-----	-----	-----
	South	1	-----	-----	-----	-----	-----
Education level	Illiterate	0.58 (0.2-1.66)	1.13 (0.44- 2.94)	-----	-----	1.43 (0.49- 4.2)	-----
	School	0.52(0.21- 1.33)	0.84 (0.38- 1.87)	-----	-----	0.9 (0.38- 2.12)	-----
	High school	0.45 (0.15- 1.38)	1.32 (0.48- 3.67)	-----	-----	<b>3.28 (1.11- 9.71)</b>	-----
	University	1	1	158-----	-----	-----	-----

Variable		AOR (CI) 2-1	AOR (CI) 4-1	AOR(CI) 3-2	AOR (CI) 4-3	AOR(CI) 4-2	AOR (CI) 3-1
MAU (1)*		-----	-----	0.51 (0.28- 0.94)	-----	-----	-----
Calories intake	1000	-----	-----	-----	-----	<b>14.92 (1.7- 130.82)</b>	-----
	1200	-----	-----	-----	-----	3.39 (0.29- 39.06)	-----
	1400	-----	-----	-----	-----	4.3 (0.41- 45.23)	-----
	1600	-----	-----	-----	-----	<b>21.32 (2.07-219.66)</b>	-----
	1800	-----	-----	-----	-----	4.17 (0.44- 39.36)	-----
	2000	-----	-----	-----	-----	6.9 (0.7- 67.7)	-----
	2200	-----	-----	-----	-----	11.63 (0.97- 139)	-----
	2400	-----	-----	-----	-----	-----	-----

\*reference category bad

**Annex 7:** Repeated measures for patients who have four HbA1c results within two years (n=255):

**Table 1:** the mean HbA1c in each of the four visits

	<b>Mean</b>	<b>Std. Deviation</b>
HbA1c 1st	9.31	2.22
HbA1c 2nd	8.73	1.94
HbA1c 3rd	8.51	1.76
HbA1c 4th	8.53	1.79

**Table 2:** Pairwise comparison

visit	Other visits	Mean Difference	Std. Error	Sig.	95% Confidence Interval for Difference	
					Lower Bound	Upper Bound
1	2	0.58*	0.09	<b>0.00</b>	0.41	0.76
	3	0.8*	0.11	<b>0.00</b>	0.59	1.01
	4	0.78*	0.11	<b>0.00</b>	0.56	1
2	1	-0.58*	0.09	<b>0.00</b>	-0.76	-0.41
	3	0.22*	0.07	<b>0.00</b>	0.07	0.36
	4	0.19*	0.09	<b>0.03</b>	0.02	0.37
3	1	-0.8*	0.11	<b>0.00</b>	-1.01	-0.59
	2	-0.22*	0.07	<b>0.00</b>	-0.36	-0.07
	4	-0.02	0.06	0.74	-0.14	0.1
4	1	-0.78*	0.11	<b>0.00</b>	-1	-0.56
	2	-0.194*	0.09	<b>0.03</b>	-0.37	-0.02
	3	0.021	0.06	0.74	-0.1	0.14

## دراسة تقييمية لبرنامج رعاية مرضى السكري في مركز السكري التابع لمستشفى المطلع في الفترة ما بين 2009 – 2005

اعداد الطالبة: سماح الخطيب  
اشراف: د. نهى الشريف

### ملخص الرسالة

**خلفية الدراسة:** يشكل برنامج التدخل الغذائي دوراً محورياً وأساسياً في إدارة مرض السكري وعلاجه، ويهدف إلى تحسين عملية السيطرة على السكري و الوقاية من المضاعفات. ينصح مرضى السكري بتطبيق برنامج غذائي صحي، واحداث تغييرات تغذوية تشمل تعديلات على العادات الغذائية والأنماط الغذائية في حياتهم اليومية مدى العمر. وبالرغم من ذلك فإن نسبة كبيرة من مرضى السكري يعانون من عدم السيطرة على المرض تبقى عالية.

**أهداف الدراسة:** هدفت هذه الدراسة إلى تقييم برنامج التغذية في مركز السكري التابع لمستشفى المطلع و فعاليتها في السيطرة على مرض السكري و تحسين مستوى مخزون السكر التراكمي و معرفة دور برنامج السكري و برنامج التدخل الغذائي في التأثير على مستوى مخزون السكر في الدم و على الصحة البدنية و مؤشر كتلة الجسم للمرضى، و معرفة الخصائص الشخصية للمرضى التي تؤثر على مستوى مخزون السكر خلال فترة الدراسة.

**منهجية الدراسة:** أجريت دراسة تقييمية على 746 ملف طبي لمرضى سكري من النوع الثاني و المراجعين في مركز السكري في مستشفى المطلع في الفترة ما بين 2009-2005 و قد تم أخذ أربع زيارات لكل مريض تشمل الأولى و الأخيرة و كانت على فترات غير منتظمة بين كل زيارة و أخرى. تم جمع معلومات الشخصية، الطبية، البدنية و نتائج الفحوصات المخبرية من ملفات المرضى.

**النتائج الرئيسية:** أظهرت نتائج الدراسة أن متوسط عمر المرضى هو  $57 \pm 9.34$  (متوسط المعدل  $\pm$  انحراف معياري). ومن نتائجنا عن الصورة العامة للمرضى تبين أن 84% متزوجين في حين 74% من المرضى لا يعملون فيما كانت نسبة الاميين 15%، ومعدل فترة الإصابة بالسكري 10.08 سنوات وكانت نسبة 57% من المرضى يملكون تأمين وزارة الصحة الفلسطينية الصحي. قد تم اعطاء 41% من المرضى نظام غذائي قليل السعرات الحرارية (1000 كالوري) خلال فترة المتابعة. تم تصنيف 82% من المرضى على أن نشاطهم البدني قليل في الزيارة الأولى و تحسنت النسبة إلى 76% في الزيارة الرابعة. متوسط معدل نتائج مخزون السكر التراكمي في الزيارة الأولى كان  $9.1 \pm 2.1$  و في الزيارة الأخيرة  $8.46 \pm 1.7$ . متوسط معدل مؤشر كتلة الجسم في الزيارة الأولى كان  $31.2 \pm 5.3$  وفي الزيارة الأخيرة  $31.9 \pm 5.3$ . وزادت النسبة المئوية للمرضى الذين لديهم ضبطاً مثالياً (أقل من 7% من مخزون السكر التراكمي) من 19.2% في الزيارة الأولى إلى 22.1% في الزيارة الأخيرة. نسبة المرضى الذين كان عندهم تحسن في نتيجة مخزون السكر التراكمي كانت 60.7% بين الزيارة الأولى و الرابعة (الأخيرة). و قد أظهرت نماذج الانحدار اللوجيستي المتعدد أن لبيانات المرضى وجود علاقة ايجابية و ذات دلالة احصائية بين الفترة الزمنية التي كان المريض يتابع فيها في المركز و يحصل على استشارات تغذوية و بين التحسن في مستوى

مخزون السكر التراكمي. و أن العمر ,الجنس ,المستوى التعليمي للمرضى نظام التأمين الصحي، مؤشر كتلة الجسم، مستوى الكوليستر عوامل لا تؤثر في التغيير و التحسن لمستوى مخزون السكر التراكمي. وقد أظهر التحليل على العينة الجزئية (255 مريض) التي كانت زياراتهم الاربعة منتظمة خلال مدة سنتين نفس النتائج.

**الاستنتاج:** من أهم ميزات هذه الدراسة أنها الأولى من نوعها في مركز السكري في مستشفى المطلع و الذي يعد من أهم المراكز الموجودة في فلسطين للعناية بمرضى السكري. و التي بينت العوامل المؤثرة على البرنامج و على المرضى حيث تبين عدم وجود فترات منتظمة بين الزيارات لبعض المرضى و التي بينت الدراسة أن لها دور مهم في تحسين مستوى مخزون السكر التراكمي. هذا ونوصي بضرورة تعديل برنامج التغذية من ناحية زيادة عدد الزيارات و الاستشارات الفردية و توثيق مدى الالتزام بتطبيق النظام الغذائي و البرنامج الرياضي و الالتزام بالادوية وفقا لاحتياجات المرضى هناك حاجة ايضا لمراجعة مواعيد المرضى و انتظام المرضى في المتابعة في المركز.