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The Package of Essential Non-Communicable diseases: Evaluation of Patients with Diabetes Follow up at Governmental Health Clinics

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Thesis Approval

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Declaration

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

Signature:…….

Eman Mustafa Abd-Arazzaq Baradeyia

Date: April 29th, 2018

Dedication

To my father soul

To my great mother for her prayers

To my beloved husband, Anas, a source of inspiration and encouragement

To my brothers and sisters, especially dearest Asil,

To all friends

Acknowledgment

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Abstract

Background: Diabetes Mellitus is one of the most occurring conditions of non- communicable diseases (NCDs) in the world. According to World Health Organization (WHO), diabetes mellitus causes 1.6 million deaths annually, and nearly 87% of non-communicable diseases deaths occurred in low and middle-income countries. In response to this serious issue, WHO introduced an innovative and action-oriented response called the Package of Essential Noncommunicable Disease (PEN) interventions to prevent and control NCDs. It can be applied especially for low-resource settings. Ministry of health (MoH) started the PEN Approach implementation in the West Bank in 2013 and completed implementation by 2015 in primary healthcare clinics (PHC).

Aim: The study aim to evaluate the effectiveness of PEN Approach in controlling diabetes mellitus among diabetes mellitus type 2 (DMT2) patients following the Approach at the MoH clinics in the West Bank.

Methods: A quantitative cross-sectional study design was used. Data collection was conducted by a tool developed to collect file-based data including HbA1c, and physical measurements including cholesterol, BMI, and waist circumference. Also surveillance STEPwise questionnaire was used for diabetes risk factors assessment. Proportional stratified sample method was used, and 500 patients were selected purposively during the study period.

Findings: the mean age of study participants was 60 years (standard deviation =10.4), more than half of them were females (56.1%). Two thirds of the participants lived in rural areas. One quarter of the participants were illiterate (27.7%), around half of participants (43%) finished their primary education.

Almost half of the participants (48.2%) had a monthly income less than 1500 shekels. The majority of the participants (79%) were unemployed, 79% of the participants were married, and the mean of diabetes duration was 9.4 years (SD = 5.7).

Analysis of the participants HbA1c levels showed significant decrease from the 1st visit to the 3rd visit after two years (P <0.001), there was an increase in the percent of patients who reach optimal glycemic control (HbA1c <7%) form 32.8% in the 1st visit to 38.7% in the 3rd visit.

Binary logistic model was done to predict improvement in glycemic control from participants' characteristics. Glycemic control was significantly improved among females rather than males (OR=1.6, P<0.001), in younger patients (age group less than 50 years) rather than in elder patients (age group more than 60 years) (OR= 1.7, P<0.001). Patients with diabetes mellitus duration for less than 5 years were also had better glycemic control than patients with diabetes mellitus duration more than 20 years (OR= 1.9, P<0.001), and among patients with income level 1500-3000 shekels rather than in those with an income of >3000 shekels (OR= 2.4, P<0.01).

Conclusion: The results of this evaluation indicated that PEN Approach was effective in meeting objectives of controlling and managing DMT2. The HbA1c levels among diabetic patients who were involved in the PEN Approach had significantly declined, and the percent of patients with optimal glycemic control increased after two years.

برنامج الأمراض غير السارية (PEN Approach) :تقييم مرضى السكري المتابعين في عيادات الرعاية الأولية

إعداد: إيمان مصطفى عبد الرزاق برادعية

إشراف: د. معتصم حمدان

ملخص الدراسة: يعتبر مرض السكري أحد الأمراض غير السارية الأكثر انتشاراً في العالم, فحسب منظمة الصحة العالمية هنالك 1.6 مليون وفاة سنوياً بسبب مرض السكري, حيث أن 87% من هذه الوفيات تحدث في الدول المنخفضة والمتوسطة الدخل. واستجابة لهذا الوضع أدخلت منظمة الصحة العالمية برنامجاً مبتكراً للأمراض غير السارية بهدف الوقاية منها والسيطرة عليها. إذ يمكن تطبيقه بشكل خاص في الدول ذات الموارد القليلة. في عام 2013 بدأت وزارة الصحة الفلسطينية بتطبيق هذا البرنامج في عيادات الرعاية الأولية التابعة للوزارة ومع نهاية عام 2015 تم تطبيق البرنامج في جميع العيادات.

الهدف: تهدف الدراسة إلى تقييم مدى فعالية برنامج الأمراض غير السارية في تنظيم مستوى السكر في الدم, في مرضى السكري من النوع الثاني والذين يتبعون البرنامج في عيادات الرعاية الاولية في وزارة الصحة الفلسطينية .

المنهجية: اعتمدت الدراسة منهجية الوصف التحليلي, من خلال دراسة كمية مقطعية, حيث تم اختيار العينة بشكل طبقي نسبي من ثلاثِ محافظات ومن ثم اختيار المرضى بشكل عمدي اذ بلغ حجم العينة 500 مريض, تم جمع البيانات من خلال أداة تم تطويرها لجمع قراءات فحص السكر التراكمي ومستويات

الكوليسترول و مؤشر الكتلة ومحيط الخصر. تم اعتماد استبيان جاهز معد لبرنامج ال STEPwise Surveillance من أجل دراسة العوامل الخطرة المرتبطة بمرض السكري .

النتائج: بلغ متوسط أعمار المشاركين بالدراسة 60 عاماً (الانحراف المعياري = 10.4), حيث كان نصفهم من الإناث اللواتي بلغن عددهن (56.1٪), ويعيش ثلثي المشاركين في المناطق الريفية, وكان ربع المشاركين من الأميين بينما أنهى نصفهم تعليمه الإبتدائي, وحوالي نصف المشاركين لديهم دخل شهري أقل من 1500 شيكل (48.2%), ومعظم المشاركين بالدراسة عاطلين عن العمل(79%), وحوالي 79% منهم متزوجين, وبلغ معدل فترة الإصابة بالسكري 9.4 (الانحراف المعياري =5.7) .أظهرت نتائج تحليل مستويات السكر التراكمي انخفاضاً ذا دلالة إحصائية ما بين الزيارة الأولى والثالثة (P<0.001), كما أن هنالك ارتفاعاً في نسبة المرضى الذين حققوا أفضل تنظيم لمستوى السكر (HbA1c < 7%)بنسبة32.8% في الزيارة الأولى إلى 38.7% في الزيارة الثالثة.

تم تطبيق الانحدار اللوجستي الثنائي للتنبؤ بخصائص المشاركين التي تساهم في تحقيق تحسن في تنظيم السكر في الدم, حيث أظهرت النتائج أن الإناث حققن تحسناً أفضل في مستويات السكر بالدم مقارنة بالذكور (OR=1.6, P<0.001) , كذلك المرضى الذين تقل أعمارهم عن 50 عاماً حققوا تحسناً أفضل في مستويات السكر بالدم مقارنة بالمرضى الأكبر سناً ممن يزيدون عن 60عاماً (OR=1.7, P<0.001) .أظهر هذا التحليل أيضاً تحسناً لدى المرضى الذين تقل فترة إصابتهم عن 5 سنوات مقارنة بمن تزيد فترة الإصابة لديهم عن 20عاما (OR=1.9, P<0.001) , كذلك حقق المرضى ممن دخلهم الشهري 1500-3000 تحسناً أفضل في مستوى السكر مقارنة بمن دخلهم أكثر من 3000 شيكل (2.4, P<0.01 .(OR=

الخلاصة:تشير نتائج هذا التقييم إلى أن برنامج PEN Approach قد نجح في تحقيق جزءٍ من أهدافه بتنظيم وإدارة مرض السكري من النوع الثاني, حيث أن المرضى قد أظهروا انخفاضاً في مستوى السكر وارتفعت نسبة من حققوا أفضل تنظيم لمستوى السكر المطلوب.

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List of Abbreviations

ADA	American Diabetes Association
WHO	World Health Organization
HbA1c	Glycosylated Hemoglobin
DMT2	Diabetes Mellitus Type 2
PHC	Primary healthcare clinics
MoH	Ministry of Health
NCD	Non-communicable disease
PEN	Package of Essential Noncommunicable Disease
BMI	Body mass index
CVDs	Cardiovascular diseases
UNRWA	United Nations Relief and Works Agency
NGOs	Non-governmental organizations
EMME	Eastern Mediterranean and Middle East
IDF	International Diabetes Federation
PCBS	Palestinian Central Bureau of Statistics

Contents

Chapter One

Introduction

1.1 Background:

Diabetes mellitus type 2(DMT2) is one of the most occurring conditions of non-communicable diseases in the world. It spreads in developed countries as same as in developing countries, and causes rapidly growing public health problems (Chan, 2009). Harmful complications of DMT2such as, cardiovascular diseases, renal failure, retinopathy and neuropathies make it the fourth leading cause of death in the world (Roglic, 2005). According to WHO, DMT2 is the cause of 1.6 million deaths annually. In addition, 2.2 million deaths occurs yearly as a result of high blood glucose levels. Nearly 80% of these deaths occurred in low and middle-income countries (WHO, 2013).

DMT2 is a chronic progressive disease characterized by elevated blood glucose levels (hyperglycemia) (Michael, 2008). WHO has defined DMT2 as "group of metabolic disorders characterized by hyperglycemia, occurs either when the pancreas does not produce enough insulin or when the body cannot effectively use the insulin it produces"(Fowler,2008).

There are many types of diabetes and the classification of these types depends on the presumed etiology that leading to diabetes. Most common known are type 1 and type 2, other types less common occurred like gestational diabetes (IDA, 2012).

DMT2 accounts for the vast majority of people with diabetes around the world. It results from the insulin resistance in the liver and skeletal muscles, it also characterized by relative insulin deficiency due to Beta cells failure. Patients can manage type 2 diabetes initially by modifying some behaviors related to exercise and diet, but many of them need to take drugs or insulin to control the condition (Stumvoll M, 2005).

Risk factors for DMT2 is divided into two categories, modifiable and non-modifiable risk factors. Modifiable risk factors include contributing factors related to person's behaviors like physical inactivity, diet, smoking, and obesity (Badran, 2012). Different measures are recommended to assess diabetes control, one of these measures is testing glycosylated hemoglobin (HbA1c) (ADA, 2012).

Non-communicable diseases (NCD) burden is increasing more rapidly in lower income countries and populations (WHO, 2017). Consequently, the World Health Organization (WHO) had introduced an innovative and action-oriented response called "the Package of Essential Noncommunicable Disease Interventions (PEN).The PEN approach uses the primary health care (PHC) units to prevent and control NCDs, and can be applied especially for low-resource settings. It makes sure supplying a set of needed interventions of acceptable quality and cost effectiveness. As diabetes mellitus is one of NCDs widely spread globally, PEN Approach can also be considered as appropriate protocol for diabetes management especially in low-income societies (WHO, 2010).

Implementation of PEN Approach is an essential part of the objective 4 of the Global Action Plan (2013-2020) which stated "strengthen and orient health systems to address the prevention and control of noncommunicable diseases and the underlying social determinants through people centered primary health care and universal health coverage" (WHO,2013). This implementation of the approach will allow early detection and management of non-communicable diseases.

Health impact objectives of PEN protocol have been beneficial on health through reduction of tobacco consumption in NCD patients; reduction of the average delay in the diagnosis of NCD by the health services (i.e. reduction of the risk of heart attacks, strokes, amputations and kidney failure); reduction of case fatality of major NCDs, prevention of acute events and complications and prolongation of the duration of stable clinical periods for CVDs, diabetes, asthma patients (WHO, 2010).

In Palestine, as a lower-middle income country, the Ministry of Health (MoH) took responsibility to implement PEN approach in order to manage and control non-communicable diseases. Palestine was the second country started applying PEN approach after Sri-Lanka. First training on protocol was conducted in September 2012 in Salfit district. Actual implementing of the program started in 2013 in Salfit district then, in most PHCs of West Bank cities by the end of 2015.

1.2 Study problem:

Health services in Palestine are provided by several organizations: the MoH, the United Nations Relief and Works Agency (UNRWA), Non-governmental organizations (NGOS) and the private sector. Health system in Palestine is challenged by a variety of obstacles due to the current political and economic situation, some of the specialized tertiary health care services are still provided by overseas providers.

Chronic diseases are considered a major burden on health systems, in general, where patients are in need for care for the whole of their lives. In addition to the high probability of complications if chronic cases are not being controlled and managed properly. This would also has a high financial burden on people and health care system (ADA, 2012).

To manage and control chronic diseases in Palestine the MoH adopted the Package of Essential non-communicable (PEN) approach. After introducing the PEN program in all health departments in 2015, the health status of diabetic patients who were being monitored by the PEN approach had not been assessed. It is necessary to assess the impact of PEN Approach on health status of these patients to detect the efficiency of the PEN Approach in managing and controlling diabetes.

There is no studies in Palestine aimed to evaluate health outcomes of PEN approach, which is the only protocol for managing diabetes in the governmental sector. This study aimed to assess health outcomes and changes in risk factors of patients with diabetes who attending the PEN approach.

1.3 Study justification:

DMT2 and its complications are among the most important health issues facing the health sector in general, the prevalence rate in 2000 was 10.5% and in the last 10 years the numbers of diabetic patients visiting the clinic have doubled, where a report issued by the MoH in 2015 has indicated that the prevalence of diabetes in Palestine is 12% (MoH, 2015).

The PEN Approach program aims to manage and control the health status of diabetic patients through committing to a group of protocols that monitor the patient and the medication they use and the required examinations that ordered at specific schedule. This program relies majorly on directing the patient through counseling and providing the accurate information about risk factors which usually links to the life style (WHO, 2010).

The health status of Palestinian patients need to be evaluated, especially, it has been two years since the full implementation of the program in all governorates. The study importance stems from the seriousness of the diabetes, one of the major causes of death in Palestine (MoH, 2015).

This study would provide preliminary information to decision makers and officials about the efficiency of the PEN program in managing diabetic patients, and the need to take the results into account when making decisions related to the development and sustainability of this program.

1.4 Study objectives:

The study aim was to evaluate the effectiveness of PEN Approach in controlling diabetes among DMT2 patients following the adopting Approach in the MoH clinics in the West Bank.

1.5 Specific objectives:

- To assess diabetic patients' anthropometric measurements (height, weight, BMI and waist circumferences, blood pressure) and laboratory tests (HbA1c and cholesterol) among patients following introducing the PEN approach. Readings will be taken at the beginning, after one year and after two years of following the approach.
- To estimate burden of complications of diabetes such as eye, foot, heart and kidney complications among patients following the PEN approach.
- To examine possible changes in some diabetes risk factors; BMI and cholesterol, also examine other factors in current situation; smoking, physical activity, and diet among patients following the PEN Approach.
- To assess the association between characteristics of patients following the program also the changes in the physical measurement and glycemic control represented by HbA1c.

1.6 Study limitations:

- Study mainly depends on patients' files, and some files may be not completed or were not properly documented especially for physical measurements of patients.
- The study is a cross-sectional study, cause- effect relationship can't be determined between dependent and independent variables.

Chapter Two

Literature Review

2.1 Epidemiology of Type 2 diabetes mellitus:

2.1.1Diabetes worldwide

DMT2is a common worldwide health issue. WHO estimates that globally, 422 million adults were living with diabetes in 2014. The number of diabetic patients has continuously increased over the past few decades, due to population growth and increase in the lifespan of the population. Universally, between 1980 and 2014, number diabetic patients has substantially increased from 108 million to four times higher, and the prevalence has grown from 4.7% to 8.5%. According to WHO, DMT2 is reported as a sixth leading cause of death in the world (WHO, 2017).

An estimation of the prevalence of diabetes for 2010 and 2030 reported that North America has the highest prevalence of type 2 diabetes mellitus for 2010 at a prevalence rate of 10.2%, followed by the Eastern Mediterranean and Middle East (EMME) and South Asia at a prevalence of 9.3% and 7.6% respectively (Shaw, 2010).In 2011, many countries in the Arab world had a high prevalence of DMT2, and some Arab countries were classified in the top 10 countries in the world regarding to the International Diabetes Federation (IDF).

Furthermore, the 2016 Annual report of the United Nations Relief and Works Agency (UNRWA) had reported that the prevalence of Type 2 diabetes mellitus among the refugees population aged

40 years and above was 12.1% compared to 10.5% in 2010. The report also revealed that the West Bank field (15.9%) had the highest rates of DM, followed by the Gaza Strip (12.9%), Jordan (11.5%), Syria (11.1%) and Lebanon (8.4%) (UNRWA, 2016).

2.1.2 Diabetes in Palestine

Diabetes mellitus is a major health challenge to health system in Palestine. In 2000, the prevalence of DMT2 was 9% among adults (MoH, 2006). Data from the STEPwise survey in West Bank (2010-2011) showed that the prevalence of DM is 12.7% in adults, 14.2% and 11.1% among males and females respectively. Same STEPwise survey reported that 9 out of every 10 Palestinians have at least one risk factor for a non-communicable disease (WHO, 2012). About 58% of men and women aged 15–64 are overweight and of these, 27% are obese, 75.3% do not exercise and 20% are currently smoking (WHO, 2012).

According to WHO, The number of new cases in Palestine reported annually, has ranged from 150 to 220 per 100,000 population, but reported cases are considered to represent half of actual cases (WHO, 2016).

A study was conducted in 2013 by Abu-Rmeileh provided estimates for future diabetes prevalence in the West Bank. It predicted that prevalence of DMT2 will be 20.8% for 2020 and 23.4% for 2030. A 2.8% reduction in diabetes prevalence could be achieved if obesity trends start to decline by 5% in a 5-year period (Abu-Rmeileh 2013).

2.2 Type 2 diabetes mellitus Management:

2.2.1 Glycemic control:

Glycosylated Hemoglobin (HbA1c) was used to examine diabetes control since it reflects glycemic situation of the patient during previous three months. According to ADA, controlled glycemia is achieved by value of HbA1c less than 7%. Currently, HbA1c test is considered as a standard parameter used to manage DMT2 properly, and an indicator to predict diabetes complications (Martin, 2006;Woerle, 2007).

Various studies have pointed out the significance of strict glycemic control to have HbA1c less than 7% for diabetic patients in order to reduce the risk of developing micro-vascular and macro-vascular complications. These studies showed that diabetes related complications can be avoided by controlling and managing glycemic levels (Ozcelik, 2010; Benhalima, 2011; ADA, 2012).

The United Kingdom prospective diabetes study (UKPDS) demonstrated that the reduction in the HbA1c level by 1% will reduce the risk of micro-vascular complications by 37% (Stratton, 2000). This reduction will be life-long if patient control HbA1c to < 7% in a short time after diagnosis (ADA, 2011).

In Palestine, a survey performed by Birzeit University in 2012, to study management, complications and quality of life among patients with DMT2. The results indicated a high prevalence of complications related to DMT2 in Ramallah governorate clinics. It also showed a significantly higher ratio of un-controlled patients (HbA1c ≥7%) with retinopathy, nephropathy and neuropathy in contrast to others with HbA1c less than 7% (Mikki, 2012).

2.2.2 Behavioral modifiable risk factors:

- **Body Mass Index (BMI)**

Increased Body mass index (BMI) is a strong risk factor for diabetes and insulin resistance. In an obese individual, the amount of substances that are involved in the development of insulin resistance are increased. Insulin resistance with impairment of β-cell function leads to the development of diabetes (Valdes, 2007; Lyssenko, 2008; Al-Goblan, 2014). Previous studies demonstrated that weight loss will lead to progressive decline in HbA1c levels (Muchmore, 1994). The Nurses' Health Study, began in 1976 and proceeded for 16 years of follow-up, had registered 3300 new cases of DMT2 from 121,700 participants. The most important predictor of diabetes was overweight or obesity. The relative risk of diabetes was 38.8% for women with a body-mass index of 35.0 or higher and 20.1% for women with a body-mass index of 30.0 to 34.9 in comparison to women with a body-mass index less than 23.0 (Hu FB,2001).

A study conducted in West Bank, showed a relationship between obesity and central obesity and some morbidities including DMT2. Significantly higher prevalence of central obesity among men rather than women (Abdul-Rahim, 2001).

- **Smoking**

Several prospective studies reported that smoking is a risk factor for developing DMT2 (Gress, 2000;Kumari, 2004). This could be due to the direct effect of nicotine or other components of cigarette on beta cells of the pancreas as suggested by the association of cigarette smoking with chronic pancreatitis and pancreatic cancer (Talamini, 1999).

A prospective study was conducted in UK (2001) reported that cigarette smoking was associated with a significant increase in risk of diabetes. Even after adjustment for age, BMI, and other

potential confounders. The benefit of giving up smoking was only apparent after 5 years of smoking cessation (Goya Wannamethee, 2001). A meta-analysis including 25 prospective studies showed that current smoking was associated with a 44% increased risk of diabetes (Willi, 2007). In Saudi Arabia, a survey showed that diabetes appears to be significantly associated with daily smoked tobacco products (Saeed, 2012).

- **Physical inactivity**

Physical activity is a major parameter in DMT2 management. Recommendations advised diabetic patients to do exercises 150 min/week of moderate –intensity activity. Exercises play an important role in improving blood glucose levels, decrease risk to cardiovascular diseases and help in weight loss (Weinstein, 2004; Fretts,2009).

Longitudinal studies have found physical inactivity to be a strong risk factor for type 2 diabetes (Fretts,2009;Gimeno, 2009). Evidence from clinical trials, which included physical activity as an integral part of life style interventions, suggested that onset of type 2 diabetes can be prevented or delayed because of successful lifestyle interventions that included physical activity as a part of this interventions (Pan, 1997; Tuomilehto, 2001; Ramachandran, 2006).

Although regular physical activity (PA) may prevent or delay diabetes and its complications, most people with type 2 diabetes are not active (Colberg, 1996; Balducci, 2006;Morrato, 2007).

In meta-analysis study conducted to evaluate the effects of exercise interventions in patients with type2 diabetes reported that most of the studies concluded that HbA1c mean levels have declined in intervention group compared to control group (Boulé, 2001).

- **Dietary pattern**

Controlled dietary pattern is an important element in prevention and management of DMT2 Recommendations to diabetic patients is to follow a healthy diet which includes dietary habits and managing meals times (Yannakoulia, 2006)

Positive association hasbeen reported between the risk of DMT2 and different patterns of food intake (Schulze, 2004; Liese, 2009). A review on the role of fats and carbohydrates on type 2 diabetes concluded that a higher intake of polyunsaturated fat and possibly long-chain fatty acids could be beneficial. Whereas, a higher intake of saturated fat and trans-fat could adversely affect glucose metabolism and insulin resistance (Hu, 2001). In addition, a low-glycemic index diet with a higher amount of fiber and minimally processed whole grain products reduces glycemic and insulinaemic responses and lowers the risk of DMT2. This leads to a conclusion that, to prevent and manage diabetes, a greater attention should be drawn on the quality of fat and carbohydrate in the diet than quantity alone (Hu, 2001). Another studies showed that higher consumption of fruits and vegetable was associated with reduced risk of DMT2 (Montonen, 2005).

A longitudinal study conducted among men demonstrated that higher consumption of processed meat was related with a higher risk for DMT2 (relative risk=1.46, for more than five times a week vs. less than once per month, $p<0.0001$) (Van Dam, 2002). Another study suggested that limiting the amount of red meat as compared to chicken had a significant effect on HbA1c,fasting blood glucose and cholesterol levels (Gross, 2002)

Progressive improvements in HbA1c levels decreased by 1-2% in DMT2 patients when they followed up by dietitian after three to six months (ADA, 2008).

Policies and programmes focusing on reducing the burden of these common risk factors are very critical to decrease rate of diabetes. Early management of non-communicable diseases risk factors help avoiding its complications. The quality of life will improve and the expenditure on the secondary (curative) care will be decreased (WHO, 2011)

2.3 Evaluating Studies:

Evaluation studies have been conducted in many countries to evaluate health programmes. In NCDs field, studies were conducted to evaluate health outcome of approaches used to control and manage non-communicable disease.

Some studies showed a better progression of type 2 diabetes patients after a period of management and follow up. In Norway, a study was carried out to assess changes in the quality of care for patients with type 2 diabetes. Two cross-sectional surveys were used to examine and identify patients with type 2 diabetes who attended selected clinics between 1995 and 2005. Significant improvements were observed among patients by their smoking habits, height, weight, and referral to eye examination. Mean HbA1c decreased from 7.74 to 7.15%, systolic blood pressure from 150 to 140 mmHg, and cholesterol from 6.28 to 5.0 mmol /l ($P < 0.001$)(Cooper, 2009).

In Bhutan (2014), a descriptive study was conducted to evaluate the performance of the PEN project in detecting and managing NCDs and their risk factors. Data were collected from the clinical forms, supervisor's report and monthly reports of the PEN project. Results showed that among 444 patients who had three follow-up visits, high 10-year-CVD risk (>20%) had declined from 13% to 7.3%. Among 400 patients with hypertension, adherence to medications was

increased and high blood pressure declined from 42.3% to 21.5%. Among 115 patients with diabetes, adherence to medications was increased and high blood sugar declined. The study concluded that implementation of the PEN intervention in the primary health care settings of Bhutan led to improvement in blood pressure and diabetes control and reduction in CVD risk (Wangchuk, 2014).

A retrospective cohort study was carried out in Jordan (2012) aimed to report outcomes and complications of type 2 diabetes mellitus among Palestinian refugees in Jordan. The results indicated that 71–78% of patients had blood glucose ≤180 mg/dl; 63–74% had cholesterol <200 mg/dl; and about 90% had blood pressure <140/90 mmHg. Obesity remained constant at 50%. The proportion of patients with late-stage complications increased from 1% at baseline to 7% at 1 year, 14% at 2 years and 15% at 3 years (Khader, 2012).

In Korea, a study has been conducted in 2017 to check outcomes of piloting WHO PEN protocols and assess the feasibility of integrating PEN Approach into the local primary healthcare system. The study concluded that the primary healthcare clinic doctors were able to detect and control risks for diabetes and cardiovascular disease after training to use the protocols of PEN Approach. Among 18,340 individuals aged over 35 years, implementation of WHO PEN interventions led to a significant reduction in the percent of people with a 10-year risk of cardiovascular disease ≥20% (from 9.5% to 3.0%) over a 1-year period. Patients with fasting blood glucose level of >7 % declined from 27.7% to 10.0% and the blood cholesterol level of >6.6 mmol/L declined from (10.7%) to (3.2%) among individuals included in study (Hyon, 2017).

Chapter Three

Conceptual framework

3.1 Introduction:

This chapter discusses the conceptual framework of the study, it also present dependent and independent variables.

3.2 Independent variables:

3.2.1 Socio-demographic variables:

- **Age:** represented in files by date of birth, researcher use it to calculate respondent's age.
- **Sex:** categorized into "male" and "female" to check sex association withHbA1c.
- **Marital status** this variable was categorized into four groups, constructed as follows: 'single', 'married', 'divorced' and 'widowed'.
- **Level of income:** Categorized into three categories according to PEN files classification "less than 1500 Sheikls", "1500-3000", "more than 3000".
- **Level of education:** The educational level of patients was constructed into four categories that represent the educational level in Palestine: "illiterate", "primary school", secondary school", and "university".
- **Place of residency**: categorized into urban/rural/camp was based on the 2007 Palestinian Central Bureau of Statistics (PCBS) classification (PCBS, 2007).
- **Employment:** categorized into "employed" and "unemployed" regardless work type.

3.2.2Variables of Disease-Related Characteristics:

- **Disease duration:** registered in files as date of diagnosis, calculated and categorized into "less than5", “6-10”, “ 11-15”, “16-20”, “more than 20” years according to previous study conducted in Palestine to evaluate applied programme for diabetes management in Augusta Victoria hospital(Khatib, 2013).
- **Medications:** the treatment type that patient has taken categorized into “oral tables”, “insulin”, and “mixed”.
- **Diabetes complications:** diabetes complications including; neuropathy, nephropathy, diabetic foot, dyslipidemia, hypertension, eye problems.

3.2.3 Laboratory tests and physical measurements:

- **Cholesterol:** total cholesterol is analyzed and its results registered in patients files, reference value for total cholesterol should be less than 200 mg/dl (Roth, 2010). Cholesterol test should be done for each patient once a year at least, and if there is a need could be more according to PEN protocols.
- **Blood pressure:** blood pressure measurements of systolic and diastolic readings. Normal values for blood pressure is lower than 138/80 mmHg (WHO, 2012). Blood pressure readings should be taken every visit according to PEN protocols.

- **Waist circumference:** provides an estimate of body girth at the level of the abdomen (Klein, 2007). Waist circumference cutoff values for substantially increased in diabetes

mellitus risk are102cm for men and 88cm for women according to WHO (WHO, 2012). Waist circumference measurement is taken every visit according to PEN protocols.

3.2.4 Diabetes risk factors:

- **Body Mass Index (BMI):** an index used to examine obesity condition of individuals, it is calculated through dividing weight in kilograms by square of height in centimeters. Persons who have BMI ≥25 classified as overweight, BMI ≥ 30 classified as obese (WHO**,** 2004).Files reported patients weight every visit and height in the first one.
- **Physical activity:** basic part of STEPwise questionnaire related to physical activity is used to describe physical activity of participants.
- **Dietary pattern:** basic part of STEPwise questionnaire related to diet is used to describe dietary pattern of participants, questions related to daily intake of fruits and vegetables, and consumption of processed food.
- **Smoking:** participants were asked if they are current smokers or not, also if they smoked previously and had stopped stop, how many cigarettes they smoke daily. Check annex 1 and 2.

3.3 Dependent variable: Glycosylated hemoglobin (HbA1c):

HbA1c is a blood test that reflects the average blood glucose during preceding two to three months. It shows the amount of glucose that stick to hemoglobin which is proportional to glucose levels in blood (ADA, 2012). According to ADA, individuals with HbA1c levels less than 7% is classified as "good controlled", and others who's HbA1c level equal or more than 7% are classified as "poorly controlled" (ADA, 2007).

The general concept to measure glycated hemoglobin is to separate the glycated from nonglycated hemoglobin and quantify its' amount. This separation based on charge differences; ion-exchange chromatography, high performance liquid chromatography (HPLC), electrophoresis and isoelectric focusing, or chemical analysis; photometry and spectrophotometry, or structural differences; affinity chromatography and immunoassay (Sacks DB, 1994).

The reference method to measure HbA1c is high performance liquid chromatography (HPLC), many studies concluded that some methods of measuring HbA1c may give results away from HPLC results (Sack, 2012).

To overcome this issue, researcher contacting the quality control center in MoH check which method is used, and he assures that all labs used the same method to measure HbA1c which is boronat affinity chromatography. And there is a periodically check for quality control of HbAIc test for all MoH labs.

3.4 Conceptual framework:

The conceptual framework used in the study is provided in Figure (3.1).

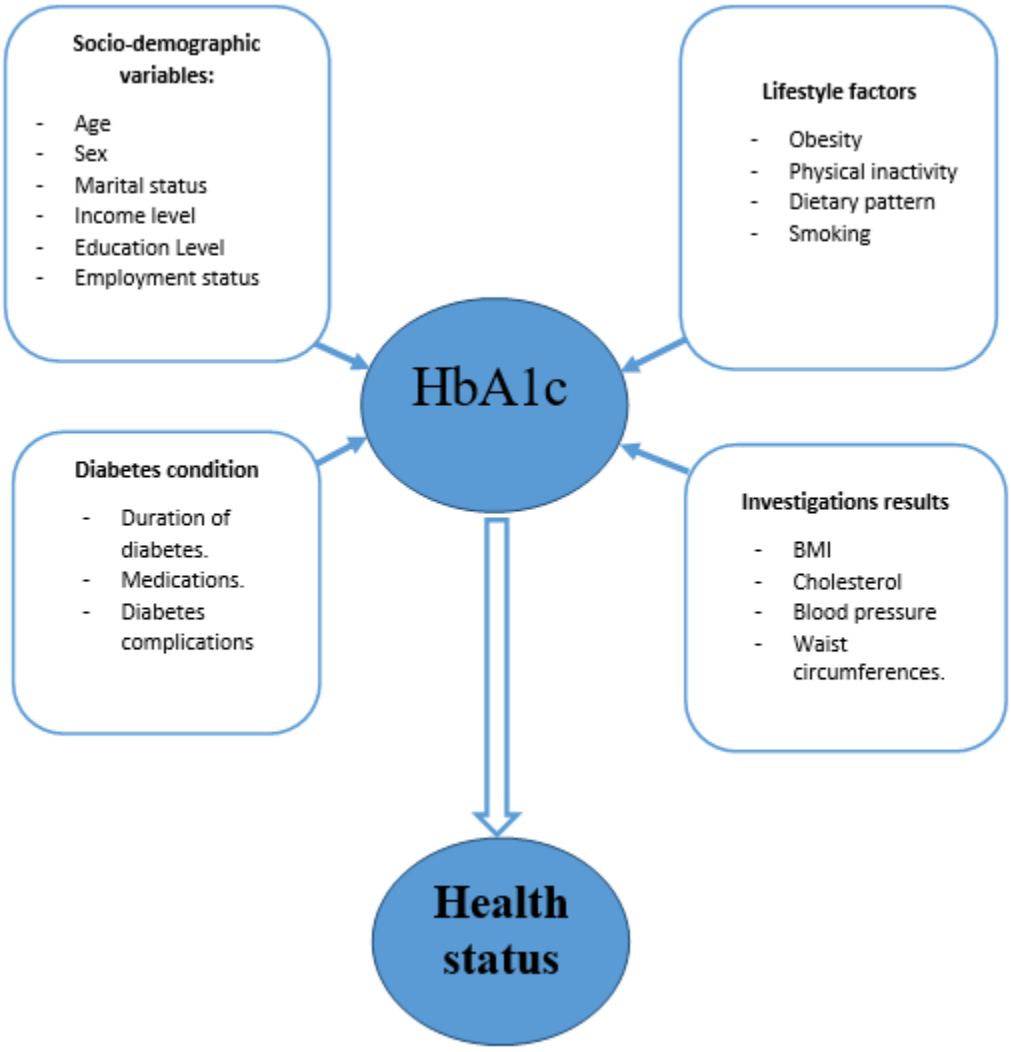

Figure (3.1): conceptual framework of study.

Chapter Four

Methodology

4.1. Introduction

The aim of this study was to evaluate glycemic control of DMT2 patients following PEN Approach in MoH health clinics. In this chapter, the research's methodology will be described including study design, study setting, sampling method and sample size.

4.2. Description of the PEN Approach used in Diabetes management

All patients attending the primary health care clinics who have type 2 diabetes mellitus are registered by the clinic nurse. In addition, all patients who are aged over 40 years are screened by asking about their lifestyles and measuring their blood pressure, height, weight and waist circumference. Patients who overweight or obese or have a high waist circumference (body mass index (BMI) ≥23 kg/m^2 or waist circumference >80 cm in women and >90 cm in men) undergo blood glucose testing.

A PEN clinical form is filled for patients who had DMT2, clinical laboratory counselling and medication data are recorded in the clinical form. This form has three sections:

- **Section I** records identification and sociodemographic data including sex, date of birth, income level, education level and marital status. In addition, clinical diagnosis including name of NCD disease and date of diagnosis are registered in this section.

- **Section II** records results of laboratory tests such as, fasting blood glucose (FBG), HbA1c and cholesterol. Blood pressure, weight and height measurements are, also, included in this section.
- **Section III** records medications and counselling data. A definitive date of follow up visits is entered in the clinical form.

During the follow-up visit, patient's clinical record is retrieved; clinical and laboratory investigations are performed according to PEN protocols and counselling provided and the data are recorded in the clinical form. Patients are asked whether they have taken all medications regularly since their last visit, and their prescriptions are refilled. Health workers entered patients' blood pressure, weight, and blood glucose test results in patients' files. Patients are expected to visit once every three months or more if needed.

4.3. Study Design

A cross-sectional quantitative study design was employed to achieve study objectives. This type of studies was used in the study case, since the researcher used patient's files mainly to collect data and ask patients some questions to get complete needed data.

4.4. Sampling methodology

Two stage-stratified sampling was employed. West Bank area was divided into three strata: North, Middle and South areas. From each strata, a random selection of one governorate was adopted

(North, Jenin; Middle, Ramallah, and South, North-Hebron). In addition to the central governmental clinic. Also, two village clinics were selected randomly from each directorate.

Within the clinics, a purposive sampling method was used in the selection of patients. . In this technique, the researcher included all patients who came to clinics during the study period and met the study inclusion criteria.

Sample size was calculated by using Raosoft® sample size calculator, the minimum recommended sample size was 381participants. The study sample included 500 participants to overcome any effects related to study design. Check tables (4.1) and (4.2).

Table 4.1: Sampling frame of the study.

Palestinian Strata	**Governorate**	**Number of patients (Sample)**
North	Jenin	11,596
Middle	Ramallah	5,419
South	North- Hebron	5,068
Total in West Bank		35,236

Inclusion criteria:

- Patients diagnosed with DMT2 who are registered on PEN Approach and had spent at least two years in the programme were included.

Exclusion criteria:

- Patients diagnosed with any type of diabetes other than DMT2, and patients who had spent less than two years in the program were excluded.

Table (4.2): Sample size from each Governorate:

Area	Frequency	Percentage
North (Jenin)	209	43.5%
Middle (Ramallah)	130	27%
South (North Hebron)	142	29.5%
Total	481	100%

4.5. Settings of the study

The study was conducted in the West Bank, specifically in primary health care units (PHC) of Ministry of Health. Because the PEN Approach is applied in PHCs as a first line for managing and controlling DMT2 in governmental sector.

4.6. Instrument of the study:

The study instrument consisted of two parts, one developed by researcher to get the needed data from PEN files including the socio- demographic information of patients, values of diabetes controls includes blood glucose, HbA1c, cholesterol, body mass index (BMI) and blood pressure. Readings of those controls will be taken at baseline, after one year, and after two years. Also, the first part included data related to any complications associated to diabetes such as eye, foot, heart and kidney complications. And follow up, education, and medications information.

The other part included data related to diabetes risk factors and not available in PEN files, were collected by STEPwise questionnaire (STEPS Instrument.Version 3.2) for non-communicable diseases risk factors surveillance (Arabic version).

4.7. Data collection:

A permission to collect data from PEN files was received from the MoH as a first step in the data collection phase. Study instrument consisted of two parts, data collection from files by researcher, and structured questions for patients asked by researcher herself. Data collection process was conducted between October to December 2017. The consent form was attached to each questionnaire. Participants were informed about the aim of study, the confidentiality of data collected and the voluntarily participation.

4.8 Data Analysis

Data was analyzed by using Statistical Package for Social Sciences (SPSS® version 23.0). At the first phase, statistical descriptive analysis was conducted for demographic data, anthropometric measurements and diabetes controls. At the second phase, univariate analysis was applied including; One-Way ANOVA of repeated measures was used to check if there is a significant change in HbA1c, cholesterol, and BMI means. Chi-Square test was used to examine the relationship between independent variables and dependent variable. At the third phase logistic regression model was conducted for variables that showed significant association with HbA1c change.

4.9 Validation of the instrument

The instrument of the study was obtained from STEPwise Approach questionnaire which is used by WHO to measure risk factors of non-communicable diseases that included type 2 diabetes mellitus. Other part related to socio-demographic anthropometric measurements, and diabetes controls were selected regarding to previous studies (Khader, 2014). Instrument as a whole was reviewed by experts in the research field and others directing PEN Approach applying from WHO and MoH.

4.10 Ethical consideration:

- The research committee of School of Public Health at Al-Quds University provided ethical approval to conduct this study.
- Ministry of Health provided permission to perform the study and collect data in its clinics.
- All patients provided verbal and written consent to participate in the study before data collection.

Chapter Five

Results

5.1 Introduction:

This chapter includes the study findings. Socio-demographic characteristics of participants, results related to diabetes characteristics and risk factors. In addition, results of statistical analysis for associations between dependent and independent variables.

5.2 Descriptive analysis:

5.2.1 Socio-demographic characteristics of the participants:

The response rate of study was 96.2%, 481 participants of 500 were included in study while other 19 participants were excluded since they refused to participate.

More than half of them were females (56.1%). The mean age of the participants was 60 years. Two-3rds of the participants lived in rural areas. One quarter of the participants were illiterate (27.7%), around half of participants (43%) finished their primary education. Almost half of the participants (48.2%) had a monthly income less than 1500 shekels. The majority of the participants (79%) were unemployed and (79%) of the participants are married (79.8 %) as shown in table (5.1).

Table (5.1): Socio-demographic distribution of participants.

Variable	Frequency	Percentage
Sex		
Male	211	43.9%
Female	270	56.1%
Age		
≤50	87	18.1%
51-60	170	35.3%
61-70	145	30.1%
>70	79	16.4%
Residency		
Urban	152	31.6%
Rural	329	68.4%
Education level		
Illiterate	133	27.7%
Primary school	208	43.2%
Secondary school	82	17%
University	58	12.1%
Income Level		
<1500	232	48.2%
1500-3000	197	41%
>3000	52	10.8%
Employment		
Yes	97	20.2%
No	384	79.8%
Marital Status		
Single	25	5.2%
Married	384	79.8%
Widowed	54	11.2%
Divorced	18	3.7%

5.2.2 Diabetes-related characteristics:

- **Disease Duration:** the mean duration of diabetes among participants was 9.4 years. One 3rd of participants have diabetes for five years or less, while around a quarter of the participants (23.9%) had diabetes for 6-10 years as shown in figure (5.1).

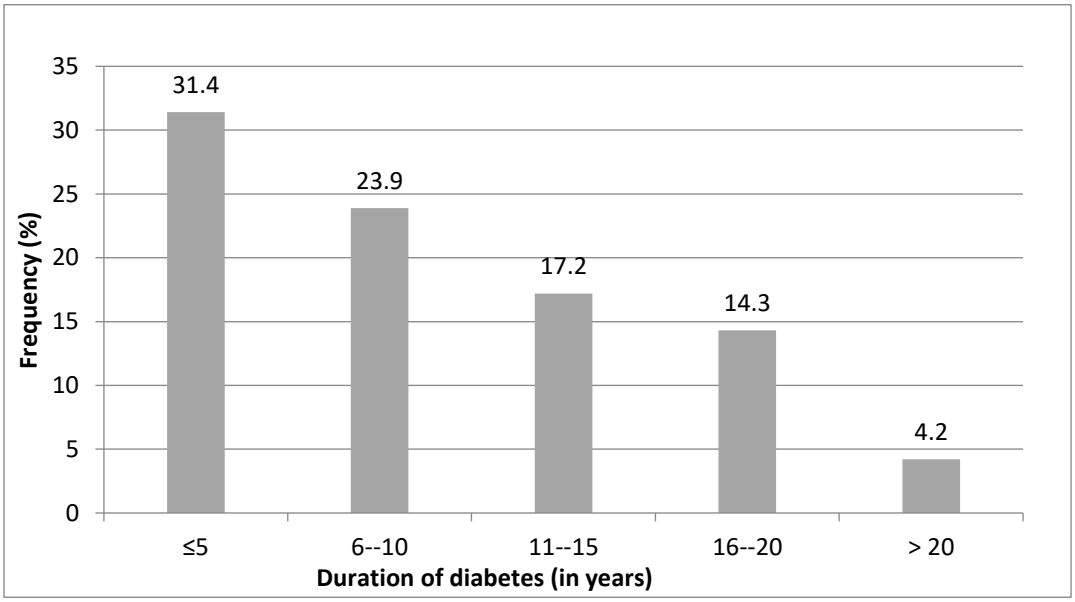

Figure (5.1): Distribution of diabetes history among participants (%)

- **Diabetes complications**: nearly half of the participants (47.2%) have neuropathy, while one 3rd of them (36.4%) have hypertension, and (35%) have dyslipidemia. Figure (5.2) shows all diabetes complications among participants.

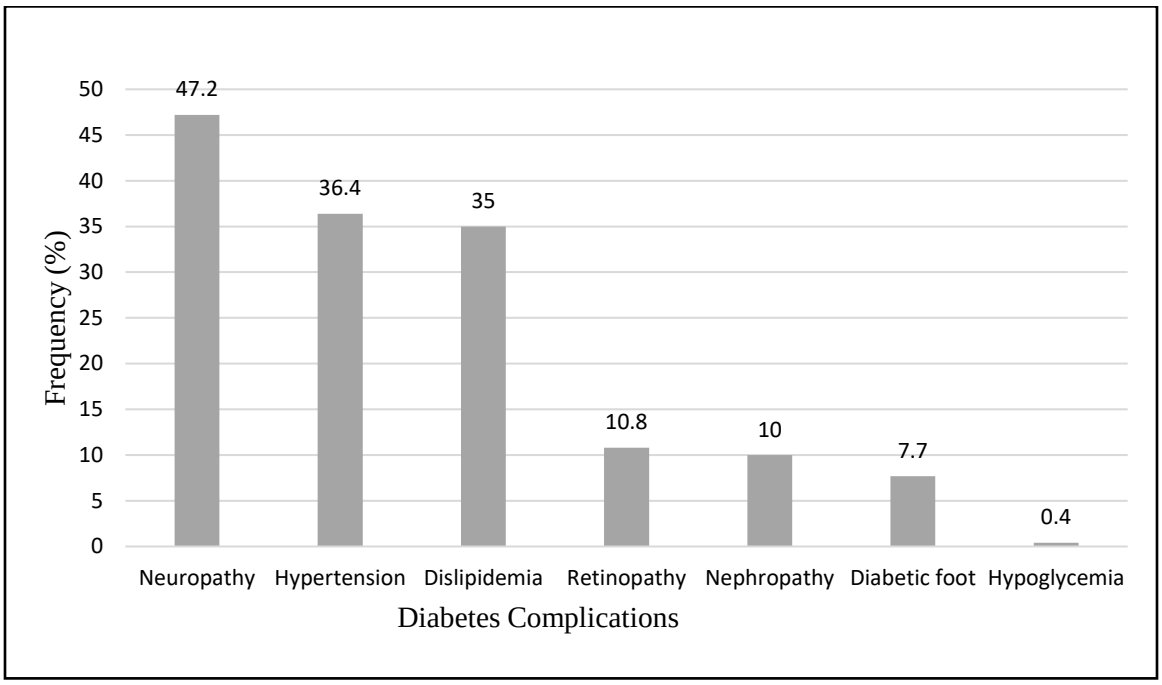

Figure (5.2): Percentage of diabetes complications among participants.

- **Diabetes Treatment:** the majority (76%) of patients are treated by oral tablets, while (10.6%) are treated by insulin only and (13%) are treated by insulin and oral tablets together.

5.2.3 Diabetes risk factors distribution:

- **Diet:**

The average mean of days in which patients eat fruits and vegetables were 6.5, 6.8 days respectively. In addition, the means of consumed serving units of fruits and vegetables during these days were 1.4, 1.6 days respectively. The majority of patients didn't add salt to the food and didn't eat processed food. See tables (5.2, 5.3) for more details.

Table (5.2): Dietary habits, fruits and vegetables consumption

Habit	Mean	SD
1- In a typical week, on how many days do you eat fruit?	6.49 days	0.692
2- How many servings of fruit do you eat on one of those days?	1.37 servings	0.522
3- In a typical week, on how many days do you eat vegetables?	6.79 days	0.450
4- How many servings of vegetables do you eat on one of those days?	1.63 servings	0.523

Table (5.3): Dietary habits, salt and sauce consumption.

Habit	Frequency (%)					
	Always	Often	Sometimes	Rarely	Never	Don't know
5- How often do you add salt or a salty sauce such as soy sauce to your food right before you eat it or as you are eating it?	2 (0.4)	5 (1)	13 (2.7)	117 (24.3)	344 (71.5)	0 (0)
6- How often do you eat processed food high in salt? By processed food high in salt, I mean foods that have been altered from their natural state, such as packaged salty snacks, canned salty food	0 (0)	4 (0.8)	28 (5.8)	61 (12.7)	388 (80.7)	0 (0)

- **Physical activity:**

Most of patients don't do moderate or vigorous-intensity activity (96.6%). The majority of the participants walk walking for at least 10 minutes a day (83.6%). The mean time of sitting (sedentary) per day was 3 hours. For more details check table (5.4). Analysis of physical activity according to Global Physical Activity Analysis guide shows that 83.1% of patients don't meet the recommended MET value by WHO which shouldn't be less than 600 minutes per week (WHO,

Table (5.4): Participants physical activity (n = 481).

No.	Physical Activity	Frequency (%)	
		Yes	**No**
1	Does your work involve vigorous-intensity activity that causes large increases in breathing or heart rate like [carrying or lifting heavy loads, digging or construction work] for at least 10 minutes continuously?	95 (19.8%)	386 (80.2%)
2	Does your work involve moderate-intensity activity that causes small increases in breathing or heart rate such as brisk walking [or carrying light loads] for at least 10 minutes continuously?	16 (3.4%)	461 (96.6%)
3	Do you walk or use a bicycle (pedal cycle) for at least 10 minutes continuously to get to and from places?	402 (83.6%)	79 (16.4%)
4	Do you do any vigorous-intensity sports, fitness or recreational (leisure) activities that cause large increases in breathing or heart rate like [running or football] for at least 10 minutes continuously?	0 (0%)	481 (100%)
5	Do you do any moderate-intensity sports, fitness or recreational (leisure) activities that cause a small increase in breathing or heart rate such as brisk walking, [cycling, swimming, volleyball] for at least 10 minutes?	0 (0%)	481 (100%)

- **Smoking:**

Most of the patients were non-smokers 94.8%, while only 5% were smokers.

5.3 Inferential analysis:

5.3.1 Body mass index (BMI) changes:

One- way ANOVA of repeated measures releaved that there is no significant difference between BMI levels in 1st, 2nd and 3rd visits (F= 2.74) (P<0.06).

5.3.2 Cholesterol levels changes:

Analysis by One- way ANOVA of repeated measures show there was a significant difference between cholesterol levels in 1st , 2nd and 3rd visits (F= 5.03) (P<0.00).levels of cholesterol have decreased from 1st visit to 3rd one. Check figure 5.3.

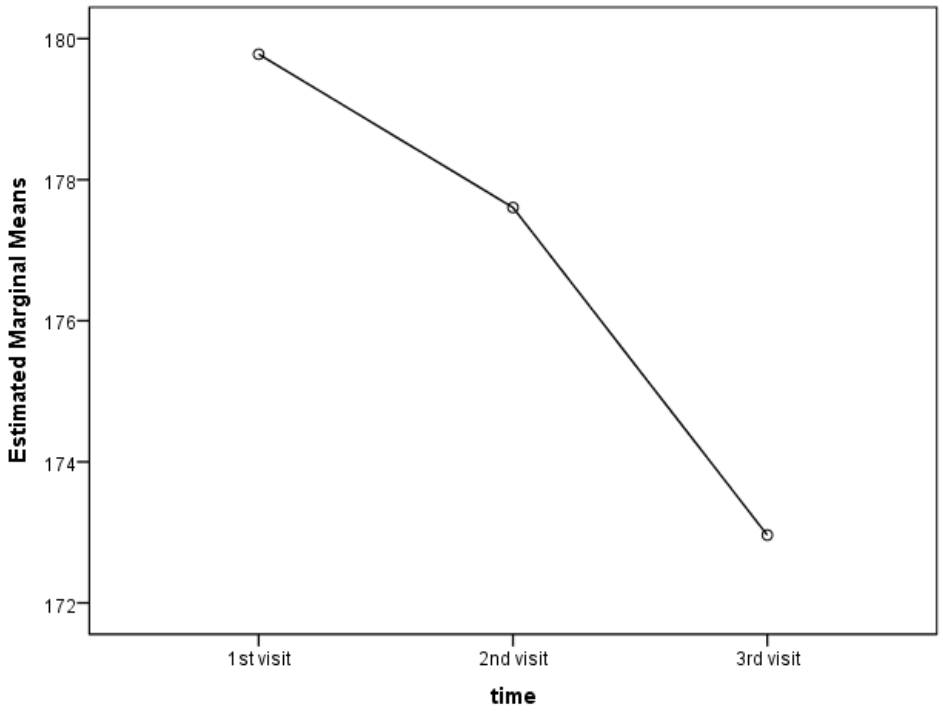

Figure (5.3): Estimated Marginal Means of Cholesterol

5.3.3 Blood pressure:

One- way ANOVA of repeated measures releaved that there is a significant difference in systolic and diastolic blood pressure levels between 1st, 2nd, and 3 rd visit (F =9.97) (P< 0.00), (F= 9.05)(P< 0.00) respectively.

Results showed that patients with good systolic pressure (<130mmHg) percentage was decreased between the 1st to the last visit. While patients with good diastolic pressure (<80mmHg) was increased from 1st to 3rd visit (table 5.5).

Table (5.5): Distribution of good and bad blood pressure in 1st and 3rd visit.

	Frequency (%)
Good systolic 1st visit	152 (31.6)
Good systolic 3rd visit	119 (25.4)
Good diastolic 1st visit	168 (35)
Good diastolic 3rd visit	247 (52.63)

5.3.4 Waist circumference:

One- Way ANOVA of repeated measures shows statistically significant difference in waist circumference levels between 1st, 2nd and 3rd vists (F= 4.43) (P0.012<). Waist cirumfernce levels have been decreased from 1st visit to 3rd one. Check figure 5.4.

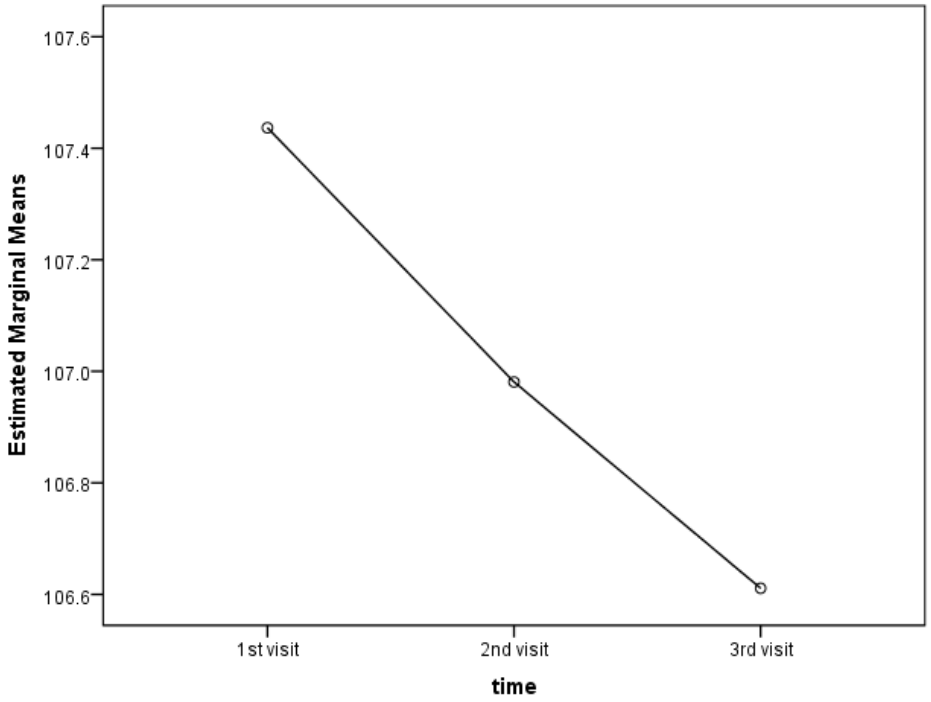

Figure (5.4): Estimated Marginal Means of waist circumference.

5.3.5 Changes in HbA1c levels among visits and distribution of controlled patients.

Results of analysis by One- Way ANOVA of repeated measures show that levels of HbA1c is statistically differes between 1st, 2nd and 3rd visits (F= 7.44) (P<0.001). Levels of HbA1c have been decreased from 1st vist to 3rd one , figure 5.5.

Results also show increase in percent of patients who achieve good glycemic control (HbA1<7%), from 1st visit (32.8%) to (38.7%) in 3rd visit (Graph 5.6).

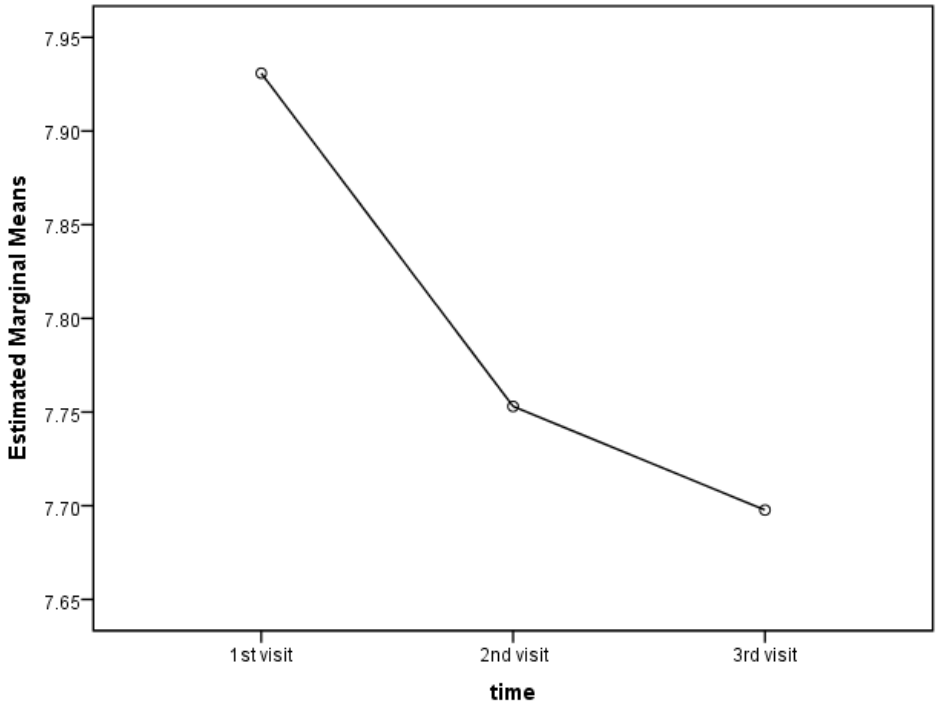

Figure (5.5): Estimated Marginal Means of HbA1c

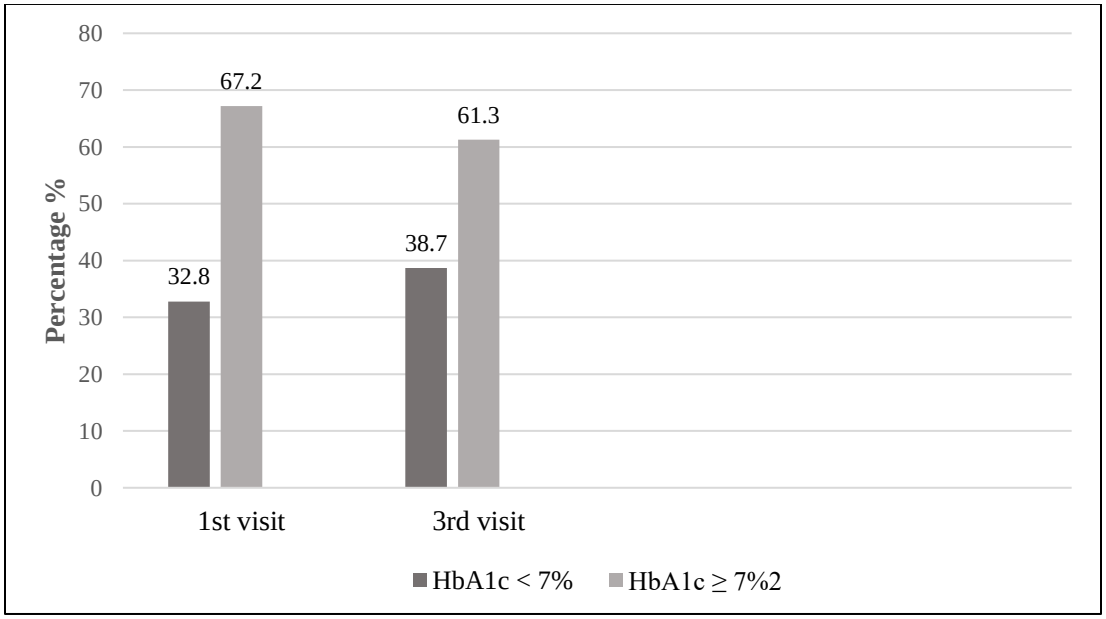

Figure (5.6): Distribution of controlled and uncontrolled patients in 1st and 3rd visits.

5.3.6 Association between HbA1c and independent variables:

Chi-square test was applied to check associations between independent variables and dependent variables. Patients were classified according to changes in HbA1c between 1st and 3rd visit, "Good HbA1c" if HbA1C was decreased, and "Bad HbA1c" if HbA1c was increased.

Results showed that sex was significantly associated with HbA1c (P< 0.01), age indicated significant association with HbA1c (P<0.001), disease duration was significantly associated with HbA1c (P<0.04), in addition, income level showed significant association with HbA1c changes (P<0.03). On the other hand, other variables wasn't significantly associated with HbA1c, including education level, marital status, place of residency, employment status, changes in BMI, physical activity, cholesterol and waist circumference (table 5.6)

Table (5.6): Associations between independent variables and HbA1c change.

Variable	Good HbA1c Frequency (%)	Bad HbA1c Frequency (%)	Chi square (p-value)
Sex Male	89 (42.1)	122 (57.8)	0.013*
Female	145 (53.7)	125 (46.2)	
Age (in years)			
≤50	59 (67.8)	28 (32.1)	0.00*
51-60	65 (38.2)	105(61.7)	
61-70	78 (53.7)	67 (46.2)	
>70	32 (40.5)	47 (59.4)	
Residency			
Urban	76 (50.0)	76 (50.0)	0.69
Rural	158 (48.0)	171 (51.9)	
Education level			
Illiterate	67 (50.3)	66 (49.6)	0.63
Primary school	95 (45.6)	113 (54.3)	
Secondary school	44 (53.6)	38 (46.3)	
University	28 (48.2)	30 (51.7)	
Income Level (in Shekels)			
<1500	103 (44.3)	129 (55.6)	0.03*
1500-3000	110 (55.8)	87 (44.1)	
>3000	21 (40.3)	31 (59.6)	

Table 5.6 continues

	Good HbA1c	Bad HbA1c	P value
	Frequency (%)	Frequency (%)	
Employment			
Employed	49 (50.5)	48 (49.4)	0.73
Non-employed	185 (48.1)	199 (51.8)	
Marital Status			
Single	13 (52.0)	12 (48.0)	0.23
Married	186 (48.4)	198 (51.5)	
Widowed	30 (55.5)	24 (44.4)	
Divorced	5 (27.7)	13 (72.2)	
Disease duration (in years)			
≤5	60 (40.0)	90 (60.0)	0.04*
6-10	86 (54.7)	71 (45.2)	
11-15	37 (45.1)	45 (54.8)	
16-20	39 (57.3)	29 (42.6)	
≥21	11 (55.0)	9 (45.0)	
Cholesterol levels			
Decrease	129 (52.0)	119 (47.9)	0.14
Increase	105 (45.0)	128 (54.9)	
BMI			
Decrease	118 (50.4)	116 (49.5)	0.46
Increase	116	131 (53.0)	
Waist circumference			
Decrease	183 (54.3)	154 (45.6)	0.88
Increase	99 (54.6)	82 (45.3)	
Physical activity			0.49
MET <600	167(83.5)	167(82.7)	
MET ≥600	33 (16.5)	35 (17.3)	

* P values are significant at $\alpha = 0.05$ level

5.3.7 Logistic regression model:

From the logistic regression model (Table 5.7), females showed higher significant association to improvement in HbA1c levels with an adjusted odds ratio 1.6. Patients with age group less than 50 years indicated higher significant association to improvement in HbA1c level compared to age group more than 70 years (OR= 1.7, P<0.001). Income level "1500-3000" showed higher significant association to improvement in HbA1c level compared to "more than 3000" group (OR= 2.4, P= 0.01). Patients who have diabetes forless than5 years have higher significant association to change HbA1c compared to more than 20 years (OR= 1.9, P<0.001).

Table (5.7): Logistic model of variables associated to improvement in HbA1c.

Variable	AOR	95% CI	P-value
Age (years)			
Less than 40	2.7	1.53-5.25	**.002**
41-50	.856	0.50-1.50	.583
51-60	1.7	0.95-2.90	.067
More than 60years*	1		
Sex			
Female	1.6	1.07- 2.35	0.01
Male*	1		
Income Level (in Shekels)			
Less than 1500	1.6	0.84-3.2	**.020**
1500-3000	2.4	1.36-5.48	.167
More than 3000*	1		
Disease Duration			
Less than 5 years	1.9	0.12-0.93	**.007**
6-10 years	1.5	0.26-1.93	.156
11-15 years	2.4	0.19- 1.25	**.005**
16-20 years	2.4	0.28- 2.33	.089
More than 20 years*	1		

AOR: **Adjusted Odds Ratio, 95%CI: 95% confidence interval,** The Model includes: Age, gender, income level, disease duration, marital status, employment status, education level, place of residency, changes in BMI, cholesterol, waist circumference.

Chapter Six

Discussion, Conclusion and Recommendations

6.1 Discussion:

The overall goal of PEN Approach was to provide effective and affordable prevention and treatment interventions to patients in low income countries (WHO, 2010). As previously outlined, program evaluation is an important tool to measure effectiveness of public health programs and assure it meets stated objectives.

The study aimed to assess the impact of PEN Approach on the health status of diabetic patients by assessing diabetes controls mainly HbA1c which is recommended by ADA, as an indicator of glycemic control. Physical measurements including BMI, waist circumference, cholesterol and blood pressure were also checked at baseline and after two years of following the programme.

The analysis of HbA1c showed significant decrease in HbA1c levels after two years of attending the PEN Approach compared to first time of approach involvement in the first visit ($P<0.001$). Furthermore, the percentage of patients who reported good glycemic control (HbA1c<7%) increased from 32.8% in the 1st visit to 38.7% in the 3rd one after two years. Our results are ;consistent with study performed in USA (2017) to examine changes in HbA1c associated treatment intensification showed that patients who received early treatment intensification achieved significant reduction in HbA1c after one year of treatment (Fu, 2017). Another study was conducted in Brazil (2016) reported significant decline in HbA1c levels after six months of introducing mobile diabetes mellitus consultancy program (Filho, 2016). In Palestine, master thesis study, aimed to evaluate diabetes management program in Augusta Victoria hospital in

Jerusalem showed that 60% of patients developed good change in HbA1c levels after two years (Khatib, 2013).

However, HbA1c has been used by clinicians as the major standard to measure patients' glycemic control over the period of 2-3 months (ADA, 2007). This would facilitate clinicians' treatment decisions in favor of glycemic control with the aim of reducing or avoiding complications associated with DMT2 (Sherwani, 2016). Concerning this point, the UK prospective diabetes study (UKPDS) predicted that reduction in the HbA1c level by 1%, will reduce the risk of micro-vascular complications by 37% (Stratton, 2000).

Our findings indicated an increase in the percentage of patients with uncontrolled blood pressure, from 1st to 3rd visit after years. These results are inconsistent with other study conducted in Shanghai (2008) to evaluate community based-diabetes management program that showed significant decrease in patients' blood pressure in intervention group compared to control group (Xiaolin, 2008). Also in Bhutan, a study was conducted to evaluate PEN Approach showed decrease in the percent of patients with uncontrolled blood pressure from at baseline 42% to 21.5% after three months (Wangchuk, 2014).

Low-income level patients are usually dependent on governmental health insurance in Palestine (WHO, 2006). Shortage in medicine supply in governmental PHC facilities and the relative high cost of medication in the private sector would promote habitual trends among patients to disregard medication schedule. Missing doses, various medications with different intake schedule and ignorance of the importance of antihypertensive medications are, also, reasons for patient poor medication adherence (Devkota, 2016).

Clinic blood pressure measurements showed large variations which may results in inaccurate classification of patients (Engl, 2003). Reliable blood pressure measurements need rest period before measuring, adjustment of the cuff, and slow deflation of the cuff. Also blood pressure may be affected by clinical environment (Ghuman, 2009).

The BMI is an index of body weight to height, and pointed out as an important risk factor of DMT2 (Hu FB, 2001). Our results showed insignificant decrease in patients' BMI between 1st and 3rd visit after two years ($P<0.06$). On the other hand, 64% of patients are still overweight (BMI>25) and 28% are still obese (BMI>30). A study in Jordan (2014) among Palestinian refugees showed a decrease in percent of patients with BMI >30 from 52% at baseline to 49% after two and half year (Khader, 2014). In Korea (2017), a study was conducted to evaluate piloting of PEN Approach showed decrease in percent of patients with BMI≥ 23 from 24.5% to 22.7% after one year of follow up (Hyon, 2017). Studies predicted that 5% reduction in the body weight results in significant improvement in HbA1c values after one year (Wing, 1987).

Cholesterol levels showed significant decrease among patients between 1st and 3rd visit after two years ($P <0.001$). These results are consistent with a study in Korea (2017), in which patients with high levels of cholesterol (>200mg/dl) had decreased after one year of PEN Approach implementation (Hyon, 2017). While in Jordan (2014), a study showed that patients with good cholesterol levels (<200mg/dl) have decreased from 74% to 63% after two and half years (Khader, 2014).

Around 35% of our study participants have dyslipidemia and this condition is registered in patients' files. This means that patients already take drugs to manage dyslipidemia and consequently the cholesterol level are expected to decrease. Also, measuring total cholesterol

doesn't reflect the whole picture of lipids, low density cholesterol (LDL) and high density cholesterol (HDL) and triglycerides should be measured and considered. The American Heart Association (AHA) states that diabetes often lowers HDL "good" cholesterol levels and raises triglycerides and LDL "bad" cholesterol levels which will increase the risk for heart disease and stroke (AHA, 2016).

The main goal of DMT2 management is to ensure optimal glycemic control. We have assessed the magnitude of good change in glycemic control and associated predictors among DMT2 patients. Binary Logistic model was applied to analyze association between predictors and changes in HbA1c levels, it showed that females achieved better improvement in HbA1c levels than males (OR=1.6, P<0.01). This result is consistent with other cross sectional study conducted in Oman (2012), showed that women reported better glycemic control than men (OR =1.5, P<0.001) (Al-Lawati, 2012). Another study was conducted in Taiwan (2016) showed that although less number of women achieved controlled glycemic control (HbA1c<7%), but women registered significantly decline in HbA1c levels than men after ten years of follow up (BeLue, 2016). While, most previous studies showed better improvement in HbA1c levels in males rather than females (Balkau, 2015; Kautzky-Willer, 2015; Yousefzadeh, 2015). Most of our study participants were women and unemployed (housewives), this would reflects higher commitment to regular visits to PHCs among female patients. Participants' selection was purposive, patients who visited clinic during the study period were selected. Men are usually employed might have lower commitment to follow-up scheduled visits.

Age indicated that younger patients achieve better improvement in HbA1c levels rather than elderly (OR=2.7, P<0.001). This result is consistent with other study (2014), showed that HbA1c

levels increased by 0.085% per 10 years of age (Dubowitz, 2014). On the other hand, previous researches suggested that younger age associated with poor glycemic control (Schetman, 2002; Al-Lawati, 2012; Kamuhabwa, 2014). Elder patients wereless likely to exercise compared to young. This may be partially explained because younger patients may have better general health, and less co-morbidity compared to elderly. However, some studies suggested that HbA1c levels increases with age may be due to nonglycemic factors like alterations in red cell turnover or hemoglobin (Pani, 2008; Dubowitz, 2014).

Diabetes duration showed association to improvement in glycemic control, patients who have DMT2 for less than 5 years showed better improvement in glycemic control (OR=1.9, P<0.001). A study was conducted in California (2005) revealed that the longer duration with diabetes, the harder to maintain glycemic control. Although self-care skills might improve with longer duration diabetes, resistance to medication and the need for higher doses or additional medications increase over time (Benoit, 2005).

Another study in Hong Kong (2012) found that patients with longer duration of diabetes and more complex treatment regimens were associated with poorer glycemic control (Ali MK, 2012). Juarez et al. (2012) also reported that patients who had had diabetes for 10 years were about nine times more likely to have poor glycemic control than those who had had diabetes for 3 years (Juarez, 2012).

DMT2 is a progressive disease and as glucose levels rise, more drugs are required to achieve control (Badedi, 2016). Insulin resistance increases with time due to progressive impairment of insulin secretion from beta cells (UKPDS, 1998).

Our findings indicated that income level associated with improvement in glycemic control, patients with middle category of income level (1500-3000 shekels) showed good improvement in glycemic control rather than others with higher income level >3000 Shekels (OR= 1.6, P=0.01). A study was conducted in China (2016) showed that higher income patients in China tended to have worse HbA1c levels, and only 7.2 % of patients with the highest income achieved good glycemic control. A proportion lower than other two groups including middle and low income level (Tao X, 2016). The possible reasons for bad glycemic in the high income population involved a more expanded diet choices and ability to have any instrument may facilitate their lives and make it easier such as having a car so no need to walk for work.

While a study in Canada (2016) revealed that poverty was related to poor glycemic control among patients with type 2 diabetes and explained this due to the way of patients perceive to their disease and copying with disease stress also to social inequality in health (Houle,2016).

This study is the first one assessed health impact of PEN Approach in West Bank, by checking some predictors of glycemic control and examining changes in HbA1c levels as an indicator for glycemic control after two years of attending the Approach. However, international studies study impact of PEN Approach by using primary healthcare clinics as a unit of follow up, to check changes in physical and laboratory measurements, means at different points of time, percent of people who attending the clinic reached optimal recommended value. They didn't check these changes in selected patients and follow them. This may fail in reflect actual impact of Approach on patients themselves since by the time new patients may attend approach and their readings out of recommended values. (Wangchuk, 2014; Hyon.2017).

The main limitation of the study that it is a cross sectional study, where it is inadequate to assess cause and effect relationships. The study didn't consider other predictors of glycemic control such as adherence to drugs. In behavioral risk factors including diet, physical inactivity and smoking only core part of STEPwise is studied to check patients' situation. This is because the study scope isn't the behavioral risk factors. Also, since it was a file based study, human errorscould be occurred in registering measurements. HbA1c is a blood test, its results may differ due to technique used for measurement, no data about techniques used in selected clinics.

Despite the previously stated limitations, the study yielded a number of important findings with implications that should be taken into consideration by the clinical researchers and healthcare policy makers for improving future practice.

6.2 Conclusion:

Overall, the results of this evaluation indicated that PEN Approach was effective in meeting some objectives, HbA1c levels among diabetic patients attending PHC implementing the PEN approach have significantly decline in HbA1c levels after two years, and percent of patients with controlled glycemic control increased after two years.

On the other hand, despite patients showed significant decrease in cholesterol, and waist circumference, high percent of them still away from optimal recommended values. This could suggest some modifications in PEN Approach to meet the need for achieving better improvements, especially with high burden of diabetes complications among participants.

6.3 Recommendations:

- **For MoH:**
  - Introduce screening for diabetes mellitus in primary healthcare clinics for adults especially adults with high risk.
  - To continue its strategy in diabetes management and introduce a comprehensive health education program through patient counseling, skills building and behavioral interventions to raise awareness among DMT2 patients about diabetes, its' complications and the importance of good glycemic control.
  - Improve PEN protocols to achieve better glycemic control by make HbA1c every three months instead of six months especially for patients with uncontrolled HbA1c, and prevent diabetes mellitus complications by screening tests and early diagnosis.
  - Develop ongoing evaluation program to follow up health status of patients and assure that the Approach is applied properly, also conduct follow up visits to PHCs and check patients' files.
  - Implement health information system, this will help healthcare workers to save time and create integration between clinics and hospitals systems for better management of diabetic patients. It is also important to ensure completeness of patient files.
- **For future research:**
  - Longitudinal studies in depth to study the cause-effect relationship between HbA1c and its predictors. This could be useful for decision makers to plan properly for diabetes management.
  - Study other predictors to glycemic control such as effect of patients' adherence to drugs.

- Evaluate cost-effectiveness of the Approach as a protocol of diabetes management for low income-countries.

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Annex (1)

جامعة القدس
Al-Quds University

كلية الصحة العامة – برنامج الدراسات العليا

عنوان البحث :

"Evaluation of Glycemic Control among Patients with Diabetes following the PEN Approach in West Bank"

الموقع:حيث سيتم اجراء الدراسة في عيادات الرعاية الاولية التابعة لوزارة الصحة في شمال الخليل ورام الله وجنين.

أنا الباحثة ايمان برادعية, أقوم ببحث بعنوان "Evaluation of Glycemic Control among Patients with Diabetes following the PEN Approach in West Bank"

وهو بحث يهتم بدراسة الوضع الصحي لمرضى السكري المسجلين على برنامج ال PEN Approach

خلال هذه الدراسة سأقوم بتجميع معلومات من ملفاتكم لها علاقة بنتائج الفحوصات الطبية وقراءات الضغط والسكر وكذلك تعبئة استبانة من خلال توجيه الاسئلة لكم.لن تستخدم هذه ا لمعلومات الا لاغراض البحث العملي فقط .

كمشارك فى هذا البحث العلمى لك الحرية في طرح أى سؤال أو إستفسار عن هذا البحث خلال اي مرحلة من المرحل. يرجى العلم بأن المشاركة بهذا البحث عمل طوعي بحت ولكم الحرية المطلقة بالموافقة او عدمها. قراركم بعدم المشاركة فى هذا البحث العلمى لا يترتب عليه اى تبعات.

لقد قرأت الوصف أعلاه من هذه الدراسة. وقد تمت الاجابة على جميع أسئلتي. وأنا أعلم أنه يمكنني ان ارفض المشاركة. **أعطي موافقتي بحرية على المشاركة في هذه الدراسة**.

توقيع المشارك: .....

الباحث: ايمان برادعية

الهاتف والبريد الالكتروني : 0568016767 emanbaradeyia@gmail.com

أ. مشارك: د. معتصم حمدان (مشرف الرسالة)

Demographic Information:

File #: .....

Date of Birth:.....

Sex:

- Male
- female

Level of education:

- Illiterate
- Primary school.
- Secondary school.
- University.

Level of income:

- Less than 1500.
- 1500 – 3000
- More than 3000.

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- Urban.
- Rural.
- Camps.

Marital status:

- Single.
- Married.
- Divorced.
- Widowed.

Employment:

- Employed
- Unemployed

Parameter	**First visit**	**After 1 year**	**After 2 year**	**Note**
Date of diagnosis				
Height				
Weight				
Waist circumferences				
Blood pressure systolic/diastolic				
HbA1c				
Cholesterol				
Drug name				
Complications	Retinopathy □ hypoglycemia□ Diabetic foot □ Nephropathy□ Neuropathy □ hypertension□ Dyslipidemia □ cutting any organ because of diabetes□			

النشاط البدني :

1-هل طبيعة عملك تتطلب بذل نشاطا بدنيا شاقا لمدة 10 دقائق مستمرة عالأقل ويسبب زيادة كبيرة في التنفس وتسارع ضربات القلب مثل (حمل أشياء ثقيلة, الحفر , أعمال المباني) ؟	1.نعم 2.لا اذا لا اذهب الى السؤال 4.
2-كم يوم في الاسبوع تقوم بنشاط شاق كجزء من عملك؟	عدد الايام
3-كم من الوقت في اليوم الواحد تقوم بنشاط شاق أثناء العمل ؟	دقيقة (.....) ساعة(.....)
4-هل طبيعة عملك تتطلب أنشطة متوسطة الجهد التي تسبب زيادة بسيطة في التنفس و نبضات القلب مثل(المشي السريع, حمل أشياء خفيفة الوزن) لمدة عشر دقائق مستمرة عالأقل.	1.نعم 2.لا اذا كانت الاجابة لا اذهب الى سؤال 7.
5-كم يوم من أيام الاسبوع تقوم بنشاط بدني متوسط كجزء من عملك؟	عدد الأيام (.....)
6-كم من الوقت في اليوم الواحد تقوم بنشاط بدني متوسط كجزء من عملك ؟	دقيقة(.....) ساعة(.....)
7-هل تسير على الأقدام من والى أماكن معينة لمدة عشر دقائق مستمرة على الأقل؟	1.نعم 2.لا اذا كانت الاجابة لا اذهب الى سؤال 10
8-كم يوما في الاسبوع تسير على الأقدام لمدة عشر دقائق مستمرة عالأقل من والى أماكن معينه؟	عدد الأيام(.....)
9-كم من الوقت تسير على الأقدام للتنقل في اليوم الواحد؟	دقيقه (.....) ساعة(.....)
10-هل تقضي وقت الفراغ بنشاط شاق سواء كان للرياضه أو اللياقه البدنيه أو النشاط الترفيهي تزيد مدته عن عن عشرة دقائق مستمرة مثل(الجري أو كرة القدم) ؟	1.نعم 2.لا اذا كانت الاجابة لا اذهب الى سؤال 13.
11-كم يوما في الاسبوع الواحد تقوم بنشاط بدني شاق كجزء من وقت فراغك كالجري أو رفع الأثقال أو القيام بأي رياضه شديده؟	عدد الايام(.....)
12-كم من الوقت في اليوم تقوم بنشاط بدني شاق أثناء وقت الفراغ؟	دقيقه(.....) ساعة(.....)
13-هل يشمل وقت فراغك القيام بأنشطة بدنية متوسطة الجهد, لمدة عشر دقائق عالأقل في المرة الواحدة مثل(المشي السريع, السباحه, كرة اليد, ركوب الدراجة أو حمل أشياء خفيفة الوزن) ؟	1.نعم 2.لا
14-كم يوما في الاسبوع تقوم بأنشطة بدنية متوسطة أثناء وقت الفراغ؟	عدد الأيام (.....)
15-كم من الوقت في اليوم الواحد تقوم بنشاط بدني متوسط أثناء وقت الفراغ؟	دقيقه(.....) ساعه(.....)

التغذية:

1-كم يوم في الاسبوع تتناول الفواكه؟	عدد الايام (.....) لا أعلم اذا صفر اذهب الى 3.
2- كم حصة فواكه تتناول في اليوم الواحد ؟	عدد الحصص (....) لا أعلم
3-كم يوم في الاسبوع تتناول الخضراوات؟	عدد الأيام (.....) لا أعلم
4-كم حصة خضراوات تتناول في اليوم الواحد؟	عدد الحصص (.....) لا أعلم
5- كم مرة تضيف الملح أو الصلصة المالحة مثل صلصة الصويا إلى طعامك قبل تناوله مباشرة أو أثناء تناوله؟	- دائما - في كثير من الأحيان - بعض الأحيان - نادرا - أبدا - لا اعرف
6-كم مرة تتناول الطعام المصنع عالي المحتوى بالملح؟ ، مثل الوجبات الخفيفة المالحة المعبأة ، والأطعمة المالحة المعلبة بما في ذلك المخللات والمعلبات ، والأطعمة المالحة التي يتم إعدادها في مطعم للوجبات السريعة ، والجبن ؟	- دائما - في كثير من الأحيان - بعض الأحيان - نادرا - أبدا - لا اعرف

استخدام التبغ:

1-هل سبق أن دخنت أي نوع من منتجات التبغ مثل السجائر ,السيجار ,الغليون, الشيشة أو المدواخ؟	1.نعم 2.لا (اذا لا اذهب الى ت9أ)
2-هل تدخن حاليا السجائر, السيجار, الغليون أو المدواخ؟	1.نعم 2.لا (اذا لا اذهب الى ت6)
3-اذا كان الجواب نعم, هل تدخن أي من هذه المنتجات يوميا؟	1.نعم 2.لا (اذهب الى ت6أ)
4-كم كان عمرك عندما بدأت بالتدخين يوميا؟	العمر بالسنوات (.....) لا أعلم, اذا كان معلوما اذهب الى ت5أ
5-اذا كنت لا تذكر كم كمرك عندما بدأت بالتدخين فهل تذكر المده الزمنية التي استغرقتها منذ بدأت بالتدخين؟ (اختر اجابة واحده فقط) 77لا أعلم	سنوات مضت (.....) اذا كان معلوما اذهب الى ت 5أ.
	أو شهور مضت (.....) اذا كان معلوما اذهب الى ت5أ .
	أو أسابيع مضت (.....)
6-ماهومعدل تدخينك لأي من هذه الأنواع ؟ (سجل كل واحده منها) 77 لا أعلم	سيجارة مصنعه (.....)
	سيجارة لف (.....)
	غليون (.....)
	سيجار-سيجار صغير (.....)
	شيشة (.....)
	مدواخ (.....)
	أنواع اخرى (.....) اذا انواع اخرى اذهب الى أنواع اخرى او انتقل الى ت6أ
	اذكر ماهي الانواع (.....)
7-في الاثني عشر شهر الماضية هل سبق أن حاولت الاقلاع عن التدخين ؟	1.نعم 2.لا
8-خلال زيارتك لأي طبيب أو غيره من الكادر الصحي في الاثني عشر شهر الماضية هل تم تقديم نصيحه لك بالاقلاع عن تدخين التبغ؟	1.نعم 2.لا 3.لا يوجد أي زيارة خلال الاثني عشر شهرا السابقة.

Annex (2)

كلية الصحة العامة – برنامج الدراسات العليا

عنوان البحث :

"Evaluation of Glycemic Control among Patients with Diabetes following the PEN Approach in West Bank"

الموقع:حيث سيتم اجراء الدراسة في عيادات الرعاية الاولية التابعة لوزارة الصحة في شمال الخليل ورام الله وجنين.

أنا الباحثة ايمان برادعية, أقوم ببحث بعنوان "Evaluation of Glycemic Control among Patients with Diabetes following the PEN Approach in West Bank"

وهو بحث يهتم بدراسة الوضع الصحي لمرضى السكري المسجلين على برنامج ال PEN Approach

خلال هذه الدراسة سأقوم بتجميع معلومات من ملفاتكم لها علاقة بنتائج الفحوصات الطبية وقراءات الضغط والسكر وكذلك تعبئة استبانة من خلال توجيه الاسئلة لكم.لن تستخدم هذه ا لمعلومات الا لاغراض البحث العملي فقط .

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الباحث: ايمان برادعية

الهاتف والبريد الالكتروني : 0568016767 emanbaradeyia@gmail.com

أ. مشارك: د. معتصم حمدان (مشرف الرسالة)

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Parameter	**First visit**	**After 1 year**	**After 2 year**	**Note**
Date of diagnosis				
Height				
Weight				
Waist circumferences				
Blood pressure systolic/diastolic				
HbA1c				
Cholesterol				
Urine albumin				
Drug name				
Complications	Retinopathy □ hypoglycemia□ Diabetic foot □ Nephropathy□ Neuropathy □ hypertension□ Dyslipidemia □ cutting any organ because of diabetes□			

Physical Activity Part:

1- Does your work involve vigorous-intensity activity that causes large increases in breathing or heart rate like [carrying or lifting heavy loads, digging or construction work] for at least 10 minutes continuously?	-Yes - No (If No, go to question 4).
2- In a typical week, on how many days do you do vigorous intensity activities as part of your work?	Number of days.....
3- How much time do you spend doing vigorous-intensity activities at work on a typical day?	Hours ..... minutes.....
4- Does your work involve moderate-intensity activity that causes small increases in breathing or heart rate such as brisk walking [or carrying light loads] for at least 10 minutes continuously?	-Yes - No (If No, go to question 7).
5- In a typical week, on how many days do you do moderateintensity activities as part of your work?	Number of days.....
6- How much time do you spend doing moderate-intensity activities at work on a typical day?	Hours ..... minutes.....
7- Do you walk or use a bicycle (pedal cycle) for at least 10 minutes continuously to get to and from places?	-Yes - No (If No, go to question 10).
8- In a typical week, on how many days do you walk or bicycle for at least 10 minutes continuously to get to and from places?	Number of days.....
9- How much time do you spend walking or bicycling for travel on a typical day?	Hours ..... minutes.....
10- Do you do any vigorous-intensity sports, fitness or recreational (leisure) activities that cause large increases in breathing or heart rate like [running or football] for at least 10 minutes continuously?	-Yes - No (If No, go to question 13).
11- In a typical week, on how many days do you do vigorousintensity sports, fitness or recreational (leisure) activities?	Number of days.....
12- How much time do you spend doing vigorous-intensity sports, fitness or recreational activities on a typical day?	Hours ..... minutes.....
13- Do you do any moderate-intensity sports, fitness or recreational (leisure) activities that cause a small increase in breathing or heart rate such as brisk walking, [cycling, swimming, and volleyball] for at least 10 minutes continuously?	-Yes - No (If No, go to question 16).

14- In a typical week, on how many days do you do moderateintensity sports, fitness or recreational (leisure) activities?	Number of days.....
15- How much time do you spend doing moderate-intensity sports, fitness or recreational (leisure) activities on a typical day?	Hours ..... minutes.....
16- How much time do you usually spend sitting or reclining on a typical day?	Hours ..... minutes.....

Diet:

7- In a typical week, on how many days do you eat fruit?	Number of days..... Don't Know (If zero, go to question 3)
8- How many servings of fruit do you eat on one of those days?	Number of servings..... Don't Know
9- In a typical week, on how many days do you eat vegetables?	Number of days..... Don't Know (If zero, go to question 5)
10- How many servings of vegetables do you eat on one of those days?	Number of servings..... Don't Know
11- How often do you add salt or a salty sauce such as soy sauce to your food right before you eat it or as you are eating it?	- Always - Often - Sometimes - Rarely - Never - Don't know
12- How often do you eat processed food high in salt? By processed food high in salt, I mean foods that have been altered from their natural state, such as packaged salty snacks, canned salty food including pickles and preserves, salty food prepared at a fast food restaurant, cheese, bacon and processed meat	- Always - Often - Sometimes - Rarely - Never - Don't know

Tobacco use	
1- Do you currently smoke any tobacco products, such as cigarettes, cigars or pipes?	- Yes - No (If No , go to question 8)
2- Do you currently smoke tobacco products daily?	- Yes - No
3- How old were you when you first started smoking?	Age..... (years) Don't know
4- Do you remember how long ago it was?	- In Years (...) - Or in Months (…) - Or in Weeks (…)
5- On average, how many of the following products do you smoke each day/week?	Product weekly daily Manufactured cigarettes ……. …… Hand-rolled cigarettes ……. …….. Pipes full of tobacco ……. …….. Cigars, cheroots, cigarillos …… …….. Number of Shisha sessions ….. ……. Other …… …….. Specify other.....