Self-Management of Insulin in Type I Diabetic Patients

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Doctorate in Pharmacy

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“A little knowledge that acts is worth infinitely more
than much knowledge that is idle”

Khalil Gibran

I am very humble, very gracious and very grateful for those who have *kept my life in perspective and balance.*
Thank you all from all my heart,

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I hope I have made you proud.

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Abstract

Flexible intensive insulin therapy (FIT) permits the patient to adjust the timing and the amount of insulin administered by using long-acting insulin which is injected once or twice daily and rapid acting insulin which is taken according to carbohydrate intake. This therapy allows patients to have greater dietary flexibility. The aims was to assess the impact of insulin therapy adjustments according to carbohydrate counting on HbA1c control among patients diagnosed with type 1 diabetes. A self-administered Carbohydrate Counting Assessment Questionnaire (CCAQ) was adapted from 'The Heart Healthy Carb Quiz' and 'The Stanford Patient Education Research Centre Diabetes Questionnaire'. The CCAQ was validated by an expert panel consisting of (1 diabetologist, 2 pharmacists, 1 diabetic nurse specialist and 1 diabetic educator). The study took place during an 8-week period from October to November 2016. Patients were chosen by convenience sampling and asked to complete the CCAQ. Two groups of patients completed the questionnaire; one group was taking insulin according to carbohydrate counting (Group 1) and the other group was on conventional insulin therapy (Group 2). Forty patients (22 male, 18 female; mean age 40 years; range 16-66 years) were in Group 1 and 40 patients (11 male, 29 female; mean age 36 years; range 14-65 years) were in Group 2. When the HbA1c values of the two patient groups were compared, the mean HbA1c value of patients in group 1 (8.09%) was significantly lower ($p=0.02$) than the mean HbA1c value of patients in group 2 (8.73%). Patients who were taking insulin according to the carbohydrate count had better glycaemic control than patients on conventional insulin therapy. The application of carbohydrate counting and flexible and intensive insulin therapy provide an advantageous outcome in glycaemic control.

List of Abbreviations

Abbreviation	Meaning
ADA	American Diabetes Association
AGEs	Advanced Glycosylated End Products
CCAQ	Carbohydrate Counting Assessment Questionnaire
CMV	Cytomegalovirus
CSII	Constant subcutaneous insulin infusion
DCCT	Diabetes Control and Complication Trail
EFAD	European Federation of Associations of Dietitians
EHES	European Health Examination Survey
FPG	Fasting Plasma Glucose
GCT	Glucose Challenge Test
GD	Gestational Diabetes
HbA1c	Glycated Hemoglobin
HHCQ	Heart Healthy Carb Quiz
HLA	Human Leukocyte Antigen
IDF	International Diabetes Federation
MDH	Mater Dei Hospital
MDI	Multiple Daily Injections

OGTT	Oral Glucose Tolerance Test
RPG	Random Plasma Glucose
SMBG	Self-Monitoring Of Blood Glucose
SPSS	Statistical Package for Social Sciences
T1D	Type 1 Diabetes
T2D	Type 2 Diabetes
UKPDS	United Kingdom Prospective Diabetes Study
WHO	World Health Organisation

Chapter 1: Introduction

1.1 Background

Diabetes is considered to be a major worldwide problem in developed and in developing countries. In 1980 there were 108 million adults suffering from diabetes. In 2014, the World Health Organisation (WHO) estimated that there were 422 million adults living with diabetes. This prevalence is expected to increase further in the next years.[1] In 2012, an estimated 1.5 million deaths were due to comorbidities related to diabetes and another 2.2 million deaths were attributable to hyperglycaemia. Almost half of all deaths attributable to hyperglycaemia occur before the age of 70 years. The WHO projects that diabetes will be the 7th leading cause of death in 2030.[1]

Tight glycaemic control is necessary to reduce the risk of microvascular and macrovascular complications. Monitoring the carbohydrate count is important in the management of diabetes. Carbohydrate counting is a technique for monitoring the amount of carbohydrates consumed in an individual's diet. This practice helps to improve glycaemic control in individuals suffering from diabetes. Before insulin treatment was available, following a controlled diet was the only possible way to avoid or control hyperglycaemia in diabetic patients (Bruttomesso et al, 2001).

The Diabetes Control and Complications Trial highlights the significance of tight glycaemic control to help prevent chronic disorders related to diabetes (Nathan et al, 2005; David et al, 2014). Pre-prandial glycaemic levels should be at 3.9 to 6.7 millimoles per litre or 70 to 120

[1] WHO. (2016). Global report on diabetes. World Health Organization., from http://apps.who.int/iris/bitstream/10665/204871/1/9789241565257_eng.pdf

mg per decilitre. The maintenance of these levels reduces the risk of retinopathy by 50%, nephropathy by 34%, neuropathy by 69% and hypercholesterolemia by 34% (Bishop et al, 2009).

1.2 History of Diabetes

For over 3,000 years, physicians have questioned the aetiology of diabetes and its various treatment stratigies. Frederick Sanger discovered the sequencing structure of insulin in 1955 and in 1967 pro-insulin hormone was discovered by Donald Steiner. In the same year, Steiner, with his colleagues, measured endogenous insulin production by using the radioimmunoassay for C-peptide which they produced. In 1967, the University of Minnesota, William Kelly and Richard Lillehei, along with their colleagues, performed the first human pancreatic transplant. In 1972, the U100 insulin (100 units of insulin in every 1 mL) was introduced to achieve better accuracy in the administration of insulin. A decade later, recombinant human insulin became available and in the 1990's, the insulin pen was produced after the discovery of short acting insulin in 1996, and long acting insulin in 2001 (Karamanou et al, 2016).

1.3 Types of Diabetes

The main types of diabetes are: type 1 diabetes, type 2 diabetes 2 and gestational diabetes.

1.3.1 Type 1 Diabetes

Type 1 diabetes (T1D) is an autoimmune disease characterised by chronic hyperglycaemia due to insulin deficiency. To date, there is no cure for T1D, so useful strategies such as flexible insulin therapy to help in the maintenance and achievement of normal glycaemic levels is needed to encourage the long-term and acute wellbeing and health status of T1D patients. Diabetic patients are required to adopt a restrictive lifestyle and diet, and to monitor their blood sugar levels frequently (Atkinson et al, 2001; Bluestone et al, 2010).

1.3.1.1 Epidemiology

T1D, also known as juvenile diabetes, is diagnosed in young adults and children. T1D is more likely to occur between the age of 5 and 7 years and close to the onset of puberty (Atkinson et al, 2014). T1D accounts for 10% of all diabetes cases, and the incidence rate of T1D has increased by 2.8% to 4.0% annually in all age groups over the last years (Soltesz et al 2007; Bach et al, 2012; Patterson.et al 2014). Figure 1.1 illustrates the incidence and prevalence of T1D worldwide. Finland has the highest incidence of T1D (around 60 cases per 100,000 people annually) followed by Italy (around 40 cases per 100,000 people annually) (Maahs et al, 2010).

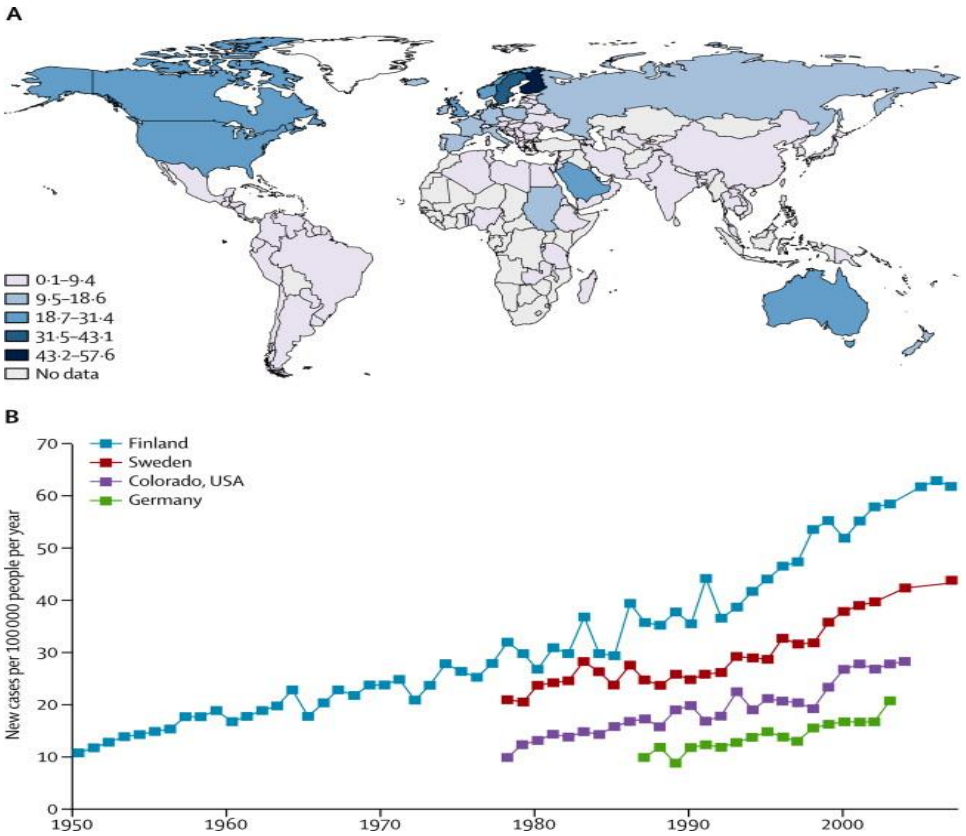

Figure 1.1 Incidence of type 1 diabetes in children aged 0–14 years, by geographical region and over time (A) Estimated global incidence of type 1 diabetes, by region, in 2011. (B) Time-based trends for the incidence of type 1 diabetes in children ages 0–14 years in areas with high or high-intermediate rates of disease. (Adopted from Atkinson MA, Eisenbarth GS, Michels AW. Type 1 diabetes. *Lancet*. 2014; 383(9911):69–82).

1.3.1.2 Pathophysiology

T1D is activated when the immune system undergoes insulin elimination due to the destruction of beta cells in the pancreas (Crowther et al, 2005). The pancreas has less insulin-producing cells and the remaining β-cells are incapable of regeneration. Recent data suggests that although most patients with longstanding T1D have a low amount of β-cells, there is evidence for β-cell regeneration in infants and very young children, but not in adolescents or adults (Keenan et al, 2010; Gregg et al, 2012). Figure 1.2 shows the presence of a chronic inflammatory infiltrate that affects pancreatic islets at symptomatic onset of T1D (Atkinson et al, 2014).

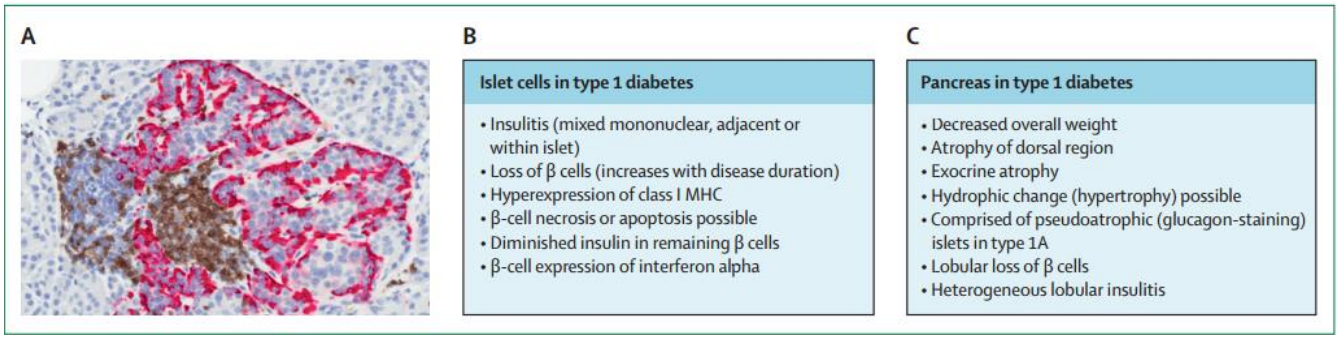

Figure 1.2: Pathological characteristics of the pancreas in type 1 diabetes (A) Islet infiltrate (i.e., insulitis) seen in a patient with recent-onset type 1 diabetes. Immunohistochemistry shows the intra-islet presence of CD3-positive cells (brown) and glucagon-producing alpha cells (pink). Image courtesy of M Campbell Thompson, University of Florida, Gainsville, FL, USA. (B) Histological features of islets and (C) gross pathological characteristics of the pancreas associated with the natural history of type 1 diabetes (i.e., preonset, onset, and postonset). (Adopted from Atkinson MA, Eisenbarth GS, Michels AW. Type 1 diabetes. *Lancet*. 2014; 383(9911):69–82).

1.3.1.3 Signs and Symptoms

Symptoms associated with the onset of T1D are polyphagia, polydipsia and polyuria. Other symptoms include weight loss due to unknown causes, fatigue, mood swings, itchiness, blurred eyesight, skin infections, cramps, vomiting and heavy breathing. An immediate need for exogenous insulin replacement is present of T1D, for which lifetime treatment is needed (American Diabetes Association, 2016).

If T1D is undiagnosed and untreated, it can lead to diabetic ketoacidosis. Diabetic ketoacidosis may occur due to the human body being unable to utilise glucose for conversion into energy. Ketones are generated instead. The high levels of blood glucose along with the ketones render the blood excessively acidic, due to which a loss of fluids and loss of salt is observed. This life-threatening scenario required hospitalization. It can occur in 1/600 children. Another complication that may present during and due to the onset of diabetic ketoacidosis is cerebral oedema (Bellamy et al, 2009).

1.3.1.4 Prevention of Type 1 Diabetes

The present research regarding T1D is primarily dealing with the delay and/or prevention of the autoimmune destructions of the beta cells (Atkinson et al, 2014). Efforts to cure or prevent T1D are done via large collaborative networks (e.g. NIH TrialNet, Immune Tolerance Network, and Islet Cell Transplantation Consortium), with rigorous mechanistic assays and uniform protocols (Atkinson et al, 2011).

1.3.1.5 Risk Factors in Type 1 Diabetes

The presence of genetic markers indicates a higher risk for development of T1D (Maahs et al, 2010). Certain ethnicities have a higher rate of T1D than others. In the United States, the prevalence of diabetes is highest among Native Americans (33%) and lowest among Alaskan natives (5.5%). Caucasians seem to be more susceptible to T1D than African-Americans and Hispanic-Americans. Chinese people have a lower risk of developing T1D, as do South Americans (Spanakis et al, 2013).

The genetic marker is located on chromosome 6, and it is a human leukocyte antigen (HLA) complex. HLA complexes have been linked to T1D. Having HLA complexes does not necessary mean that diabetes will develop since less than 10% of individuals with HLA complexes develop diabetes. T1D is considered to be an inherited disease. If both parents have T1D, the chances of the child developing T1D is higher than if one parent has diabetes (Maahs et al, 2010).

Researchers have found that T1D has been associated with viral infections, including enteroviruses, rubella, mumps, rotavirus, parvovirus and cytomegalovirus (CMV). These viruses may trigger the development of T1D by causing an immune system reaction against the host (Van der Werf et al, 2007).

1.3.2 Type 2 Diabetes

Type 2 diabetes (T2D) used to be referred to as "adult-onset" diabetes because it is often diagnosed later in life. it becomes increasingly difficult for the body's cells to absorb and use the insulin, resulting from the combination of resistance to insulin action, inadequate insulin secretion, and excessive or inappropriate glucagon secretion. T2D occurs due to insulin resistance, where the cells in the human body remain unresponsive to the production of insulin. As T2D progresses, decreased levels of insulin can be observed. This type of diabetes is called adult onset diabetes or non-insulin dependent diabetes (Brunkhorst et al, 2008).

1.3.2.1 Epidemiology

The American Diabetes Association (ADA) has estimated that in 2012, 29.1 million Americans, or 9.3% of the American population, suffered from T2D (American Diabetes

Association, 2016). T2D is the most common type of diabetes in adults. Almost 90% to 95% of diagnosed individuals suffer from this form of diabetes. Individuals may develop T2D at any stage of their life (Brunkhorst et al, 2008). In 2013, the estimated prevalence for T2D in Malta was 10.14% and this is expected to increase to 11.44% by 2035 (International Diabetes Federation, 2015).

T2D occurs more commonly in adults than in children. T2D is associated with a lack of physical activity, excess weight gain and a poorly controlled diet. T2D starts with resistance, where there is an excess of fat cells, liver cells and muscle cells which occur due to a failure of the body to use insulin adequately. The human body requires more insulin to break down glucose to create energy. In T2D, the pancreas is unable to produce enough insulin to keep up with the intake of glucose during meals, hence the levels of blood glucose rise (Alberti et al, 1998).

1.3.2.2 Pathophysiology

When the body becomes resilient to insulin or after the pancreas stops forming an adequate amount of insulin, the T2D is develops. The reason for this remains unknown, genetics and conversational factors - for example additional weight and idleness are comorbidity factors. (Khardori et al, 2011).

1.3.2.3 Signs and Symptoms

Symptoms of T2D may show during primary stages of the condition. It is important to identify the signs at an early stage to avoid damage and complications. Signs of T2D will gradually show and may not be present at all times (Cnop et al, 2005).

T2D may exhibit a number of symptoms such as polyphagia, polydipsia, polyuria, weight or muscle mass loss, blurred vision and increased susceptibility to infections, especially yeast or fungal infections (Tong et al, 2012).

1.3.2.4 Preventing of Type 2 Diabetes

The Finnish Diabetes Prevention Study stated that lifestyle interventions in individuals with impaired glucose tolerance have shown that the development of T2D can be postponed or prevented (Wild et al, 2004; Lindstrom et al, 2006). In 2014, a systematic review done for the Community Preventive Services Task Force found that programs used in the community or in health care settings reduced the risk in individuals who were at higher risk for developing diabetes. This included reduction of weight and other risk factors for cardiovascular disease, such as hypertensive conditions and hyperlipidaemia (Balk et al, 2015).

1.3.2.5 Risk Factors in Type 2 Diabetes

A number of metabolic disorders have been consistently associated with the development of T2D, and are considered to be risk factors. Obesity has been linked with hyperinsulinemia and insulin resistance, which are both recognized as precursors to T2D. In 2008, the Canadian Diabetes Association Clinical Practice Guidelines for the Prevention and Treatment of Diabetes recommended weight loss of 5 to 10 per cent to improve insulin sensitivity and glycaemic control, and to lower blood pressure and cholesterol levels (CDA, 2008).

A study by Gress et al, has shown that patients suffering from T2D were almost 2.5 times as likely to develop in the presence of hypertension when compared to those having normal blood pressure. The study mentioned that patients who were taking a thiazide diuretic, angiotensin-

converting-enzyme inhibitor, or calcium-channel antagonist were not at a higher risk of developing diabetes (Gress et al, 2000).

1.3.3 Gestational Diabetes

Gestational diabetes (GD) formerly known as decreased carbohydrate tolerance, is detected during the initial phase of pregnancy. Even though most GD cases are resolved after childbirth, the definition applies regardless of whether the condition persists after pregnancy (Ben-Haroush et al, 2004). This does not rule out the possibility that unrecognized glucose intolerance may have begun with or even alongside the pregnancy. GD results when placental hormones prevent the body from utilizing insulin effectively. Although the cause of GD is not known, some of the hormones produced by the placenta (human placental lactogen, estrogen and cortisol) could lead to a blocking effect on insulin. The insulin blocking effect, known as contra-insulin effect starts at about 20 – 24 weeks into the pregnancy (Dabelea et al, 2005). Diabetes in pregnancy, because of the higher risk of hyperglycaemia, could result in macrosomia and foetal growth. GD can lead to further short-term complications, for example, neonatal hypoglycaemia, shoulder dystocia, obstructed labour or the risk of neurological damage (Hod et al, 2015).

1.3.3.1 Epidemiology

Recent research outcomes have shown a substantial increase in the prevalence of GD amongst women in different geographic regions and of various racial/ethnic backgrounds. GD prevalence has been reported to vary between 1% and 28% (Hod et al, 2015). Diabetes in pregnancy may either have been pre-existing (T1D or T2D) or is first-time diagnosed during pregnancy (Hod et al, 2015).

GD presents a significant risk factor for the development of T2D and cardiovascular disease in women. Mothers who had diabetes during pregnancy would pose an increased risk to their children of having T2D and obesity at a young age (Ben-Haroush et al, 2004). Women diagnosed with GD during the first half of the pregnancy, form part of a high-risk subgroup with a recurrence of GD in subsequent pregnancies, increased incidences of obstetric complications and future development of T2D. Obesity in women and the need for insulin used for glycaemic control are factors that place women with GD at a high risk for T2D (Tabák et al, 2012).

1.3.3.2 Signs and Symptoms

There are no noticeable signs or symptoms for GD in most women. GD can cause the developing foetus to grow larger than normal and result in a complicated delivery. In the case of hyperglycaemia, some women may develop symptoms such as polydipsia, dry mouth, polyuria and tiredness. Some of the symptoms associated with GD are also common during normal pregnancies, and women should attend for screening to identify whether they could be suffering from GD (Hod et al, 2015).

Hypertensive disorders during pregnancy may seem more prevalent in women with GD. If GD is poorly controlled in a pregnancy, this may affect the child with a greater risk of jaundice, a higher chance of death/mortality at birth and an increased respiratory distress syndrome risk. There is also an increased risk of miscarriage and birth defects compared to women without diabetes if GD is present during the early pregnancy stages (Tabák et al, 2012).

1.3.3.4 Prevention and Treatment of GD

Women are advised to maintain a healthy body weight and exercise before conception and during pregnancy. Women who are affected should ideally have their blood sugar tested four times daily. Insulin injections, exercise and a restricted diet are strategies for GD. Insulin sensitivity can be improved with drugs such as metformin (Callaway et al, 2010).

Screening for GD during the early pregnancy stages will help to decrease the effects associated with GD in later pregnancy. Screening with a 50 g glucose challenge test (GCT), followed by a 100 g oral glucose tolerance test (OGTT) is recommended by ADA. A woman can plan for future pregnancies to ensure that there would be no recurrence of GD or an increased awareness that they may experience diabetes for the first time. Diabetic women should visit a diabetes pre-conception clinic for help to ensure that their condition is well-controlled before conception (American Diabetes Association, 2016).

1.4 Diabetes in Malta

Diabetes was first documented in Malta in 1886. In 1886 the prevalence and mortality related to diabetes was more than 2 deaths per 10,000 of the population. The diabetes-related mortality rate continued to rise in 1900; the rate increased to 4.5 per 10,000 of the population. The prevalence almost double in 1942, with 8.7 per 10,000 of the population. By 1955, Malta had the highest documented rate of diabetes related mortality in worldwide, with 26.1 deaths per 100,000 of the population followed by Belgium with 23.9, the USA with 15.5 and Italy with 11.1 deaths per 100,000 of the population (Cassar, 1982).

In 2010, a pilot survey by the European Health Examination Survey (EHES) was conducted in Malta to estimate the prevalence of diabetes. Ten percent of the survey population (with the population sample all of 18 years of age and over) were found to have diabetes.[2]

According to the National Statistics Office report in 2013, the total population of Malta was approximately 420,000. It is estimated that in Malta, there are more than 30,000 adults who are diabetic. [3] These figures do not include patients with impaired glucose tolerance or impaired fasting glucose levels. Malta has the second highest percentage of diabetics in the Mediterranean, surpassed by Cyprus.[4]

A study conducted by the International Diabetes Federation in 2015 reported that there were 44,100 cases of diabetes in Malta. The prevalence of diabetes in adults was 13.9% in the age range from 20 to 79 years. The cost per person with diabetes was around 2,173.6 (USD) (IDF, 2015). This percentage places Malta in the first quartile within Europe. Figure 1.3 illustrates Malta and World prevalence of diabetes.[5]

[2] Directorate for Health Information and Research. The European Health Examination Survey Pilot Study 2010.
[3] National Statistics Office. **Annual Reports**. 2013
[4] The Malta Independent. **Malta has second highest incidence of diabetes in the Med**. 2014
[5] International Diabetes Federation. IDF Diabetes Atlas. Brussels: International Diabetes Federation; 2009. Available at: http://www.diabetesatlas.org/downloads. Accessed November 1, 2016.

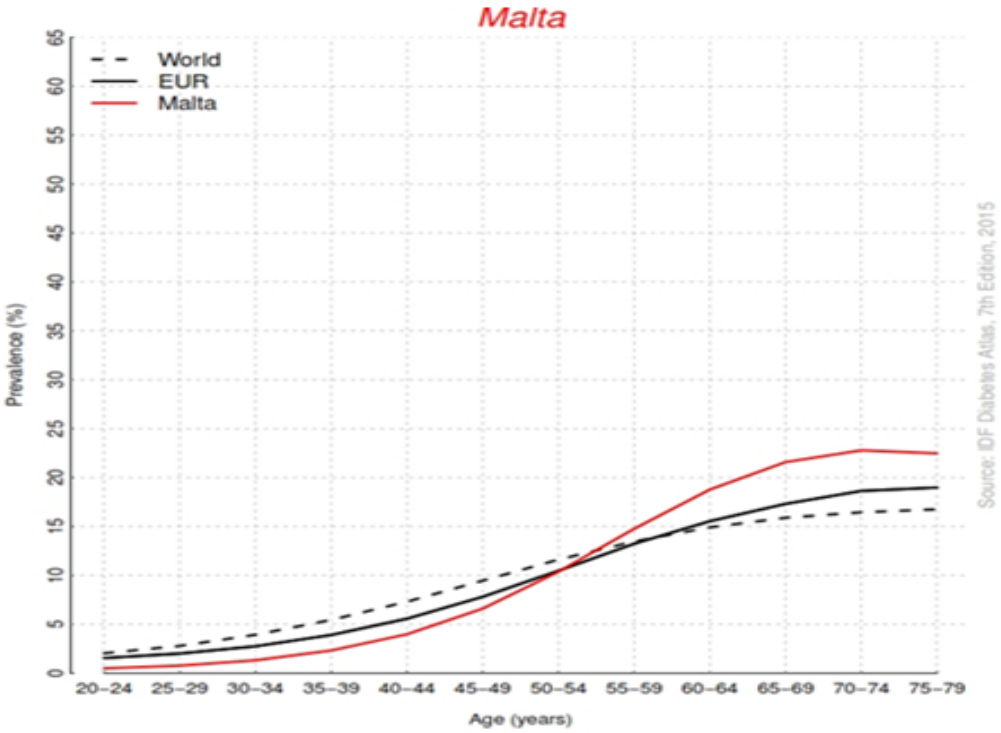

Figure 1.3 Malta vs World prevalence of diabetes (International Diabetes Federation. IDF Diabetes Atlas, Seventh edition. Brussels, Belgium: International Diabetes Federation, 2015. Available from: http: //www.idf.org/diabetesatlas.).

Buttigieg et al, in 2005, stated that 10% of the Maltese population has diabetes when compared to 2 to 3% of their European neighbours. The authors concluded that 84% of the Maltese diabetic population was overweight or obese (Buttigieg et al, 2005).

1.4.1 Predisposing Factors for Diabetes in Malta

Throughout the years, Malta has acquired distinctive cultural changes as one ruling realm assumed control from another, leaving an ethnic blend, significant socio-assorted qualities and varied genetic imprints on the Maltese population. The risk of developing T1D is increased by certain variants of the HLA-DQA1, HLA-DQB1, and HLA-DRB1 genes. These genes provide instructions for making proteins that play a critical role in the immune system (Savona-Ventura

et al, 2003; Formosa et al, 2012; Pace et al, 2013). In 2008, Al-Ashtar reported that the Libyan and Maltese populations had similar metabolic profiles and genetics (Al-Ashtar et al, 2008).

1.4.2 Epidemiological Studies in Malta

A diabetes clinic was established at the largest public hospital in Malta as the diabetes burden was increasing over the years in 1939. By the 1950's, there was an expansion of the diabetic clinics in the community across Malta as diabetes was considered to be one of the major public health problems. This uplifted the keen interest of local academia and by 1964, the first epidemiological diabetes pilot study was conducted by Prof. J. Zammit Maempel (Galea et al, 1963; Savona-Ventura et al, 2001).

In 1981, the WHO conducted the second prevalence-related study on diabetes in Malta. During the same year, the Maltese Diabetes Association was established and one year later (1982), the association became part of the International Diabetes Federation (IDF).[6]

No further population-based studies have been conducted in Malta until recently in 2010. A pilot study was done by the local Centre of the European Health Examination Survey, in which the survey examined the fasting glucose level of 400 randomized adult participants (18 years and older) and on the basis of a fasting glucose level, obtained a diabetes prevalence of almost 10% of the selected population were suffering from diabetes. Females (10.7%) had an increased blood glucose average compared to the male participants (9%) (Cuschieri et al, 2014).

[6] Katona G, Aganovic I, Vuskan V, Skrabalo Z. National Diabetes Programme in Malta: Phase 1 and II Final Report. World Health Organisation. 1983.

There is no national diabetes strategy or diabetes register in Malta, despite that there has been the arrangement of an administrative diabetes centre gathering. There is a need to update prevalence studies to include genetic factors in the Maltese population (Cuschieri et al, 2014).

1.5 Complications of Diabetes

Patients with diabetes have a higher risk of developing a number of comorbidities. Hyperglycaemia can lead to cardiovascular, ocular, and renal and nervous systems comorbidities. People with diabetes have an increased risk of developing secondary infections (Fong et al, 2004).

1.5.1 Microvascular Complications of Diabetes

The underlying driver of microvascular disease is tissue exposure to chronic hyperglycaemia. Microvascular disease tends to occur predominantly in tissues where glucose uptake is independent of insulin activity (eg kidney, retina and vascular endothelium) because these tissues are exposed to glucose levels that correlate very closely with blood glucose levels (Goh et al, 2002).

1.5.1.1 Diabetic Retinopathy

Diabetic retinopathy is the most common microvascular complication of diabetes. Retinopathy is responsible for more than 10,000 new cases of blindness every year in the United States (Fong et al, 2004). The risk for patients developing diabetic retinopathy mainly depends on the duration and severity of the hyperglycaemia. The UK Prospective Diabetes Study (UKPDS) revealed that both improved glucose control and improved blood pressure control reduced the risk of retinopathy (UKPDS, 1998).

Diabetic retinopathy is classified as being background or proliferative. Background retinopathy includes symptoms such as small haemorrhages in the middle layers of the retina. Haemorrhages appear as dots, and are frequently referred to as dot haemorrhages. Proliferative retinopathy is the more advanced form of the disease and it is characterized by angiogenesis on the surface of the retina, which can lead to vitreous haemorrhage. White areas on the retina, "cotton wool spots" can be a sign of impending proliferative retinopathy. If retinopathy is left untreated, blindness may occur. Laser photocoagulation can often prevent proliferative retinopathy from progressing to blindness (Warwick et al, 2017).

1.5.1.2 Diabetic Nephropathy

In the United States, diabetic nephropathy is the leading cause of renal failure (Gross et al, 2005). It is characterized by microalbuminuria (proteinuria of more than 500 mg/day) in a diabetic individual. Microalbuminuria is characterized by albumin excretion of 30 to 299 mg/24 hours. In patients with T1D and T2D that have been left without intervention, microalbuminuria develops into proteinuria, and overt diabetic nephropathy (Gross et al, 2005).

Treating patients with angiotensin-converting enzyme inhibitors has shown to decrease the risk of developing cardiovascular and nephropathic events in patients with T2D, but has not shown to prevent the development of microalbuminuria in patients with T1D (Adler et al, 2003; Gross et al, 2005).

1.6.1.3 Diabetic Neuropathy

The ADA defined diabetic neuropathy as "the presence of symptoms and/or signs of peripheral nerve dysfunction in people with diabetes after the exclusion of other causes" (American Diabetes Association, 2007).

The effect of hyperglycaemia on peripheral nerve damage is not very well understood. This is likely to be related to mechanisms such as polyol accumulation from high glucose concentrations that can promote non-enzymatic formation of advanced glycosylated end products (AGEs), and oxidative stress (Giacco et al, 2010). More than 80% of amputations in diabetic patients occur after foot injury or ulcerations, which can result from diabetic neuropathy (Gross et al, 2005). Identifying diabetic peripheral neuropathy is important, as other types of neuropathy may mimic diabetic sensory neuropathy, including vitamin B_{12} deficiency, chronic inflammatory polyneuropathy, uraemia and hypothyroidism (Boulton et al, 2005).

1.6.2 Macrovascular Complications of Diabetes

Macrovascular complications are conditions and diseases of the large blood vessels caused by diabetes. Factors contributing to macrovascular complications include insulin resistance, hyperglycaemia, hypertension, smoking, abnormalities in blood clotting and hypercholesterolemia. The reason as to what causes some individuals to develop diabetes-related cardiovascular complications while others do not remains unknown. It is thought that some individuals may have unidentified factors and tissues that are resistant to damage. Inherited factors and lifestyle may increase the risk of macrovascular complications (Boyle et al, 2007).

Cerebrovascular disease and peripheral artery disease are the most common macrovascular complications. Diabetes is a risk factor for stroke. The risk for stroke in individuals with diabetes is two to four fold greater in Caucasian and women (Paterson et al, 2007). Diabetes contributes highly to sudden deaths from stroke. Individuals with diabetes who experience a stroke tend to have more severe disabilities and neurological deficits, a higher possibility of stroke recurrence and poorer long term prognosis compared to patients without diabetes (Paterson et al, 2007). The presence of diabetes adversely affects cerebrovascular circulation, increasing the risk of extracranial and intracranial atherosclerosis. Hyperglycaemia is a significant determinant of fatal and non-fatal strokes. Hyperinsulinemia appears to pose a risk for the occurrence of stroke but the exact relationship is still not determined. Factors such as hyperuricemia and microalbuminuria pose a high risk for stroke occurrence (Hogan et al, 2003; Paterson et al, 2007).

Peripheral artery disease, another macrovascular complication of diabetes, is a result of the occlusion of the lower extremity arteries. Lower extremity amputation is more evident in people with diabetes and peripheral artery disease than in the non-diabetic population. Peripheral artery disease, like other vascular diseases, becomes more severe with increasing duration (Cade et al, 2008).

A major risk factor in macrovascular disease is atherosclerosis, which results in the narrowing of arterial walls. Among the macrovascular complications, studies have shown that coronary heart disease has been associated with diabetes. The presence of microvascular disease is a predictor of coronary heart events (Donaghue et al, 2009). T2D remains an independent risk factor for the development of stroke, ischemic disease and death (Fowler et al, 2008). Diabetes

has been a major risk factor in the development of cardiovascular disease. Coronary artery disease is the leading cause of death in patients with diabetes (Donaghue et al, 2009). Clinical manifestations of macrovascular complications include peripheral vascular disease, stroke and congestive heart failure. The relative risk of macrovascular complications in diabetes is more eminent in women than men, compared to the non-diabetic population. Most patients with T2D portray signs of macrovascular disease during the diagnosis of diabetes (Nathan et al, 2005). Major cardiovascular risk factors such as hypertension, obesity and diabetes are all conditions of insulin resistance. A model of multiple metabolic syndromes primarily places insulin resistance at the centre of the pathogenesis of macrovascular complications (Nathan et al, 2005).

Risk factor reduction and medical management are essential in preventing the progression of vascular-related diseases. Practices that should be emphasized at the onset of diabetes and reinforced in long-term management are moderate exercise, smoking cessation and weight loss. Intensive treatment of hypertension has notably reduced macrovascular complications and microvascular end points. When glycaemic control is well-managed, it is known to reduce the more acute complications of diabetes, as well as improving the day-to-day life of the patient (Fowler et al, 2008).

1.6 Diagnostic Tests for Diabetes

Testing for T1D occurs in patients with diabetes symptoms such as polyuria, polydipsia and polyphagia. There are several ways to diagnose diabetes. Each way usually needs to be repeated on a second day to diagnose diabetes (American Diabetes Association, 2016).

1.6.1 Fasting Plasma Glucose Test

The Fasting Plasma Glucose Test (FPG) test, is used for detecting pre-diabetes and diabetes. The FPG test is a common test utilised for the diagnosis of diabetes, is widely available and inexpensive compared to the Oral Glucose Tolerance Test (Wang et al, 2013). FPG is used for measuring the blood glucose levels in an individual who has fasted for a period of 8 hours. Its reliability is at its maximum when it is conducted in the morning. Individuals should have a fasting glucose level ranging between 100 to 125 mg/dL (5.6 to 7.0 mmol/L). When the FPG level increases to above 126 mg/dL (7.0 mmol/L), this means that the individual is suffering from diabetes (Buchanan et al, 2005).

1.6.2 Oral Glucose Tolerance Test

The Oral Glucose Tolerance Test (OGTT), is a test used for the diagnosis of diabetes, GD and prediabetes. The OGTT is more sensitive when compared to the FPG test, but it is less convenient to conduct since OGTT requires the individual to fast for at least 8 hours before the test is conducted. The plasma glucose is measured immediately before and 2 hours after the individual drinks a solution containing 75 grams of glucose dissolved in water (Wang et al, 2013). When the level of blood glucose is between 140 and 199 mg/dL (7.8 to 11.1 mmol/L), the individual may have a case of prediabetes known as impaired glucose tolerance (IGT). After confirmation from a second test, the two-hour level of glucose exceeding the 200 mg/dL (11.1 mmol/L) mark is a clear warning sign for diabetes (Crowther et al, 2005).

1.6.3 Glycated Hemoglobin (HbA1c) Test

The HbA1c test is a blood test which shows the blood glucose control of a particular individual during the last 3 months. It does not indicate any daily fluctuation in blood glucose levels. The HbA1c test is comparatively more convenient for diabetic patients as opposed to conventional

glucose tests, since it does not require fasting. It can be conducted at any time. A standard HbA1c reading should be below 5.7%. An HbA1c between 5.7% and 6.4% is an indication of an individual with prediabetes. Individuals with prediabetes are at a risk of diabetes in the future, depending on the degree of the risk factors. Individuals with HbA1c percentage above 6% are at a high risk of being diagnosed with diabetes. A level of 6.5% or greater is a clear indicator of diabetes (Buchanan et al, 2005).

1.6.4 Random Plasma Glucose Test

The random plasma glucose (RPG) test is a simple blood glucose test. The patient is not required to fast to perform the test. RPG levels of more than 200 mg/dL (11.1 mmol/L) are a sign that the patient's blood glucose is not controlled (Crowther et al, 2005).

1.7 Diabetes Treatment and Management

Patients with T1D require lifelong insulin therapy. Most require 2 or more injections of insulin daily, with doses adjusted on the basis of self-monitoring of blood glucose levels. The ADA released a position statement on the diagnosis and management of T1D in all age groups. The statement includes a new pediatric glycemic control target of HbA1c of less than 7.5% across all pediatric age groups, replacing earlier guidelines that specified different glycemic control targets by age (American Diabetes Association, 2016). The ADA has released condensed recommendations for "Standards of Medical Care in Diabetes: Abridged for Primary Care Providers" for T1D, focusses particularly on the following aspects:

1.7.1 Lifestyle changes

Lifestyle interventions can be as effective as drug treatment. Certain barriers to lifestyle changes and physical activity may exist (Hansen et al, 2011). Disease manifestation from environmental factors is largely preventable. Diet is one of the major factors now linked to a

wide range of diseases including diabetes. The amount and type of food consumed is a fundamental determinant of human health. Diet constitutes a crucial aspect of the overall management of diabetes (Asif et al, 2014).

1.7.1.1 Consumption of Alcohol

Alcohol can reduce the levels of blood glucose. Hypoglycaemia and alcohol impact cognitive functions. Patients with diabetes should refrain from alcohol intake. Decreasing the amount of alcohol intake can result in decreasing weight. Individuals with diabetes should be well-informed on alcohol consumption in to help prevent hypoglycaemia (UK Prospective Diabetes Study, 2003).

1.7.1.2 Smoking Cessation

A study by Hirai et al, concluded that smokers have a higher risk of severe hypoglycaemia in T1D. The researchers divided individuals with T1D into three groups; those who never smoked, those who had smoked in the past but quit successfully at least one year before the study, and currently smokers. The researchers found that individuals who never smoked had three times less risk of experiencing severe hypoglycaemia than individuals who smoked (Hirai et al, 2007).

1.7.1.3 Physical activity

Physical activity improves physical strength and fitness, reduces cardiovascular risk factors and improves well-being in T1D. Physical activity reduces insulin requirements (Chimen et al, 2012). Most adults with T1D participate less frequently in physical activity and may adopt unhealthy lifestyles. Although the reasons for this are multifactorial, including concerns over loss of control and low fitness levels, the overriding barrier to physical activity appears to be fear of severe hypoglycaemia (Colberg et al, 2015).

1.7.1.4 Self-monitoring

Self-monitoring of blood glucose (SMBG) is an important component of therapy for diabetes. The goal of SMBG is to collect information about blood glucose levels at different time points to enable maintenance of more constant glucose levels. Self-monitoring can be used to aid in the adjustment of a therapeutic regimen in response to blood glucose values and to help patients adjust their dietary intake, physical activity, and insulin doses to improve glycaemic control (Asif et al, 2014). Lack of regular SMBG predicts hospitalization for diabetes-related complications. Self-monitoring of blood glucose is an essential tool for individuals with diabetes who are taking insulin or for patients who experience fluctuations in blood glucose levels, especially hypoglycaemia (American Diabetes Association, 2016).

1.7.1.5 Glycaemic Control and Carbohydrate counting

Individuals with diabetes may need meal planning to decrease glycaemic levels. Foods with a low glycaemic index and high fibre are recommended (American Diabetes Association 2010). Carbohydrate counting was developed in the last half of the 20th century as a procedure to monitor the intake of carbohydrates but did not develop into a broadly accepted procedure until its practice in the Diabetes Control and Complication Trail (DCCT) in the 1990's (DCCT, 1992).

The ADA identifies that carbohydrate counting is important to sustain effective glycaemic control among patients suffering from diabetes and lists carbohydrate counting as an important strategy to assess dietary intake (Bishop et al, 2009). It is suggested by the ADA that individuals with T1D should utilise carbohydrate monitoring to match the doses of insulin-to-carbohydrate intake, or to match the intake of carbohydrates with the doses of insulin (American Diabetes Association, 2016).

Carbohydrates are an important element influencing post-prandial blood glucose levels in individuals suffering from T1D, but patients frequently fail to assess carbohydrate content accurately. Poor individual education is believed to contribute to glycemic control (Bruttomesso et al, 2001). T1D patients are capable of adjusting the doses of insulin according to the carbohydrate quantity of a meal, including blood glucose levels, as they require glycaemic control to manage their condition (Asif et al, 2014). Through better glycaemic control, T1D patients have reduced the risk of long-term microvascular complexities related to T1D. Carbohydrates, whether from starches or sugars, have a higher influence on the post-prandial blood levels in comparison to fat and protein. Carbohydrate assessment is mainstay in diabetes education and management (Finner et al, 2015).

Individuals with T1D require insulin to convert carbohydrates into energy. In a healthy individual, the pancreas releases insulin following meals. T1D patients need additional insulin to maintain appropriate levels of blood glucose. Carbohydrate counting is used to keep the level of blood glucose stable, while improved carbohydrate counting assists with measuring the dose of insulin that is required to balance out the meal that is being ingested. Carbohydrate counting provides diabetic patients with the freedom to select the meals that individuals take pleasure in (Finner et al, 2015). Improving patient's education introduces advanced carbohydrate counting as a tool to improve the management of blood glucose, assess advanced and basic carbohydrate need. Intensive diabetes treatment might be related to increased of hypoglycaemia, specifically among T1D patients and patients with insulin-treated T2D (Asif et al, 2014).

Traditionally, insulin therapy is inflexible, with dietary education mainly focused to sustaining a prescribed intake of a meal matched to an inflexible insulin dose. Approaches have been conducted to categorise and quantify foods in practice, as well as calories, food exchange, total

available glucose and carbohydrate points. The goal of carbohydrate counting was to sustain a continuous intake of glucose through matched insulin treatment (Bell et al, 2014). Carbohydrate counting leans on three main concepts; 1) clinical research studies have indicated that carbohydrates are the key factor that influence postprandial blood glucose level and are related to the requirement level of insulin. 2) Carbohydrates are changed into glucose within 2 hours once absorbed. 3) The requirement of the appropriate insulin levels and postprandial glycaemic levels are controlled by the overall amount of carbohydrate ingested. Current research is to examin the influence of the carbohydrate-counting approach and medical meal strategy on the patient's quality of life, including the success of treatment among T1D patients (Bell et al, 2014).

Studies have shown that the same extent of carbohydrates from diverse food sources generates a wide difference in insulin and glycaemic responses. Postprandial insulin reactions to foods containing fat, protein and carbohydrates are not directly related to carbohydrate content, inferring that carbohydrate counting will fall short in T1D management (Bell et al, 2014; Finner et al, 2015).

Carbohydrates are found in fibre, starches, and sugars. Healthy carbohydrates like vegetables, fruits and whole grains are recommended as part of healthy diet plans as they deliver both nutrients and energy, like minerals, vitamins and fibre. Fibre may assist individuals in controlling their weight and reduce cholesterol levels (Collier et al, 2007).
Carbohydrates influence the levels of blood glucose in the body, particularly in children with T1D (Bishop etal, 2009).

Weight gain in T1D may be caused by physical inactivity and an imbalance in diet. One of the main problems which may be encountered whilst performing carbohydrate counting together with administration of flexible insulin, is that although patients may control their intake of carbohydrates, these patients might tend to also increase the intake of other foods which do not contain carbohydrates, an example of this is red meat. An increase in carbohydrate intake may lead to an increase in weight (Collier et al, 2007). Weight gain is an increasing problem among diabetic patients. Weight gain among T1D patients may be caused due to irregular nutritional aspects such as unhealthy food, along with meal time irregularity (Son et al, 2014).

Diabetes is a condition that progresses with both psychological and physical issues and impairs the quality of life in a significant manner. The underlying chronic and acute disorders influence the quality of life of the patient. The patient's level of education, social status, and diabetes-related food intake, perception of illness, treatment and exercise affect the glycaemic control and quality of life of diabetic patients (Son et al, 2014).

The treatment for T1D is diet control and insulin therapy. Medical dietary treatment supports normal growth and targeted glycaemic control. The recommendation of nutrition for patients with T1D must consider objectives for obtaining a target level of blood glucose that sustains normal development and growth without excessive hypoglycaemia. Nutrition and food directly influence glycaemic control, particularly carbohydrates. Carbohydrate counting may be utilised, to adjust the insulin dose when consuming snacks and meals, and estimating the carbohydrate intake using the insulin-to-carbohydrate ratio (Loghmani et al, 2005). A study by Bevier et al, identifies the insulin-to-carbohydrate ratio as "being the amount of insulin needed to balance the amount of carbohydrate in a meal or snack to keep the blood glucose at an acceptable level after eating". Calculating insulin-to-carbohydrate ratios is challenging for

T1D patients, as individuals must measure pre-prandial blood glucose levels, any recent insulin correction doses, the time of the day to administer insulin, insulin sensitivity and bolus insulin administered. If any of the variables is miscalculated, the post-prandial glucose level is affected (Bevier et al, 2007).

Every individual has a different response and potential resistance to insulin, which means that different diabetic people have a different insulin-to-carbohydrate ratio. The insulin-to-carbohydrate ratio defined as 'one unit of insulin that can cover an amount (grams) of carbohydrate'. The estimation of carbohydrate to insulin ratio in children is 1 unit of insulin equal or equivalent to 20 to 30 grams of carbohydrate and even up to 15 grams in adults (Costa et al, 2005).

Carbohydrates are divided into three classes. The first class is simple carbohydrates, which consist of two types of sugars (Souto et al, 2010); 1) Natural sugars such as fruits or milk and 2) Added sugars in food processing such as syrups or cakes. The second class of carbohydrate is starch, which is complex carbohydrates. Foods that contain starch are vegetables like corn, potatoes, peas and lima beans. Grains like rice, oats and barley contain starch. The third class of carbohydrate is fibre, which is mainly derived from plant foods. When consuming food containing fibre (e.g. vegetables, fruits, whole grains, legumes and nuts), most of it is not absorbed by the intestines. Adults need to eat around 25 – 30 grams of fibre each day (Souto et al, 2010).

1.7.2 Insulin Treatment for Diabetes

Insulin is used for the treatment of diabetes, especially in patients suffering from T1D. Insulin therapy has adverse effect when the amount is increased as it is a key glucose-decreasing agent. Insulin therapy has also been marred by pharmacological complications. There are a considerable number of disadvantages in using insulin therapy such as hypoglycaemia and diabetic ketoacidosis (National Diabetes Data Group, 1979; American Diabetes Association, 2006).

There are four main types of insulin: short-acting, rapid-acting, intermediate-acting and long-acting insulins. Table 1.1 illustrates the type, onset time, peak time and the duration of each type of insulin (American Diabetes Association, 2016).

Table 1.1 Types of Insulin

Type of Insulin	Brand Name	Active Ingredient Name	Onset of action	Peak Plasma lvl	Duration of action (hours)
Rapid-acting	Novo Log®	Insulin aspart	15 minutes	30 to 90 minutes	3 to 5
	Apidra®	Insulin glulisine	15 minutes	30 to 90 minutes	3 to 5
	Humalog®	Insulin lispro	15 minutes	30 to 90 minutes	3 to 5
Short-acting	Humulin R®	Regular insulin human (R)	30 to 60 minutes	2 to 4 hours	5 to 8
	Novolin R®				
Intermediate-acting	Humulin N®	NPH* (N)	1 to 3 hours	8 hours	12 to 16
	Novolin N®				
Long-acting	Levemir®	Insulin detemir	1 hour	Peakless	20 to 26
	Lantus®	Insulin glargine ^			
Pre-mixed NPH* (intermediate-acting) and regular (short-acting)	Humulin® 70/30 Novolin 70/30	70% NPH* and 30% regular	30 to 60 minutes	Varies	10 to 16
	Humulin® 50/50	50% NPH* and 50% regular insulin human	30 to 60 minutes	Varies	10 to 16
Pre-mixed insulin lispro protamine suspension (intermediate-acting) and insulin lispro (rapid-acting)	Humalog® Mix 75/25	75% insulin lispro protamine and 25% insulin lispro	10 to 15 minutes	Varies	10 to 16
	Humalog® Mix 50/50	50% insulin lispro protamine and 50% insulin lispro	10 to 15 minutes	Varies	10 to 16
Pre-mixed insulin aspart protamine suspension {intermediate-acting) and insulin aspart (rapid-acting)	NovoLog® Mix 70/30	70% insulin aspart protamine and 30% insulin aspart	5 to 15 minutes	Varies	10 to 16

*NPH (Neutral Protamine Hagedorn) insulins.

1.8 Implications of the Study

Carbohydrate counting is performed using knowledge about carbohydrate-containing meals and their influence on the levels of blood glucose and by counting the grams of carbohydrate or the exchange of carbohydrates eaten in relation to insulin taken. The ratio of carbohydrate-to-insulin to measure the bolus does is necessary (Bell et al, 2014). Patients should be educated to be able to select their meals according to their blood glucse levels (Tow et al, 2013).

A study by Bell et al, investigated utilising carbohydrate counting to lower the doses of insulin according to the HbA1c levels. This improved patients' quality of life and satisfaction. Even though measuring the content of carbohydrates is an important factor in measuring insulin doses, other approaches can also be utilised to measure the intake of carbohydrates (Bell et al, 2014).

If an individual is living with T1D, using carbohydrate counting is a useful and effective way to manage blood glucose levels. Being knowledgeable about carbohydrate counting in drinks and meals is important in diabetic patients, since carbohydrate counting is useful for patients on basal-bolus insulin treatment. Carbohydrate counting may lead to better control of blood glucose and higher flexibility in the amount of carbohydrates which can be consumed (Finner et al, 2015).

When an individual decides to calculate the carbohydrate intake, knowledge of the insulin-to-carbohydrate ratio is important. The ratio of insulin-to-carbohydrate differs from person to person (Tow et al, 2013). A multi-disciplinary team can assist to identify each patient's insulin-to-carbohydrate ratio. The insulin-to- carbohydrate portion is estimated and the portion is fine-tuned based on blood glucose control. If patients determine how many grams of carbohydrate

are in a meal and determine their carbohydrate-to-insulin portion, the number of units of bolus insulin required can be calculated (Finner et al, 2015).

Studies have been conducted about different aspects regarding carbohydrate counting education among T1D patients (Bell et al, 2014; Finner et al, 2015). The importance of conducting this study is related to education and management of carbohydrate counting having an influence in controlling blood glucose levels.

1.9 Aim of the Study

The aim of this study was to evaluate how education about insulin treatment, insulin adjustments and dietary freedom can affect the glycaemic control among patients diagnosed with T1D.

1.10 Objectives of the Study

- To evaluate the knowledge of T1D patients about carbohydrate counting
- To compare HbA1c levels in patients using flexible insulin therapy with HbA1c levels in patients using traditional insulin therapy
- To evaluate HbA1c levels with age and education levels.
- To evaluate whether patients test their blood glucose and perform physical activity.

Chapter 2: Methodology

The methodology included literature review, design and development of a questionnaire realated to carbohydrate counting in T1D patients and data analysis.

2.1 Setting

The study was carried out at the Diabetic Outpaitents Clinic at Mater Dei Hospital (MDH). MDH is an acute general teaching hospital offering a full range of hospital services. It provides an extensive range of specialist services. The 250,000 square metre complex includes 825 beds and 25 operating theatres. All patients with diabetes regardless of the aetiology and the classification of their diabetes have admittance to specialist care provided within the Diabetes Outpatient Clinic at MDH.

2.2 Ethics Approval

The study took place during an 8-week period (October to November 2016), following approval from the University Research Ethics Committee, approval from the consultants and nursing officer at the diabetes clinic, MDH administration and approval from the data protection officer. University Research Ethics Committee approval was obtained (Appendix 1).

2.3 Literature Review

A literature search was conducted. The study was conducted using PubMed, MEDLINE, Medscape and Google Scholar and online journals. No restriction on the language or year of publication was applied during the literature search. Related terms used in the research included ‘diabetes’ ‘clinical pharmacy in diabetic clinic’, ‘carbohydrate-counting method’ and ‘T1D’. A search of related dissertations was also performed.

2.4 Study Design

The study investigated the knowledge that T1D patients had about carbohydrate counting. The study aimed to assess the effect that educational sessions about carbohydrate counting which were being held at MDH had on T1D patients. These effects were to be assessed by checking blood glucose levels of patients at time 0, 3 and 6 months following the educational session. In late June 2016, these sessions on carbohydrate counting at MDH were stopped due to shortage of staff and a questionnaire entitled Carbohydrate Counting Assessment Questionnaire (CCAQ) aimed to assess patient knowledge on carbohydrate counting glucose testing and physical activity was set up. The aim of the questionnaire was to gather knowledge from T1D patients about carbohydrate counting, glucose testing and physical activity. The questionnaire was self-administered to the patients. A validation panel was set-up to validate the questionnaire following its development.

2.4.1 Questionnaire Development

The CCAQ was developed (Appendix 2). The CCAQ determined symptoms the patients were suffering from, level of physical activity, problems in glycaemic control that the patients were experiencing and patients' carbohydrate counting skills.

The self-administered CCAQ was adopted from both The Heart Healthy Carb Quiz (HHCQ) and the Stanford Patient Education Research Centre diabetes questionnaire. The HHCQ was developed by Walker et al, to assess carbohydrate counting skills and knowledge of heart-healthy diet, and nutrition label-reading skills (Appendix 3) (Walker et al, 2012). The team that developed The Stanford Patient Education Research Centre diabetes questionnaire, has more than 20 years of experience developing, adapting, and testing self-administered scales for research subjects with chronic diseases (Appendix 4) (Lorig et al, 2016). The rationale when

developing the CCAQ consisted of determining knowledge of whether the patients could identify foods containing high amount of carbohydrates.

CCAQ consisted of 4 sections. Section 1 consisted of patients' demographic data, which was adopted from the Stanford Patient Education Research Centre diabetes questionnaire. Questions were removed when developing the CCAQ such as ethnic origin since only Maltese people participated in the study, relationship status; psychology and sleep-related questions which were beyond the scope of this study and were eliminated. Other questions were modified such as level of education to be grouped as secondary, post-secondary, graduate and postgraduate.

Section 2 contained information about patient general health and symptoms that patients suffered from such as fatigue, light-headedness and dry mouth. Patients were asked whether they visited their physician in hospital for a routine check-up in the past 6 months. Questions in section 2 were adopted from the Stanford Patient Education Research Centre diabetes questionnaire. Some questions were modified to simplify the questions for the participants. Other questions about pain and shortness of breath, which were mostly related to T2D and its comorbidities, were eliminated.

Section 3 consisted of glucose testing, physical activity and the type of insulin used by the patients, which was adopted from the Stanford Patient Education Research Centre diabetes questionnaire. Some questions were modified. The physical activities section was changed to

help determine how often patients performed physical activity rather than type of exercise performed which was beyond the scope of this study.

Section 4 consisted of 14 different carbohydrate counting questions to assess the patients' knowledge about carbohydrate counting and a list of consumed food was included in this section. Questions on commonly consumed foods were included following recommendation made by the dietitian Section 4 was based on the HHCQ. Questions about carbohydrate counting were modified to make it more user-friendly and easy to understand / more comprehensive by the patients.

2.3.2 Questionnaire Validation

Internal validity of a questionnaire measures and evaluates whether or not a tool assesses what it should, and this may consist of surface validity, content validity and/or criterion-related validity. External validity refers to the extent to which the results from a study are applied for other populations (Bland et al, 2002).

To validate the CCAQ, the focus was measurement of internal validity. Face validity, which is a basic test to assess the questionnaire, was carried to evaluate the accuracy of the questionnaire, and is followed up with the content validity to measure the extent to which the questionnaire tests the skill(s) that it is supposed to test (Fitzgerald et al, 1998; Rattray et al, 2006). A meeting with an expert panel after the questionnaire was set-up was done to validate the CCAQ. The expert panel consisted of one diabetologist, one certified diabetes educator, two pharmacists and one dietician who works with patients with diabetes at Mater Dei Hospital. After meeting with the panel, the CCAQ was improved by removing any poorly

written or unrelated questions, and creating new questions such as changing foods units from cup to ml. The dietician, who took part in the CCAQ modifications, had experience with the possible target population and helped in identifying foods commonly consumed by the patients which were included in the CCAQ. The modified CCAQ was given the expert panel for second review and the finalised questionnaire after validation was translated into Maltese language.

The readability of the final version of the CCAQ was assessed by Gunning Fog and Flesch Reading Ease as being at a sixth-grade reading level, and easy to read. (Koontz 2010).

2.3.2 Inclusion and Exclusion Criteria

The participants included in Group 1 were older than 12 years of age, diagnosed with T1D and reported to use carbohydrate counting. Participants had to be able to read and write in Maltese and/or English at a sixth-grade level of reading. The Group 2 were participants older than 12 years of age, did not use carbohydrate counting and were able to read and write in Maltese and/or English at a sixth grade reading level. Participants were excluded if they did not self-select foods or required assistance in daily diabetes-related self-care.

2.4.4 Patient recruitment

The participants recruited were selected by convenience sampling from the outpatients of the diabetes clinic at Mater Dei Hospital to patients meeting the inclusion and exclusion criteria. The questionnaires were distributed to diabetic patients while they were waiting for their outpatient appointment. Patients who agreed to meet with the researcher after being introduced by a nursing officer at the diabetic clinic, were explained the aims of the study.

An information sheet was given to the patients who agreed to use the CCAQ following their signing of a consent form (appendix 5). The total time taken by every patient was between 8 to 15 minutes to complete the CCAQ with mean time of 10 minutes.

2.4.5 Data Analysis

Data was analyzed descriptively. Mean, standard deviation and ranges were used for continuous variables. Frequencies were calculated for categorical variables. Pearson's chi-squared test was used to examine the association between HbA1c level in Group 1 and Group 2. All statistical analyses were conducted using IBM Statistical Package for Social Sciences (SPSS) 21.0. A p-value <0.05 indicated statistical significance.

Chapter 3: Results

3.1 Overview of data collected

Azzopardi defines practicality as "the feasibility of using the measurement instrument in practice and applicability as the adaptability of the measurement instrument within the setting where it is intended to be used" (Azzopardi et al, 2000). The measurement instrument, in this case, was a questionnaire and documentation form.

Eighty diabetic patients were selected from the diabetes clinic at MDH by convenience sampling. The experimental group consisted of 40 patients using flexible insulin therapy and carbohydrate counting. The control group consisted of 40 patients on Conventional Insulin Therapy. HbA1c readings were taken from each patient's medical records.

3.2 Demographical Analysis

This study involved 80 participants (47 female, 33 male) with a mean age of 38 years (range 14 – 66). These participants were divided into two groups, Group 1 and Group 2.

3.2.1 Age and Gender

There were 22 male participants and 18 female participants in Group 1. The mean age of Group 1 was 40 years (range 16 - 66 years) with a standard deviation of 14. For Group 2, the number of male participants was 11 while the number of female participants was 29. The mean age of Group 2 was 36 years (range 14 – 65 years) with a standard deviation of 16.25.

3.2.2 Education

Figure 3.1 represents the education level of the patients which was as follows: secondary, post-secondary, graduate and postgraduate. Most of the patients had a post-secondary level of education.

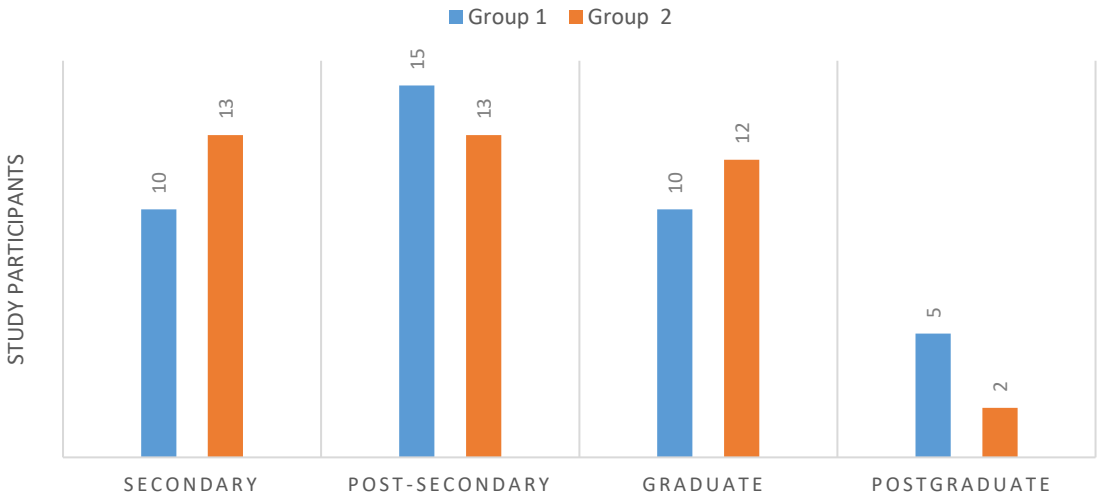

Figure 3.1: Education level Comparison Between Group 1 and 2 Patients N=80

3.2.3 Duration of diabetes

Figure 3.2 represents the duration of diabetes since diagnosis in Group 1 and 2 patients. Most patients (11 participants) had diabetes diagnosed between 10 and 14 years ago and Most patients (12 participants) had diabetes diagnosed between 10 and 14 years ago.

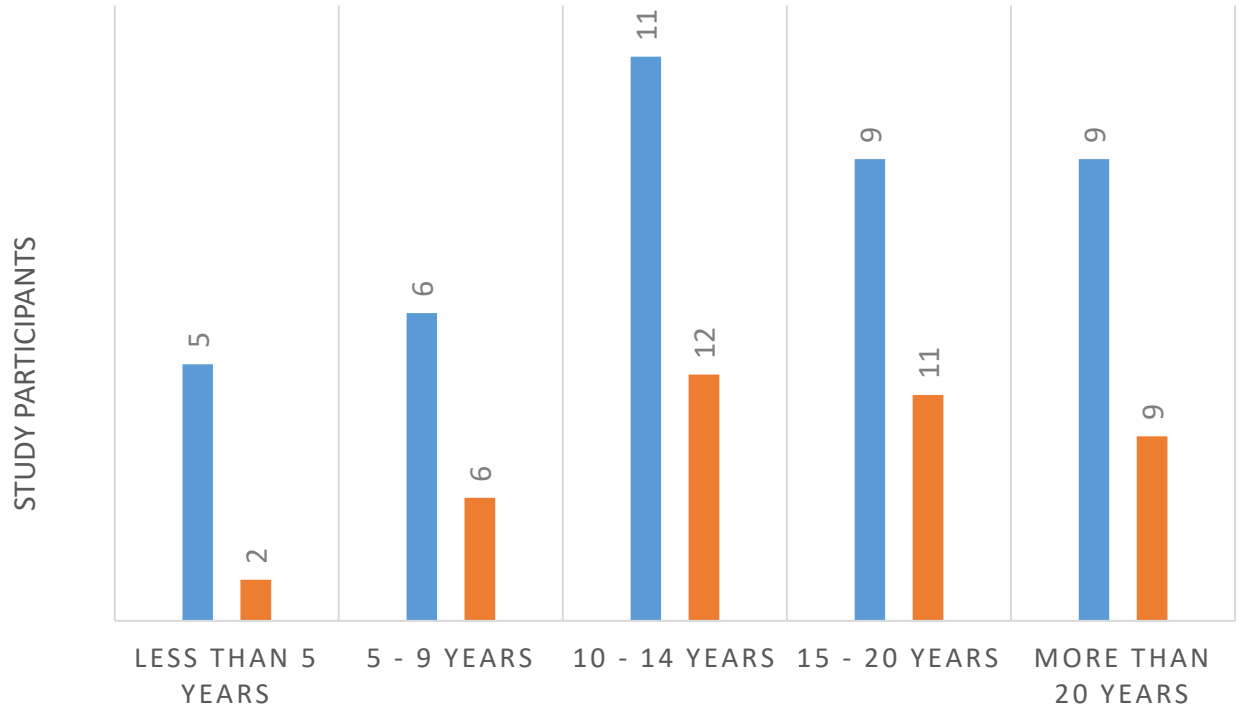

Figure 3.2 Duration of Diabetes in Group 1 And 2 (N=80)

3.2.1.4 Signs and Symptoms

The most common symptoms patients suffered from in Group 1 were related to severely high blood sugar (blood glucose readings of 16.6 mmol/L or higher) with 28 participants experiencing this. No patients claimed to have 'passed out, fainted or lost consciousness'. The participants were asked if they had visited the hospital recently. Most of the patients (n=37) said that they visited their physician in hospital in the past 6 months. Table 3.1 lists the symptoms patients experienced in the past six weeks and their hospital visits in the last six months.

Table 3.1 Group 1 participants' symptoms in the past six weeks and hospital visits (n=40)			
1. Nausea or vomiting?	No 35	Yes 3	Don't know 2
2. Abdominal pain?	No 35	Yes 5	Don't know 0
3. Light-headedness?	No 29	Yes 10	Don't know 1
4. Severely high blood sugar (blood glucose readings of 16.6 mmol/L Or higher?)	No 12	Yes 28	Don't know 0
5. Passing out, fainting or loss of consciousness, even For a short time?	No 40	Yes 0	Don't know 0
6. Fatigue?	No 28	Yes 9	Don't know 3
7. Dry mouth?	No 31	Yes 9	Don't know 0
8. Did you go to a hospital emergency department?	No 32	Yes 8	
9. Were you hospitalized for one night or longer?	No 35	Yes 5	
10. Did you visit a physician for routine check-up in the past 6 months?	No 3	Yes 37	

As shown in Table 3.2, the most common symptoms patients suffered from in Group 2 was related to 'Severely high blood sugar (blood glucose readings of 16.6 mmol/L or higher)' with 33 participants experiencing this. Three patients claimed to have 'passed out, fainted or lost consciousnesses and experienced 'abdominal pain'.

Table 3.2 Group 2 participants' symptoms in the past six weeks and hospital visits (n=40)			
1. Nausea or vomiting?	No 30	Yes 5	Don't know 5
2. Abdominal pain?	No 37	Yes 3	Don't know 0
3. Light-headedness?	No 23	Yes 11	Don't know 6
4. Severely high blood sugar (blood glucose readings of 16.6 mmol/L Or higher?)	No 7	Yes 33	Don't know 0
5. Passing out, fainting or loss of consciousness, even For a short time?	No 37	Yes 3	Don't know 0
6. Fatigue?	No 30	Yes 7	Don't know 3
7. Dry mouth?	No 31	Yes 6	Don't know 3
8. Did you go to a hospital emergency department?	No 30	Yes 10	
9. Were you hospitalized for one night or longer?	No 33	Yes 7	
10. Did you visit a physician for routine check-up?	No 6	Yes 34	

3.2.5 Glucose Testing

All patients in Group 1 and 2 said they have a glucometer at home and claimed that they measure their blood glucose every day. Figures 3.3 shows how often the patients measure their blood glucose for Group 1 and 2 patients. Thirty participants in Group 1 said they were testing the blood glucose four times a day, while 24 participants of Group 2 answered the that they were testing the blood gloucose four times a day.

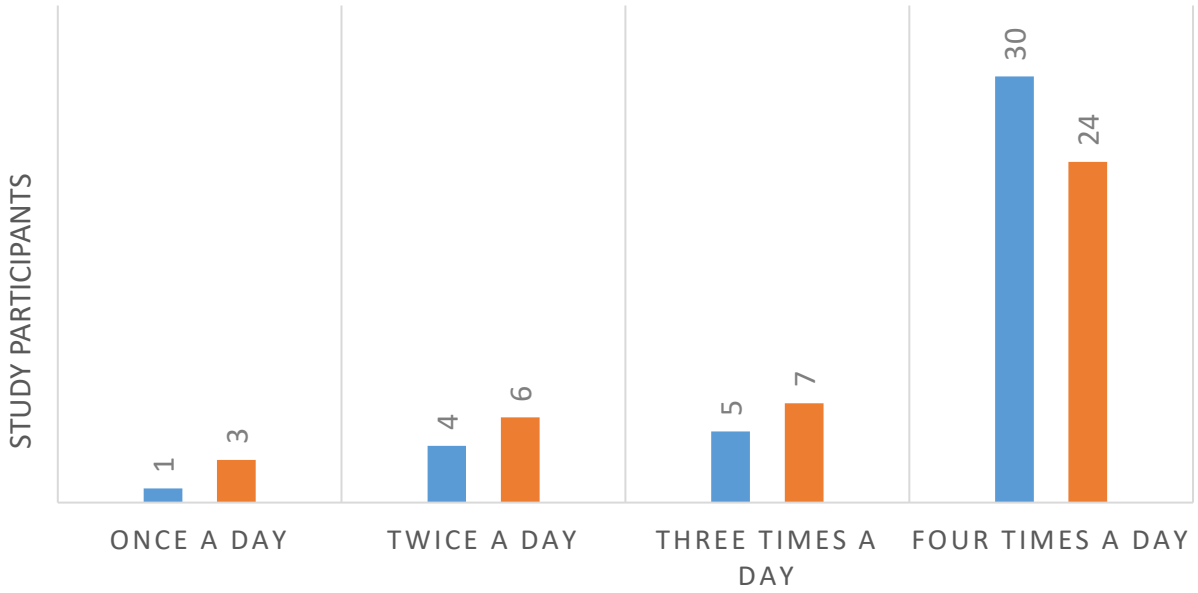

Figure 3.3 Freqency of Blood Glucose Monitoring in Group 1 and 2 Patients (N=80)

3.2.6 Physical Activity

Twenty-one participants in Group 1 performed daily physical exercise. Eleven participants were not active. Figure 3.4 shows the frequency of activity of patients in Group 1 and 2 patients. Seventeen participants were performing regular exercise in Group 1 and 11 were not active. Twenty-one participants were performing regular exercise in Group 2 while 14 were not active.

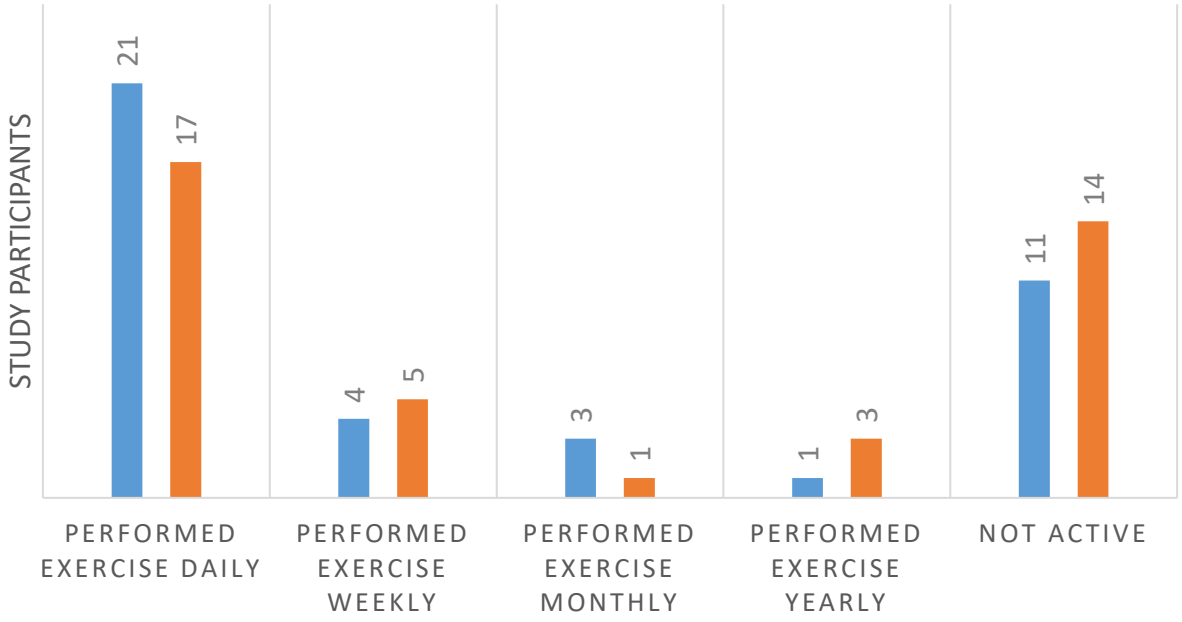

Figure 3.4 Physical Activities Performed By Participants In Group 1 and 2 (N=80)

3.2.7 Diet and Education

The participants were asked if they know about insulin carbohydrate counting. There were 14 different questions to evaluate participant carbohydrate knowledge. Tables 3.3 and 3.4 shows the results of the questions answered by the participants in Group 1 and 2 respectively. The correct answer is marked by (✓). The average number of correct answers of the question in the questionnaire in Group 1 was 11.3 out of 14 questions while the correct answers in Group 2 was 10.4 out of 14 questions.

Table 3.3 Group 1 Insulin Carbohydrate Counting Questions (n=40)			
Do these meals have carbohydrates?			
1. Bread	No 3	Yes ✓ 37	Don't know 0
2. Bagel	No 4	Yes ✓ 34	Don't know 2
3. Milk	No 2	Yes ✓ 38	Don't know 0
4. Orange juice	No 2	Yes ✓ 38	Don't know 0
5. Diet soda	No ✓ 32	Yes 6	Don't know 2
6. French fries	No 6	Yes ✓ 33	Don't know 1
7. Banana	No 2	Yes ✓ 38	Don't know 0
8. Eggs	No ✓ 36	Yes 4	Don't know 0
9. Pizza sauce	No 10	Yes ✓ 27	Don't know 3
10. Potato chips	No 0	Yes ✓ 40	Don't know 0

11. How many grams of carbohydrates are in Can (350ml) regular soda	**0 gm** 0	**15 gm** 9	**30 gm** ✓ 12	**45 gm** 16	**60 gm** 2	**75 gm** 0	**Don't know** 1
12. How many grams of carbohydrates are in 1 cup of milk?	**0 gm** 0	**15 gm** ✓ 35	**30 gm** 5	**45 gm** 0	**60 gm** 0	**75 gm** 0	**Don't know** 0
13. How many grams of carbohydrates are in 1 cup pasta (no sauce)?	**0 gm** 0	**15 gm** 6	**30 gm** 9	**45 gm** ✓ 11	**60 gm** 8	**75 gm** 0	**Don't know** 6
14. Insulin-to-carbohydrate ratio is 1 unit of insulin per 10 grams carbohydrate. For 30 grams of carbohydrates, how many units of insulin should you take?	**0** 0	**1.5** 0	**2** 0	**2.5** 5	**3** ✓ 34	**3.5** 0	**Don't know** 1

Table 3.4 Group 2 Insulin Carbohydrate Counting Questions (n=40)			
Do these meals have carbohydrates?			
1. Bread	No 3	Yes ✓ 37	Don't know 0
2. Bagel	No 4	Yes ✓ 32	Don't know 4
3. Milk	No 2	Yes ✓ 38	Don't know 0
4. Orange juice	No 2	Yes ✓ 36	Don't know 2
5. Diet soda	No ✓ 28	Yes 8	Don't know 2
6. French fries	No 6	Yes ✓ 30	Don't know 4
7. Banana	No 4	Yes ✓ 34	Don't know 2
8. Eggs	No ✓ 34	Yes 6	Don't know 0
9. Pizza sauce	No 12	Yes ✓ 24	Don't know 4
10. Potato chips	No 0	Yes ✓ 40	Don't know 0

11. How many grams of carbohydrates are in Can (350ml) regular soda	**0 gm** 0	**15 gm** 7	**30 gm** ✓ 8	**45 gm** 18	**60 gm** 2	**75 gm** 0	**Don't know** 5
12. How many grams of carbohydrates are in 1 cup of milk?	**0 gm** 0	**15 gm** ✓ 21	**30 gm** 5	**45 gm** 5	**60 gm** 3	**75 gm** 0	**Don't know** 6
13. How many grams of carbohydrates are in 1 cup pasta (no sauce)?	**0 gm** 3	**15 gm** 6	**30 gm** 8	**45 gm** ✓ 10	**60 gm** 8	**75 gm** 0	**Don't know** 5
14. Insulin-to-carbohydrate ratio is 1 unit of insulin per 10 grams carbohydrate. For 30 grams of carbohydrates, how many units of insulin should you take?	**0** 0	**1.5** 0	**2** 5	**2.5** 5	**3** ✓ 24	**3.5** 0	**Don't know** 6

3.2.1.8 Insulin Management

All 80 of the participants mentioned that they were using NovoRapid® (insulin aspart) daily and Lantus® (insulin glargine) at night.

3.3 HbA1c Levels

The mean HbA1c of Group 1 patients was 8.09% (range 6.10% to 10.5%), while the mean HbA1c of Group 2 patients was 8.73% (range 6.60% to 12.50%). The participants in Group 1 who were using carbohydrate counting had lower levels for HbA1c compared with Group 2 (*p*-value of 0.016). Table 3.5 shows the mean HbA1c of both groups and the *p* -value. Figure 3.8 shows the HbA1c levels in Group 1 and Group 2.

Table 3.5 HbA1c data analysis in both groups

	Group	N	Mean	Std. Deviation	Std. Error Mean
HbA1c	Group1	40	8.0900	1.09540	.17320
	Group 2	40	8.7350	1.25034	.19770

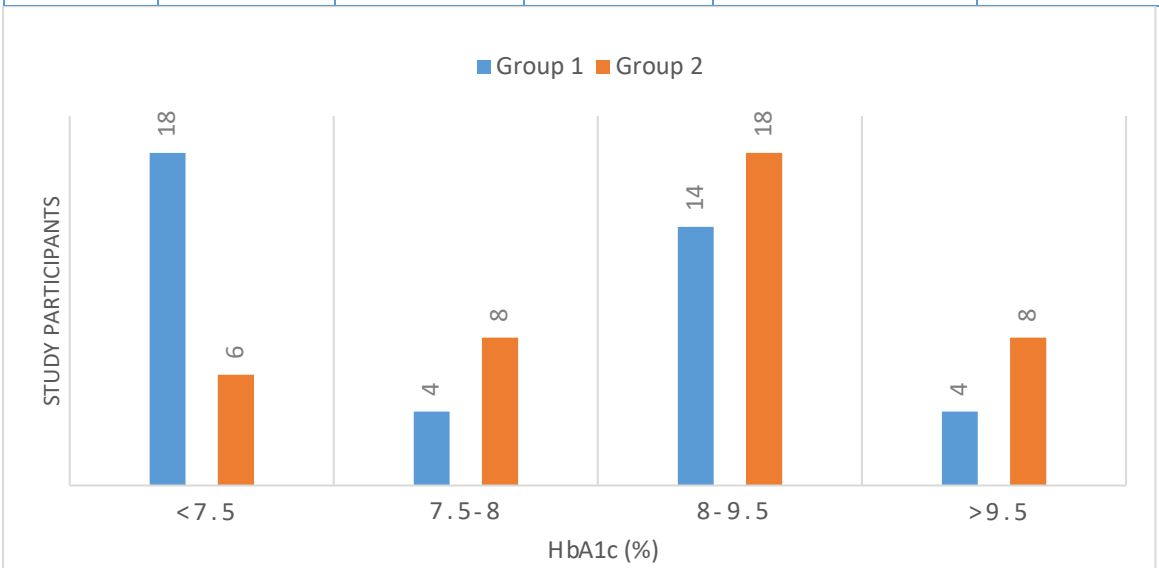

Figure 3.8: Hba1c Levels In Group 1 And Group 2 (N=80)

3.3.1 HbA1c and Age

Chi Square analysis was used to compare HbA1c levels of patients (experimental and control) with age to measure whether the HbA1c level increases with age.

3.3.1.1 Group 1

Figure 3.9 represents the HbA1c levels according to age group in Group 1. There was no statistically significant relationship between HbA1c and Age in Group 1 (p = 0.107).

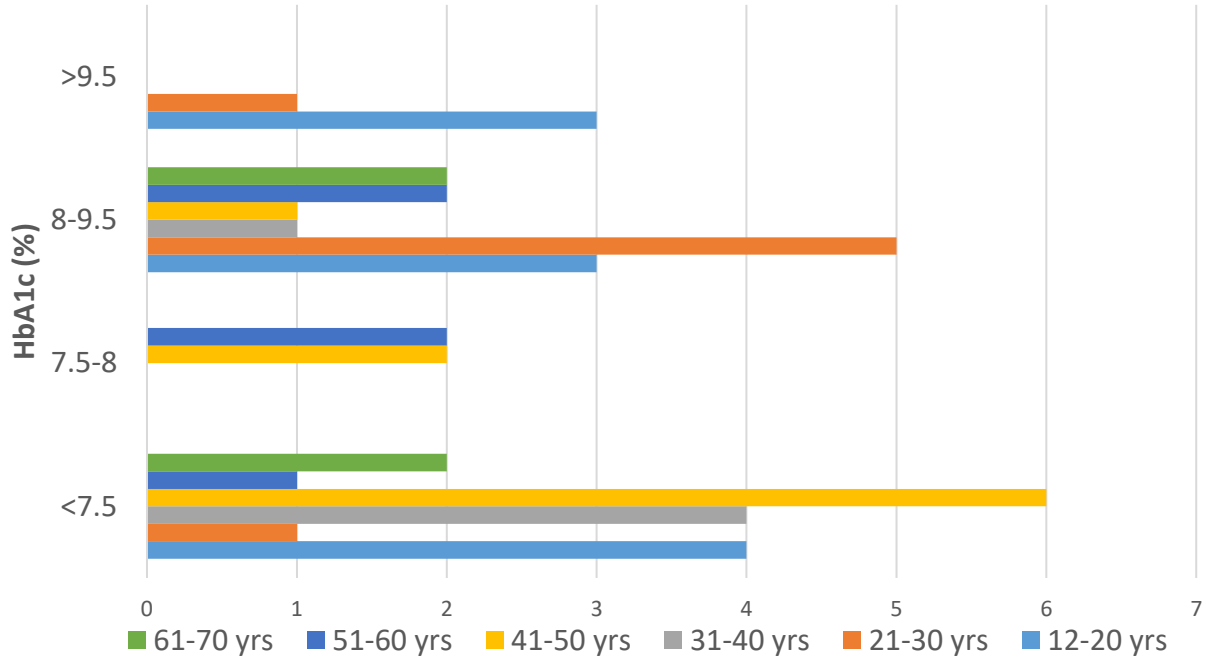

Figure 3.9 Hba1c Levels and Age Group in Group 1 (n=40)

3.3.1.2 Group 2

Figure 3.10 represents the HbA1c levels according to age group in Group 2. There was no statistically significant relationship between HbA1c and Age in Group 2 (p = 0.257).

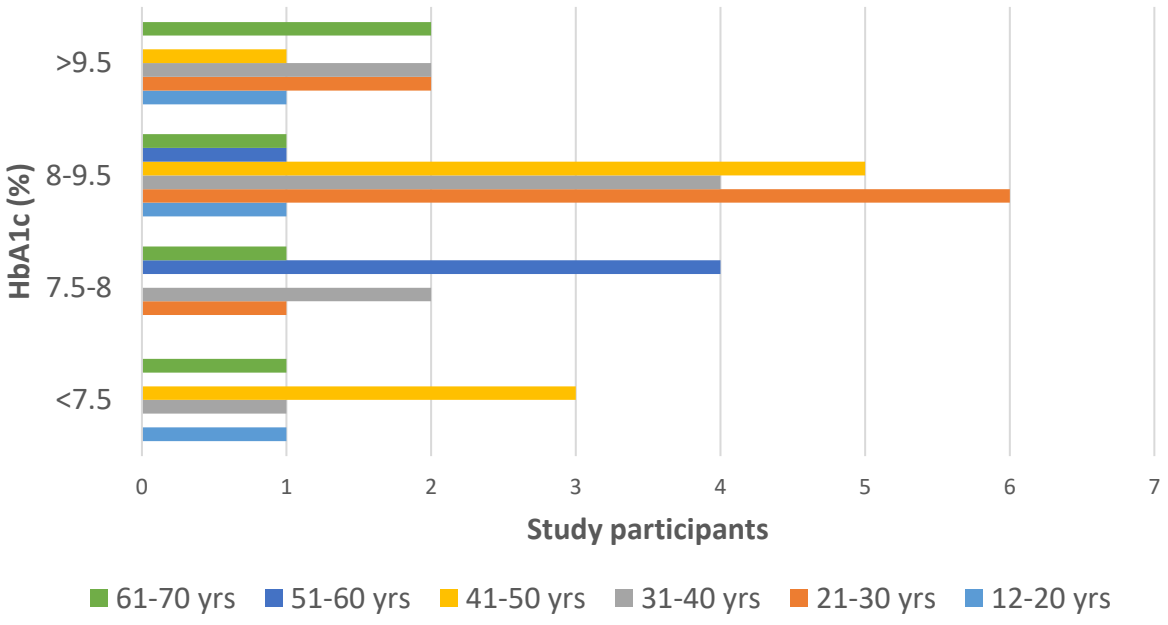

Figure 3.10 HbA1c levels and Age Group in Group 2 (n=40)

3.3.2 HbA1c and Educational Level

Chi Square analysis was used to compare HbA1c level of all patients (experimental and control) with education level to measure whether the HbA1c level increases with the level of education.

3.3.2.1 Group 1

Figure 3.11 represents the HbA1c levels according to education level in Group 1. There was no statistically significant relationship between HbA1c and education level in Group 1 (p = 0.618).

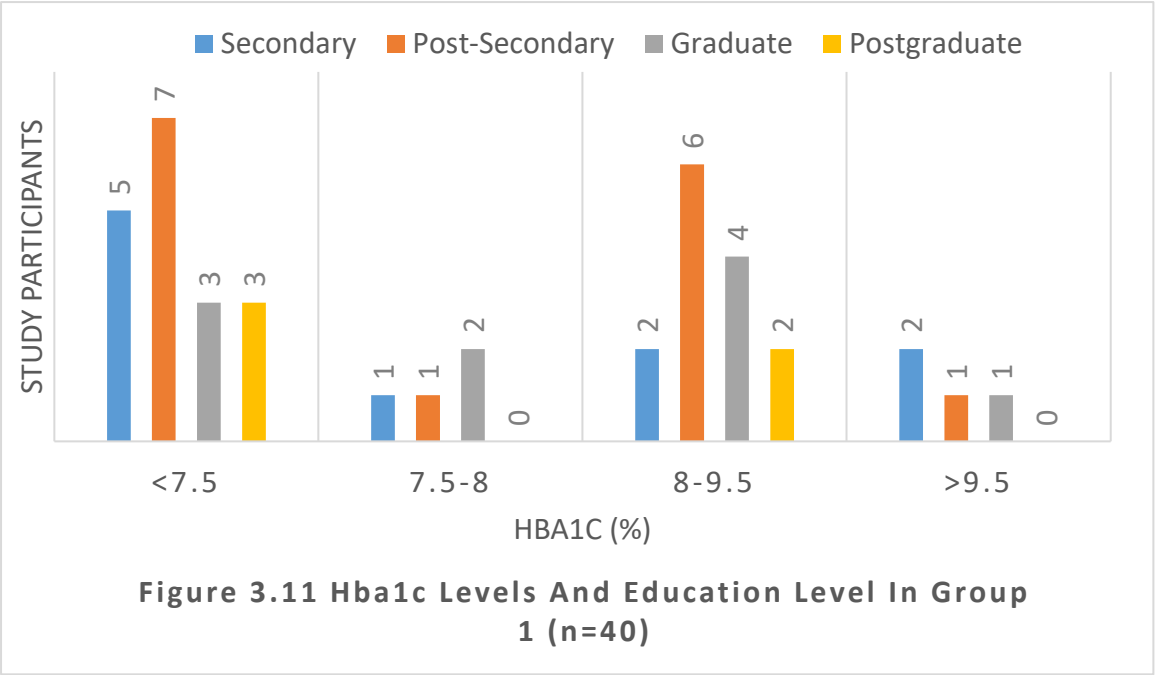

Figure 3.11 Hba1c Levels And Education Level In Group 1 (n=40)

3.3.2.2 Group 2

Figure 3.12 represents the HbA1c levels according to education level in Group 2. There was no statistically significant relationship between HbA1c and education level in Group 2 (p = 0.861).

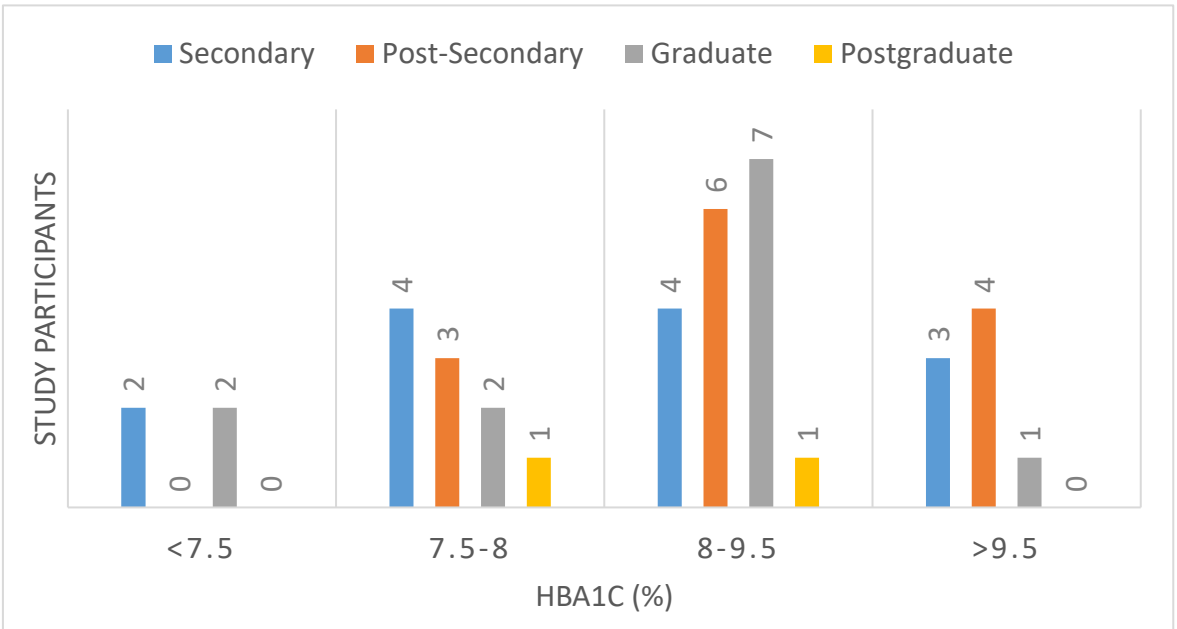

Figure 3.12 Hba1c Levels And Education Level In Group 2 (n=40)

Chapter 4: Discussion

4.1 General discussion

The aim of this research was to examine whether insulin adjustments and dietary freedom can improve glycaemic control amongst T1D patients. It has been found from past studies that structured training "intended to sustain the glucose control and enabling dietary choice" was effective. This training improved significantly on the levels of HbA1c, and there was no significant rise in the incidence of serious hypoglycaemia (DAFNE, 2002). The goal of a diabetic treatment plan involves symptomatic relief, the providence of safeguarding from diabetes-related complications and the improvement of the quality of life. Maintaining steady blood glucose levels in diabetic patients assists in the reduction of the risk of early mortality (Bevier et al, 2007).

The current treatment guidelines from the ADA (2016) suggest starting the administration of flexible insulin therapy for children from 7 years of age. Table 4.1 outlines some of the differences between conventional insulin therapy and flexible insulin therapy regimens. Flexible insulin therapy is designed to achieve and maintain optimal blood glucose levels that mimic those in individuals without diabetes, while minimizing the potentially life threatening side effects of this treatment. Flexible insulin therapy allows for a greater flexibility with meal planning (content, times), but also requires multiple blood glucose testing and short acting insulin boluses. Conventional insulin therapy does not allow for as much flexibility or metabolic control, but offers a decreased likelihood of some of the life threatening complications associated with flexible regimens, such as diabetic ketoacidosis and hypoglycaemia (Keough et al, 2009).

Flexible insulin therapy regimens are administered through a constant subcutaneous insulin infusion device (CSII) (also referred to as a pump) or multiple daily injections (MDI). Conventional insulin therapy may be administered less often.

Table 4.1. Differences in Conventional and Flexible insulin therapy.

Regimen Type	Number of Insulin Administration and/or Dose Adjustments	Number of Blood Glucose Monitoring (BGM) per Day	Dietary Impact
Flexible	6-7	4-8 *at least 4 times per day & with exercise and nocturnal glucose monitoring	Flexible meal (content, times) determines insulin dose
Conventional	2-4	2-4 *at least 4 times per day & with exercise and nocturnal glucose monitoring	Predetermined, timed meals/snacks and dietary content

(Adopted from Groupa CT. Effect of intensive diabetes treatment on the development and progression of long-term complications in adolescents with insulin-dependent diabetes: Diabetes Control and Complications Trial. *The Journal of pediatrics*. 1994; 31;125(2):177-88 and Silverstein J, Klingensmith G, Copeland K, Plotnick L, Kaufman F, Laffel L, et al. Care of children and adolescents with type 1 diabetes. *Diabetes Care*. 2005; 1;28(1):186-212.)

4.2 Overview of data

4.2.1 Glucose testing

Frequent blood glucose measurements are an essential element in intensive diabetes management. SMBG plays an important role in maintaining HbA1c levels, as it is able to discriminate between fasting, pre-prandial, and postprandial hyperglycaemia; perceives

glycaemic excursions and detects hypoglycaemia (Freckmann et al, 2007). Patients in Malta are advised by their physician to check capillary blood glucose at least 4 times every day. The majority of the patients in this study comply with this advice as 54 out of 80 were checking their capillary blood glucose 4 times a day. Since September 2014, the number of blood glucose strips provided free-of-charge, for individuals with T1D in Malta, increased to 4 per day. This reduced the financial burden for patients to get blood glucose strips and helped increase their adherence in checking their blood glucose (Formosa et al, 2016).

4.2.2 Physical activity

More than half of the study participants in Group 1 (n=21) performed daily physical activities, but in Group 2, 17 patients performed daily physical activities. Eleven participants of Group 1 and 14 participants of Group 2 had a sedentary life-style. A study by Cuschieri et al in Malta had mentioned that the majority of the diabetic patients knew about the importance of physical activity and 58% were aware that at least 30 minutes of daily physical exercise is required (Cuschieri et al, 2016). A study done by Brazeau et al, 2008 mentioned "the four barriers to physical activity in type I diabetes". These barriers are the fear of hypoglycaemia, work schedule, loss of control over diabetes, and low fitness level. The factors associated with these four barriers to physical activity include a basic knowledge about insulin pharmacokinetics and the implementation of strategies to prevent hypoglycaemia (Brazeau et al, 2008).

4.2.3 Diet and Education

Nutritional management plays a role in the diabetic therapeutic approach, as diabetes is a metabolic disorder and affects macronutrient metabolism. In both T1D and T2D, the quantity of carbohydrate intake has a significant effect on blood glucose levels rather than the source of

carbohydrates taken during main and intermediate meals (Mansell et al, 2012). In conventional therapy, the insulin dose is not adjusted according to the carbohydrate content of the meal and this may interfere with the HbA1c level. Recently, the interest in medical diet therapy has increased in the treatment of diabetes because dietary control in diabetic individuals was demonstrated to indicate an improved glycaemic control as confirmed by an approximate reduction of 1-2 percent in HbA1c levels (Bruttomesso et al, 2001; Kelley et al, 2003; Dias et al, 2010). Another study reported that the HbA1c levels can be reduced by 1–1.5 percent with the proper adjustment of the insulin dose according to the carbohydrate content of the meal (Son et al, 2014).

European Federation of Associations of Dietitians (EFAD) mentioned in their annual report of 2013 that 'the nutrition and dietetic service in Malta and Gozo is under developed when compared to other EU countries'. Data from the European Federation of the Association of Dietitians shows that dietitian staffing ratio is at an average of 15 dietitians per 100,000 of patients (EFAD, 2014).[7] Currently at Mater Dei Hospital, the workforce consists of 3 full-time dietitians and 1 part-time dietitian dealing with all medical cases that require dietetic intervention. There are currently no dietitians who are dedicated to the care of diabetic patients. The recommended number of specialised dietitians to cover diabetes alone in all levels of healthcare is of at least 7 full-time dietitians (Goenka et al, 2011).

This study included diabetic patients with different educational backgrounds ranging from secondary to postgraduate level. In Group 1, 13 participants are at post-secondary level whereas in Group 2, more participants were at post-secondary level (15 participants). A study by

[7] European Federation of the Association of Dietitians (EFAD). EFAD Annual Report January 2013 - December 2013. 2014 1:4.

Cuschieri et al revealed that 39% of the participants had only finished secondary level while only 4% had finished graduate level of education (Cuschieri et al, 2016).

The participants of both groups were asked to answer 14 questions about carbohydrates to assess their knowledge. Group 1 had an average correct answers of 11.3 out of 14 questions while Group 2 had an average answered of 10.4 out of 14. It has shown that diabetes knowledge may have improved even though the prevalence of diabetes along with its complications in Malta has increased. The reason behind the improved diabetes knowledge could be due to the frequent occurrence of this disease within families and this may influence diabetes knowledge (Cuschieri et al, 2016). This is consistent with the Foma et al study, where a correlation between having a family member with diabetes and diabetes knowledge was found (Foma et al, 2013). Another reason could be the increased coverage of aspects of diabetes care and prevention by social media and in televised diabetic educational programs and in the national newspapers which are likely to cause increased public awareness. Such initiatives should be developed further.

Along with the different approaches including SMBG and flexible insulin therapy, nutritional therapy and physical activity are important for diabetes management. Nutritional therapy emphasizes upholding and maintaining healthy eating patterns by eating nutrient-rich foods in proper portions to improve overall health. The major influence on glycaemic response is related to the total amount of carbohydrates consumed. Improved glycaemic control can be obtained with the participation of diabetic individuals using intensive flexible insulin therapy education programs and using the carbohydrate counting meal planning approach.

The key strategy in achieving glycaemic control is carbohydrate monitoring (e.g., carbohydrate counting, or experience-based estimation). Improved glucose control, flexibility in food choices, and the simplification of meal planning are some of the potential advantages of carbohydrate counting (Gray et al, 2015). In the study data, it was found that Group 1 patients had better knowledge of the carbohydrate content in their food and it influenced their incorporation of carbohydrate counting. Twenty-eight of the participants in Group 1 had 'severely high blood sugar (blood glucose readings of 16.6 mmol/L or higher)'.This value was higher in Group 2 with 32 participants.

Carbohydrate counting, provides diet flexibility and improves the quality of life within the dietary regimen. The improvements observed in the short term is reported to be maintained even in the long-term (Walker et al, 2012). In the study, the strategy based on the adjustment of the insulin dose is believed to be more successful when the carbohydrate content of the meal is being managed. This approach facilitates the selection and consumption of food for diabetic individuals while maintaining an appropriate level of glycaemic control. In diabetic patients, the proper instructions for the daily adjustment of the insulin doses according to blood glucose level, as well as attaining a carbohydrate counting method can help provide the opportunity to reduce the restrictions on eating habits of diabetic patients (Son et al, 2014).

4.2.4 HbA1c level

The improvement in HbA1c level in the experimental group in this study was comparable to that reported in similar interventions. The Dusseldorf group reported lower HbA1c levels (by 1.5%) one year after training with carbohydrate counting, compared with group teaching of diabetes related information alone (Mühlhauser et al, 1987). Two studies by Pieber et al and

Bott et al had similar improvements in HbA1c levels and required levels were maintained for three and six years (Pieber et al, 1995; Bott et al, 1997). The 'Dose Adjustment for Normal Eating (DAFNE) education programme' is 'a structured education programme that teaches the use of flexible intensive insulin therapy to optimise glycaemic control through independent self-management'. The DAFNE study had similar improvements in the HbA1c level in the first 6 months of the study (DAFNE, 2002). In a cohort of all the participants undergoing DAFNE education in the UK in 2005, the overall HbAlc level fell from 8.5% to 8.2% after a 1-year follow-up (Hopkins et al, 2012).

HbA1c levels of Group 1 was 8.09% and 8.73% in Group 2 which is considered above the HbA1c target. According to the recent guidelines on the apparent relationship between HbA1c level and diabetic complications, it has been proposed that the glycaemic control target of the HbA1c level should be less than 7.5% across all ages, whereas in adults, the HbA1c target should be <7% for T1D patients (Viswanathan et al, 2015).

Studies have shown that HbA1c levels greater than 7% increase the risk for diabetes and its complication, including microalbuminuria and retinopathy progression (Hopkins et al, 2012; Viswanathan et al, 2015). Other research results documented that approximately 30% to 75% of diabetes-related complications including retinopathy, nephropathy, and neuropathy can be delayed with intensive treatment (Long et al, 2011). The Diabetes Control and Complications Trial reported that intensive insulin treatment can reduce the risk of albuminuria and microalbuminuria by 54% and 39% respectively. The reduction of HbA1c levels by even 1% has considerably reduced the risk of microvascular complications (DCCT, 1993).

4.3 Limitations of the Study

Convenience sampling was used in this study to select the participants. Because this method of sampling was not random it could represent a potential for bias. There were limitations to collecting the data required from the diabetic patients. One example of this is that the body mass index, blood pressure and lipid profile of diabetic patients was not calculated. There was a need to increase the sample size but due to time limits, it was not possible to obtain an adequate number of responses. The study observation period was relatively short, and further improvements could have been obtained from the long-term practice of flexible insulin therapy and the use of SMBG.

The improvement in blood glucose control in the experimental group is above the target level of HbA1c of 7.5% and patients are still at a higher risk of diabetic complications. Learning carbohydrate counting is not suitable for all – for example, those who do not choose a flexible insulin regimen or who are unable to learn due to disability, language issues or the inability to free up the time required for carbohydrate counting.

A diabetes clinical information system has been in place since the 1990s at the diabetes clinic at St Luke's hospital which was previously the public general hospital. The information system is now updated at Mater dei Hospital. Currently the diabetes clinical information system holds data for over 23,000 patients. This data could be used as a basis to create a national diabetes register due to the amount of clinical data that is available. This data is not complete as not all diabetologists make use of the system and the diabetes clinical information system is not available to the private sector. Data from patients receiving their care in the private sector is not available.

4.4 Future Directions

The research that has been used for this study has highlighted topics on which further research would be beneficial. Improving and using the questionnaire by adding more questions related to food, increasing the sample size from the population and taking the patients' blood pressure, Body Mass Index and lipid profiles before starting the education programme in both the experimental and control group, and evaluating the participants every 3 months for at least a 12 months period would be useful to give more information on the relation between diabetes and its co-morbidities. The results of this programme could provide more information to indicate whether carbohydrate counting establishes a better level of glycaemic control in the Maltase population. This study result can be used to conduct a large-scale clinical study in future to detect the combined effects of SMBG and the application of carbohydrate counting.

4.5 Conclusion

Clinicians support the application of the carbohydrate counting method in the diabetic treatment plan as it provides dietary flexibility and increases the quality of life for diabetic patients (Dias et al, 2010). The study´s result is an example of how diabetes self-management education can facilitate the improvement observed in the HbA1c levels of participants that are using carbohydrate counting. HbA1c levels in particpants that are using carbohydrate counting had better glycemic control than particpants that are using conventional insulin therapy. The success of this method depends on how much carbohydrate counting can be recognized and followed by the diabetic individual. In the provision of diabetes self-management, education is required for all diabetic patients so they can understand how their condition can be improved. SMBG, the application of carbohydrate counting and flexible and intensive insulin therapy provides an advantageous effect in the improvement of glycaemic control. It is expected that

SMBG, the application of carbohydrate counting, and flexible insulin therapy become tools to maintain the quality of life, treatment tolerability and the overall well-being of the patient. The application of carbohydrate counting can improve signs and symptoms, decrease emergency hospital visits and reduce hospital stays. It suggested that healthcare staff should educate diabetic patients, paying special attention to the less educated patients for the successful use of the tools available to them. This can motivate diabetic patients to care about their health, so they will actively participate in self-management of their condition.

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Appendices

Appendix 1: University Research Ethics Committee Approval

L-UNIVERSITÀ TA' MALTA

Msida – Malta
Skola Medika
Sptar Mater Dei

UNIVERSITY OF MALTA

Msida – Malta
Medical School
Mater Dei Hospital

Ref No: **33/2016**

Monday 8th August 2016

Mr Khaled Abdelmaula
28 Flat 2, Triq l-Ahwa Cannataci
Birkirkara

Dear Mr Khaled Abdelmaula

Please refer to your application submitted to the Research Ethics Committee in connection with your research entitled:

Self-Management of Insulin in Type I Diabetic Patients

The University Research Ethics Committee granted ethical approval for the above mentioned protocol.

Yours sincerely,

Dr. Mario Vassallo
Chairman
Research Ethics Committee

Email: umms@um.edu.mt • ***Web:*** http://www.um.edu.mt/ms

Appendix 2: Carbohydrate Counting Assessment Questionnaire (CCAQ)

Questionnaire

Name _____ Duration of diabetes: _____

Date of Birth: _____ Sex: Male ☐ Female ☐

Occupation: _____

Last known HbA1c: _____

Background

1. Please Tick the ***highest level*** of school completed:

☐ MATSEC /O levels or less? ☐ A / IB levels?

☐ Undergraduate ☐ Postgraduate

General Health

1. In general, would you say your health is:

(Circle one)

Excellent 1

Very good.....2

Good.....3

Fair 4

Poor.....5

Symptoms

In the PAST WEEK, did you have any of the following symptoms…

1. Nausea or vomiting? ..... ☐No ☐Yes ☐Don't know

2. Abdominal pain?..... ☐No ☐Yes ☐Don't know

3. Light-headedness?..... ☐No ☐Yes ☐Don't know

4. Severely high blood sugar (blood glucose readings of

16.6 mmol/L or higher?) ……..... ☐No ☐Yes ☐Don't know

5. Passeing out, fainting or loss of

consciousness, even for a short time? ..... ☐No ☐Yes ☐Don't know

6. Fatigue?..... ☐No ☐Yes ☐Don't know

7. Dry mouth? ..... ☐No ☐Yes ☐Don't know

In the **past 6 months,**

8. How many times did you go to a hospital emergency department? _____ Times

9. How many times were you hospitalized for one night or longer? _____ Times

10. How many times did you visit a physician for routine check-up? _____ Times

Glucose Testing

1. Do you have a glucometer to measure your blood sugar (glucose) level? ☐Yes ☐No

2. On how many days in the **last week** did you test your blood sugar level _____ days

3. On **days** that you test your blood sugar, how many **times** do you test on **average**? _____Times

Physical Activities

1. Do you exercise or play sports regularly?

☐Daily ☐weekly ☐monthly ☐yearly ☐not active

2. Would you say that you are physically more active, less active, or about as active as other persons your age?

☐More active ☐less active ☐ about as active

3. Compared to your own level of physical activity 1 year ago, would you say you are now more active, less active, or about the same as you were then?

☐More active ☐less active ☐ about as active

Management

Please write down the dose and type of insulin treatment that you are currently using?

……

……

……

Diet and Education

1. Do you know about the "Insulin Carbohydrate Counting"? (Tick one)

☐ Yes and I am using it. (If you choose this answer, please go to section 2, page 5)

☐ Yes but I am Not using it. (If you choose this answer, please go to section 3, page 6)

☐ No, I never heard of it. (If you choose this answer, please go to section 4, page 6)

2. Please read the following and answer the question if you are currently using insulin carbohydrate counts:

A) Does this food have carbohydrate?	**Please tick only one answer in this column. (Yes, no, or don't know)**
1. Bread	☐ Yes ☐ No ☐ Don't Know
2. Bagel	☐ Yes ☐ No ☐ Don't Know
3. Milk	☐ Yes ☐ No ☐ Don't Know
4. Orange juice	☐ Yes ☐ No ☐ Don't Know
5. Diet soda pop	☐ Yes ☐ No ☐ Don't Know
6. French fries	☐ Yes ☐ No ☐ Don't Know
7. Banana	☐ Yes ☐ No ☐ Don't Know
8. Eggs	☐ Yes ☐ No ☐ Don't Know
9. Pizza sauce	☐ Yes ☐ No ☐ Don't Know
10. Potato chips	☐ Yes ☐ No ☐ Don't Know

B) How many grams of carbohydrates are in this portion of food?	**Please tick only one answer in this column. (Yes, no, or don't know)**
11. 1 can (350ml) regular soda pop	☐ 0 ☐ 15 ☐ 30 ☐ 45 ☐ 60 ☐ 75 ☐ Don't know
12. 1 cup milk (100ml)	☐ 0 ☐ 15 ☐ 30 ☐ 45 ☐ 60 ☐ 75 ☐ Don't know
13. 1 cup pasta (no sauce)	☐ 0 ☐ 15 ☐ 30 ☐ 45 ☐ 60 ☐ 75 ☐ Don't know

C) insulin-to-carbohydrate ratio is 1 unit of insulin per 10 grams carbohydrate. Circle the best answer.

14. For 30 grams of carbohydrates, how many units of insulin should you take?

Don't know ☐ 1 ½ ☐ 2 ½ ☐ 3 ☐ 3 ½ ☐ 0 ☐

. If you already know about the Insulin Carbohydrate counts why you didn't use it, please specify your reasons:

……

……

……

……

……

……

……

4. Now that you know about Insulin Carbohydrate counts

A. Do you think this program is easy for you to learn? ☐Yes ☐ No

B. Do you think patients on this program have a better quality of life? ☐ Yes ☐ No

C. Would you recommend this program to someone (diabetic) you know? ☐ Yes ☐ No D. Do you think if you learn about how to adjust your insulin dose according to your meal you will have a better glucose control? ☐Yes ☐ No

E. Would you want to join this program? ☐ Yes ☐ No

(if no please specify.....……)

If you want to join this program, please write your contact details

....……

……

……

Thank you for your time!

Kwestjonarju

Isem _____ Kemm ilni bid-diabete:_____

Data tat-twelid:_____ Xogħol: _____

Sess: □Raġel □Mara

L-aħħar riżultat tal-HbA1c: _____

Sfond

1. Immarka sa' liema livell edukattiv wasalt:

□ MATSEC /O levels jew inqas □ A / IB levels? □ Undergraduate

□ postgraduate

Saħħa
Ġenerali

1. In ġenerali, taħseb li saħħtek hi:

*(Immarka **waħda biss***

b'ċirku)

Eċċellenti.....1

Tajba ħafna.....2

Tajba.....3

Mhux ħażin 4

Batuta.....5

Sintomi

Fil-ĠIMGĦA LI GĦADDIET, kellek xi sintomi minn dawn li ġejjin…

1. Dardir jew remettar? ..... ☐Iva ☐Le ☐ Ma nafx

2. Uġiegħ addominali?..... ☐Iva ☐Le ☐ Ma nafx

3. Sturdament?..... ☐Iva ☐Le ☐ Ma nafx

4. Zokkor għoli ħafna (riżultat taz-zokkor fid-demm 16.6mmol/L jew għola?)

…….....☐Iva ☐Le ☐ Ma nafx

5. Stardament, ħass ħażin jew telf minn sensik .....☐..... Iva ☐Le ☐Ma nafx

6. Għejja?..... ☐Iva ☐Le ☐ Ma nafx

7. Ħalqek xott?..... ☐Iva ☐Le ☐ Ma nafx

Waqt **l-aħħar 6 xhur,**

8. Kemm –il darba mort l-emerġenza? _____ Drabi

9. Kemm –il darba qattajt lejl jew aktar l-isptar? _____ Drabi

10. Kemm –il darba mort vista ta' rutina għand tabib? _____ Drabi

---

Test taz-Zokkor

1. Għandek magna biex tiċċekja z-zokkor? ☐Iva ☐Le

2. **Fil-ġimgħa li għaddiet** –il darba (f'kemm –il ġurnata) iċċekjajt iz-zokkor? ġranet

3. Fil-**ġranet** li tiċċekja z-zokkor, **kemm –il darba** tagħmel it-test **bejn wieħed u ieħor**? _____drabi

Attivita Fiżika

1. Tagħmel eżerċizzju jew tipprattika sport?

□kuljum □darba f'ġimgħa □darba f'xahar □darba f'sena □qatt

2. Taħseb li int aktar attiv/a, anqas attiv/a, jew attiv/a daqs persuni ta' l-eta' tiegħek?

□ aktar attiv/a □ anqas attiv/a □ attiv/a daqs persuni ta' l-eta' tiegħek

Jekk tqabbel ma **sena ilu**, tahseb li int aktar attiv/a, anqas attiv/a, jew

attiv/a daqs kemm kont dak iż-żmien? □ aktar attiv/a □ anqas attiv/a

□ attiv/a daqs is-sena l-oħra

Immaniġjar

Ikteb id-doża u t-tip ta' trattament ta' l-insulina li qed tieħu bħalissa?

……
……

……
……

……
……

Tagħlim Dwar id-Dieta

1.Smajt dwar l-"Insulin Carbohydrate Counting"?*(Agħżel waħda)*

□ Iva u qed nużaha. (**Jekk għażilt din, mur f'sezzjoni 2, f'paġna 5)**

□ Iva smajt biha imma **mhux** qed nużaha.(**Jekk għażilt din, mur f'sezzjoni 3, f'paġna 6)**

□ Le qatt ma smajt biha. (**Jekk għażilt din, mur f'sezzjoni 4, f'paġna 6)**

2. Jekk jogħġbok aqra li ġej u wieġeb il-mistoqsija jekk inti bħalissa qed tuża l-'insulin carbohydrate counts'.

A) Dan l-ikel fih karboidrati?	**Jekk jogħgbok immarka tweġiba waħda biss f'din il-kolonna (Iva, le jew ma nafx)**		
1. Ħobż	Iva	Le	Ma Nafx
2. Panina	□Iva	□Le	□Ma Nafx
3. Ħalib	□Iva	□Le	□Ma Nafx
4. 'Juice' tal-larinġ	□Iva	□Le	□Ma Nafx
5. Luminata tad-dieta	□Iva	□Le	□Ma Nafx
6. Chips	□Iva	□Le	□Ma Nafx
7. Banana	□Iva	□Le	□Ma Nafx
8. Bajd	□Iva	□Le	□Ma Nafx
9. Zalza tal-pizza	□Iva	□Le	□Ma Nafx
10. laqx tal-patata	□Iva	□Le	□Ma Nafx

B) Kemm hemm grammi ta' karboidrati f'din il-porjoni ta'ikel	Jekk jogħgbok immarka tweġiba waħda biss f'din il-kolonna
11. bott (350ml) luminata normali	□0 □15 □30 □45 □60 □75 □Ma nafx
12. 1 tazza ħalib (100ml)	□0 □15 □30 □45 □60 □75 □Ma nafx
13. 1 tazza għaġin (bla zalza)	□0 □15 □30 □45 □60 □75 □Ma nafx

C) Il-proporzjon ta insulina għal karboidrati huwa 1 unit ta' insulina għal 10 grammi karboidrati. Immarka l-aħjar tweġiba.

14. Għal 30 gramma ta karboidrati kemm units ta' insulina għandek tieħu?

Ma nafx□ 1 ½□ 2 ½□ 3□ 3 ½□ 0□

3. Jekk diġa taf bl-Insulin Carbohydrate Counts għaliex mhux qed issegwi dan il- programm? Iddeskrivi r-raġunijiet tiegħek:

……

……

……

……

4. Issa li taf dwar l-Insulin Carbohydrate counts

A. Taħseb li dan il-programm faċli biex titgħallmu? ☐ Iva ☐ Le

B. Taħseb li persuni li jsegwu dan il-programm għandhom kwalita' tal-ħajja aħjar? ☐ Iva ☐ Le

C. Tirrakkomanda dan il-programm lil xi ħadd (diabetiku) li taf? ☐ Iva ☐ Le

D. Taħseb li jekk titgħallem kif tirregola id-doża ta' l-insulina skond l-ikla lit kun qed tieħu jkollok aktar kontroll fuq il-livell taz-zokkor fid-demm? ☐ Iva ☐ Le

E. Tkun tixtieq li ssegwi dan il-programm? ☐ Iva ☐ Le (jekk le spjega għaliex .....……)

Jekk tixtieq li ssegwi dan il-programm, ikteb id-dettalji tiegħek (indirizz, numru tat- telfown, etc..

....……....……

……....……....……

……....……

Grazzi tal-ħin tiegħek!

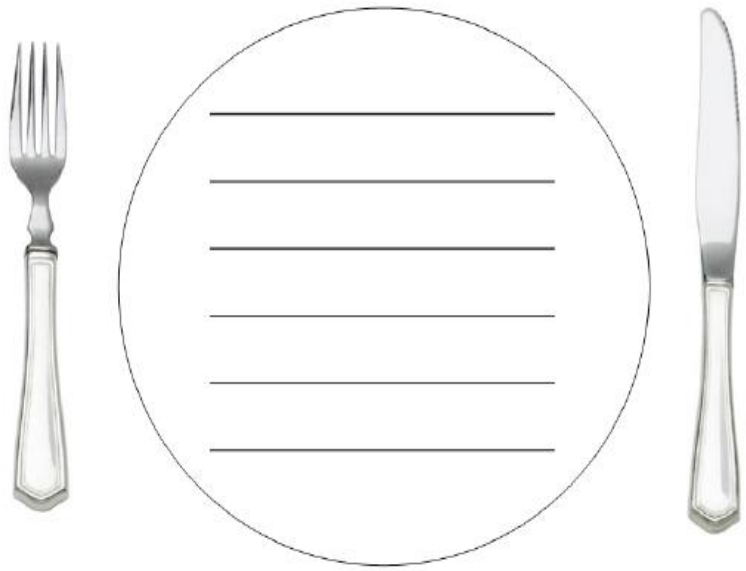
Appendix 3: Heart Healthy Carb Quiz

Heart Healthy Carb Quiz Vs. 2 Subject #:_____

1. **Circle the foods in the box that contain <u>15 grams</u> of carbohydrate OR MORE per serving (1 carb choice or more).**

1 cup cooked dry beans	1 cup noodles	½ cup carrots	1/3 cup white rice
½ cup spaghetti sauce	1 cup 2% milk	4 oz grilled salmon	1 cup fruit juice
2-inch chocolate chip cookie	½ cup green peas	Can of regular soda	Can of diet soda
3 oz grilled chicken breast	1 slice cheese pizza	1 cup canned fruit	2 Tbsp. Peanut butter
1 slice 100% whole wheat bread	8 oz. T-bone steak	Taco Bell soft taco	½ cup corn
Medium French Fries	1 cup tossed salad	Medium apple	McDonald's Big Mac
1 packet salad dressing	String Cheese	1 oz. bag Doritos	Deli turkey sandwich
6-inch beef tostado	½ cup ice cream	Hot dog on bun	Small baked potato

2. **Choose foods from the box to MAKE A MEAL that has <u>60 grams</u> of carbohydrates (<u>4 carb choices</u>). Write the foods in the plate below. Use as many lines as you need.**



3. Circle the food that is the most heart-healthy of each group:

Group 1:	Group 2:	Group 3:
A. Olive Oil	A. White hamburger bun	A. Pulled pork
B. Margarine	B. Enriched white bread	B. T-bone steak
C. Butter	C. 100% Whole wheat bread	C. Grilled Salmon

For the rest of the questions, use the Nutrition Facts labels on the left:

Food A:

Nutrition Facts	
Serving Size 1 cup (56g)	
Servings Per Container about 4	
Amount Per Serving	
Calories 210	Calories from Fat 10
	% Daily Value
Total Fat 1 g	**2%**
Saturated Fat 0 g	**0%**
Trans Fat 0 g	
Cholesterol 0 mg	**0%**
Sodium 115 mg	**5%**
Total Carbohydrate 45 g	**15%**
Dietary Fiber 7 g	**26%**
Sugars 18 g	
Protein 4 g	
Vitamin A 15%	Vitamin C 10%
Calcium 4%	Iron 25%

Food B:

Nutrition Facts	
Serving Size ½ sandwich(108g)	
Servings Per Container 2	
Amount Per Serving	
Calories 270	Calories from Fat 130
	% Daily Value
Total Fat 15 g	**23%**
Saturated Fat 5 g	**25%**
Trans Fat 0.8 g	
Cholesterol 38 mg	**13%**
Sodium 520 mg	**22%**
Total Carbohydrate 22 g	**8%**
Dietary Fiber 1.5 g	**7%**
Sugars 5 g	
Protein 13 g	
Vitamin A 3%	Vitamin C 1%
Calcium 13%	Iron 13%

4. What is the serving size for Food A? _____

5. How many grams of carbohydrates are in one cup of Food A? _____

6. How many calories would you eat if you ate the entire package of Food A?

_____

7a. Is Food A or Food B more heart-healthy?

a. Food A
b. Food B
c. I don't know

7b. List 3 things that make the food you chose heart-healthy:

_____
_____
_____

7c. List 3 things that are not heart-healthy about the other food:

_____
_____
_____

8. On a food label, circle the 2 most important things to look for and use in carb counting:

Sugar	Protein	Calcium	Serving Size
Total Carbohydrates	Fat	Fiber	Calories

Appendix 4: Stanford Patient Education Research Center

Diabetes Questionnaire

Stanford Patient Education Research Center
Stanford University School of Medicine

SAMPLE QUESTIONNAIRE

DIABETES

Stanford Patient Education Research Center
1000 Welch Road, Suite 204
Palo Alto CA 94304
(650) 723-7935 voice • (650) 725-9422 fax
http://patienteducation.stanford.edu
self-management@stanford.edu

Name: _____ Today's date: _____

Address: _____

City, state, zip: _____

Telephone: home (____) _____ - _____ Date of birth: _____

work (____) _____ - _____ Sex: ❑ Female ❑ Male

Background

1. Ethnic origin *(check ✓**only one**):*

❑ White not Hispanic
❑ Black not Hispanic
❑ Hispanic
❑ Asian or Pacific Islander
❑ Filipino
❑ American Indian/Alaskan Native
❑ Other: _____

2. Please circle the ***highest*** year of school completed:

1 2 3 4 5 6 *(primary)* 7 8 9 10 11 12 *(high school)* 13 14 15 16 *(college/university)* 17 18 19 20 21 22 *(graduate school)* 23+

3. Are you currently *(check ✓**only one**):*

❑ married ❑ separated ❑ widowed
❑ single ❑ divorced

4. Please indicate below which chronic condition(s) you have:

❑ Diabetes type 2 ❑ Diabetes type 1 ❑ High cholesterol ❑ High blood pressure

❑ Heart disease *Type of heart disease:* _____

❑ Lung disease *Type of lung disease:* _____

❑ Other chronic condition *Specify:* _____

General Health

1. In general, would you say your health is:

(Circle one)

Excellent 1

Very good.....2

Good.....3

Fair.....4

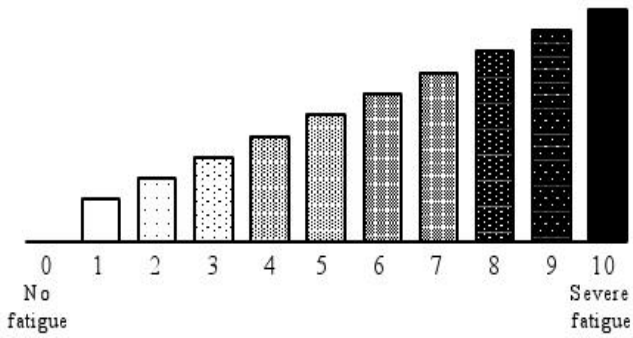
Poor.....5

Symptoms

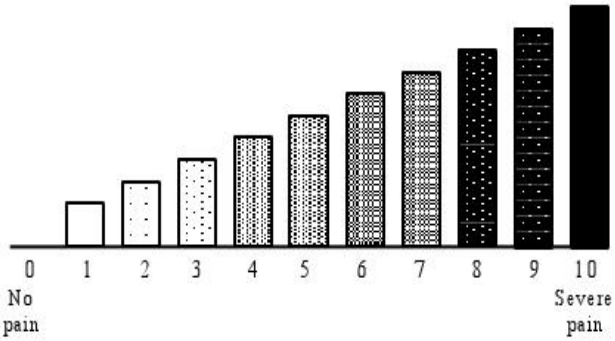
How much time during the **past month**...

	None of the time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time
1. Were you discouraged by your health problems?.....	0	1	2	3	4	5
2. Were you fearful about your future health?.....	0	1	2	3	4	5
3. Was your health a worry in your life?....	0	1	2	3	4	5
4. Were you frustrated by your health problems?.....	0	1	2	3	4	5

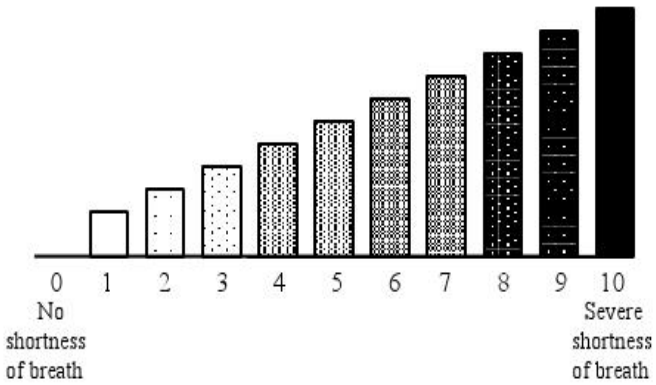
5. We are interested in learning whether or not you are affected by fatigue. Please *circle* the *number* below that describes your **fatigue** in the **past 2 weeks:**



6. We are interested in learning whether or not you are affected by pain. Please *circle* the *number* below that describes your **pain** in the **past 2 weeks.**



7. We are interested in learning whether or not you are affected by shortness of breath. Please *circle* the *number* below that describes your **shortness of breath** in the **past 2 weeks:**



In the PAST WEEK, did you ever have any of the following symptoms…

8. Increased thirst?	❑ No	❑ Yes	❑ Don't know
9. Dry mouth?	❑ No	❑ Yes	❑ Don't know
10. Decreased appetite?	❑ No	❑ Yes	❑ Don't know
11. Nausea or vomiting?	❑ No	❑ Yes	❑ Don't know
12. Abdominal pain?	❑ No	❑ Yes	❑ Don't know
13. Frequent urination at night? Do you have to get up to urinate 3 or more times a night?	❑ No	❑ Yes	❑ Don't know
14. Severely high blood sugar (blood glucose readings of 300 mg or higher?)	❑ No	❑ Yes	❑ Don't know
15. Morning headaches?	❑ No	❑ Yes	❑ Don't know

In the PAST WEEK, did you ever have any of the following symptoms…

16. Nightmares?	❑ No	❑ Yes	❑ Don't know
17. Night sweats?	❑ No	❑ Yes	❑ Don't know
14. Lightheadedness?	❑ No	❑ Yes	❑ Don't know
18. Shakiness or weakness?	❑ No	❑ Yes	❑ Don't know
19. Intense hunger?	❑ No	❑ Yes	❑ Don't know
20. Times when you passed out fainted or lost consciousness, even for a short time?	❑ No	❑ Yes	❑ Don't know

Daily Activities

During the **past 4 weeks**, how much... *(Circle **one**)*

	Not at all	Slightly	Moderately	Quite a bit	Almost totally
1. Has your health interfered with your normal social activities with family, friends, neighbors or groups?	0	1	2	3	4
2. Has your health interfered with your hobbies or recreational activities?	0	1	2	3	4
3. Has your health interfered with your household chores?	0	1	2	3	4
4. Has your health interfered with your errands and shopping?	0	1	2	3	4

Your Glucose Testing

1. Do you have a machine to measure your blood sugar (glucose) level? ❑ Yes ❑ No

2. On how many days in the **last week** did you test your blood sugar level? *(If you were sick in the last week, think of the most recent 7 days when you were NOT sick)*

   _____ days

3. On **days** that you test your blood sugar, how many **times** do you test on **average**? _____ times

Physical Activities

During the past week, even if it was not a typical week for you, how much **total** time *(for the **entire week**)* did you spend on each of the following? *(Please circle **one** number for each question.)*

	none	less than 30 min/wk	30-60 min/wk	1-3 hrs per week	more than 3 hrs/wk
1. Stretching or strengthening exercises (range of motion, using weights, etc.)	0	1	2	3	4
2. Walk for exercise	0	1	2	3	4
3. Swimming or aquatic exercise	0	1	2	3	4
4. Bicycling (including stationary exercise bikes)	0	1	2	3	4
5. Other aerobic exercise equipment (Stairmaster, rowing, skiing machine, etc.)	0	1	2	3	4
6. Other aerobic exercise *Specify*_____	0	1	2	3	4

Confidence About Doing Things

For each of the following questions, please ***circle*** the number that corresponds with your **confidence** that you can do the tasks regularly at the present time.

1. **How confident** do you feel that you can eat your meals every 4 to 5 hours every day, including breakfast every day?

Not at all confident 1 2 3 4 5 6 7 8 9 10 Very confident

2. **How confident** do you feel that you can follow your diet when you have to prepare or share food with other people who do not have diabetes?

Not at all confident 1 2 3 4 5 6 7 8 9 10 Very confident

3. **How confident** do you feel that you can chose the appropriate foods to eat when you are hungry (for example, snacks)?

Not at all confident 1 2 3 4 5 6 7 8 9 10 Very confident

4. **How confident** do you feel that you can exercise 15 to 30 minutes, 4 to 5 times a week?

Not at all confident 1 2 3 4 5 6 7 8 9 10 Very confident

5. **How confident** do you feel that you can do something to prevent your blood sugar level from dropping when you exercise?

Not at all confident 1 2 3 4 5 6 7 8 9 10 Very confident

6. **How confident** do you feel that you know what

Not at all 1 2 3 4 5 6 7 8 9 10 Very

Medical Care

1. When you **visit your doctor**, how often do you do the following *(please circle **one** number for each question):*

	Never	Almost never	Some-times	Fairly often	Very often	Always
a. Prepare a list of questions for your doctor	0	1	2	3	4	5
b. Ask questions about the things you want to know and things you don't understand about your treatment	0	1	2	3	4	5
c. Discuss any personal problems that may be related to your illness	0	1	2	3	4	5

2. **In the past 6 months**, how many times did you visit a physician?
*Do **not** include visits while in the hospital or the hospital emergency department*... _____ visits

3. **In the past 6 months**, how many times did you go to a **hospital** emergency department? _____ times

4. **In the past 6 months**, how many TIMES were you hospitalized for one night or longer? _____ times

   a. How many total NIGHTS did you spend in the hospital **in the past 6 months**? _____ nights

   b. Were any of these hospitalizations at a skilled nursing facility, convalescent hospital, or other minimum care facility? ❑ Yes ❑ No

5. When was the last time you had your eyes examined? (example: for glaucoma or any other problem) _____
   Month Year

6. How many **times** did the doctor or nurse examine your feet in the last 6 months? _____ times

Thank you for your help!

.

Appendix 5: Information Sheets and Consent forms

1. Information

Sheet

My name is Khaled Abdelmaula, I am a Pharm D student currently conducting a research named: "***Self- Management of Insulin in Type I Diabetic Patients***".

I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask me or the rest of the staff.

This is a research about an estimation of how many patients of Type I diabetes know about Insulin - Carbohydrates Counts and to evaluate whether a course teaching flexible insulin treatment combining dietary freedom and insulin adjustment can improve glycaemic control in Type I diabetes.

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. This research will not influence your current treatment. You are only giving the consent to review your hospital record for research purposes, hereby no personal risks or benefits are involved.

Right to refuse or withdraw

You have the right to refuse the collection of the sample at any time of the study.

2. Certificate of consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to be a participant in this research.

Name of Participant (Block letters)

Signature of Participant _____

Date _____

Print Name of Researcher/person taking the consent **Khaled Abdelmaula**

Contact details Mobile: **99624438** Email**:pharmadr@yahoo.com**

Signature of Researcher /person taking the consent

Date 3/6/2016

KUNSES TAL-PAZJENT

[Verżjoni bil-Malti]

Formola ta' informazzjoni ta kunsens ta _____

Din il-formola ta' kunses informat hi għal dawk il-pazjenti biex tiġbor il-karatteristiċi neċessarji sabiex issir riċerka bl-isem: "***Self-Management of Insulin in Type I Diabetic Patients***".

Dan il-kunses informat fih żewġ partijiet:

1. Folja ta informazzjoni (sabiex naqsam informazzjoni dwar din-ir-riċerka miegħek)

2. Ċertifikat ta' Kunses (biex tiffirma jekk taċċetta li tieħu sehem)

1. Folja ta informazzjoni

Jiena jisimni Khaled Abdelmaula u jiena student tal-Pharm D u bħalissa qed nagħmel riċerka jisimha: "***Self-Management of Insulin in Type I Diabetic Patients***".

Jiena ser nagħtik informazzjoni u nistiednek biex tkun parti min din ir-riċerka. M'hemmx għalfejn tiddeciedi illum kemm jekk tixtieq jew anke jekk ma tixtieqx tieħu sehem fir-riċerka. Qabel tiddeċiedi, tista tkellem ma min tħossok komdu dwar din ir-riċerka.

Jista' jkun hemm xi kliem li ma tifhimhomx. Fejn ma tifhimx, jekk joghġbok, ghidli biex nieqaf waqt li nkun qed nispjegalek l-informazzjoni u jiena nieħu l-ħin biex nispjegalek. Jekk ikollok domandi wara, tista' tistaqsi lili jew inkella lil xi ħadd mil-istaff.

Din hija riċerka dwar stima ta kemm pazjenti bid-dijabete ta Tip 1 jafu dwar l-'Insulin-Carbohydrate counts' u biex tevalwa jekk kors li jgħallem terapija bl-insulina flessibbli ikkombinata ma ħelsien dietarju u aġġustament tal-insulina jistax itejjeb il-kontroll gliċemiku f'dijabete ta Tip 1.

Il-parteċipazzjoni tiegħek f'din ir-riċerka hija kompletament volontarja. Hija għażla tiegħek jekk tipparteċipax jew le. Din ir-riċerka mhux ser taffettwa it-trattament preżenti tiegħek. Inti ser tkun tagħti l-kunsens tiegħek biss għar-reviżjoni tar-rekords tiegħek tal-isptar għal għanijiet ta' riċerka, għalhekk mhemmx involuti riskji jew benefiċċji personali.

Id-dritt li tirrifjuta jew li titlaq

Inti għandek id-dritt li tirrifjuta li taghti kampjun waqt kull parti tal-istudju.

2. Ċertifikat ta' kunsens

Jiena qrajt l-informazzjoni t'hawn fuq, jew inkella inqratli. Jiena kelli l-opportunita' li nistaqsi mistoqsijiet dwarha u jekk staqsejt xi mistoqsijiet gew imwieġba għas-sodisfazzjon tiegħi. Jiena nagħti l-kunsens volontarju biex inkun parteċipant f'din ir-riċerka.

Isem tal-Parteċipant (Ittri Kapitali)

Firma tal-Parteċipant _____

Date _____

L-isem ta ' riċerkatur/persuna filwaqt li l-kunsens ta ' l-ipprintjar **Khaled Abdelmaula**

Ikkuntattja d-dettalji tat-telefonija ċellulari: **99624438** Indirizz elettroniku:**pharmadr@yahoo.com**

Firma ta ' l-imprendituri /person filwaqt li l-kunsens

Id-data 3/6/2016

Appendix 6: Statistical Data

Duration of diabetes group 1

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	less than 5 years	5	12.5	12.5	12.5
	5 - 10 years	6	15.0	15.0	27.5
	10 - 15 years	11	27.5	27.5	55.0
	15 - 20 years	9	22.5	22.5	77.5
	more than 20 years	9	22.5	22.5	100.0
	Total	40	100.0	100.0	

Duration of diabetes group 1

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	less than 5 years	5	12.5	12.5	12.5
	5 - 10 years	6	15.0	15.0	27.5
	10 - 15 years	11	27.5	27.5	55.0
	15 - 20 years	9	22.5	22.5	77.5
	more than 20 years	9	22.5	22.5	100.0
	Total	40	100.0	100.0	

Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
HbA1c Group 2	40	6.60	12.50	8.7350	1.25034
HbA1c Group 1	40	6.10	10.50	8.0900	1.09540
Valid N (listwise)	40				

Group 1
education

HbA1c Level	Secondary	Post-Secondary	Graduate	postgraduate	Total
6.1	0.00%	2.50%	0.00%	2.50%	5.00%
7.0	7.50%	2.50%	0.00%	0.00%	10.00%
7.2	0.00%	2.50%	5.00%	2.50%	10.00%
7.3	0.00%	2.50%	7.50%	0.00%	10.00%
7.4	0.00%	7.50%	0.00%	2.50%	10.00%
7.9	2.50%	0.00%	2.50%	0.00%	5.00%
8.0	0.00%	2.50%	2.50%	0.00%	5.00%
8.1	0.00%	2.50%	0.00%	2.50%	5.00%
8.4	2.50%	0.00%	2.50%	0.00%	5.00%
8.9	0.00%	0.00%	5.00%	0.00%	5.00%
9.0	0.00%	5.00%	5.00%	0.00%	10.00%
9.1	2.50%	0.00%	0.00%	2.50%	5.00%
9.4	0.00%	5.00%	0.00%	0.00%	5.00%
9.6	0.00%	0.00%	5.00%	0.00%	5.00%
11.0	2.50%	2.50%	0.00%	0.00%	5.00%
Total	17.50%	35.00%	35.00%	12.50%	100.00%

Group 2
Education

HbA1c Level	Secondary	Post-Secondary	Graduate	postgraduate	Total
6.6	0.0%	0.0%	5.0%	0.0%	5.0%
7.4	2.5%	0.0%	2.5%	0.0%	5.0%
7.5	0.0%	2.5%	2.5%	0.0%	5.0%
7.6	2.5%	0.0%	2.5%	0.0%	5.0%
8	0.00%	7.50%	0.00%	2.50%	10.00%
7.9	2.50%	0.00%	2.50%	0.00%	5.00%
8.0	2.5%	5.0%	5.0%	2.5%	15.0%
8.1	0.0%	2.5%	2.5%	0.0%	5.0%
8.4	0.0%	0.0%	5.0%	0.0%	5.0%
8.8	0.00%	0.00%	5.00%	0.00%	5.00%
8.9	0.0%	5.0%	5.0%	0.0%	10.0%
9.1	5.0%	2.5%	7.5%	0.0%	15.0%
9.9	2.5%	2.5%	0.0%	0.0%	5.0%
10.0	2.5%	5.0%	2.5%	0.0%	10.0%
12.5	0.0%	2.5%	2.5%	0.0%	5.0%
Total	17.5%	27.5%	50.0%	5.0%	100.0%

HbA1c Group 1 * education_expermient Crosstabulation

			education_expermient				Total
			Secondary	**Post-Secondary**	**Graduate**	**postgraduate**	
HbA1c Group 1	6.1	Count	0	1	0	1	2
		% within HbA1c Group 1	0.00%	50.00%	0.00%	50.00%	100.00%
		% within education_expermient	0.00%	7.10%	0.00%	20.00%	5.00%
		% of Total	0.00%	2.50%	0.00%	2.50%	5.00%
	7	Count	3	1	0	0	4
		% within HbA1c Group 1	75.00%	25.00%	0.00%	0.00%	100.00%
		% within education_expermient	42.90%	7.10%	0.00%	0.00%	10.00%
		% of Total	7.50%	2.50%	0.00%	0.00%	10.00%
	7.2	Count	0	1	2	1	4
		% within HbA1c Group 1	0.00%	25.00%	50.00%	25.00%	100.00%
		% within education_expermient	0.00%	7.10%	14.30%	20.00%	10.00%
		% of Total	0.00%	2.50%	5.00%	2.50%	10.00%
	7.3	Count	0	1	3	0	4
		% within HbA1c Group 1	0.00%	25.00%	75.00%	0.00%	100.00%
		% within education_expermient	0.00%	7.10%	21.40%	0.00%	10.00%
		% of Total	0.00%	2.50%	7.50%	0.00%	10.00%
	7.4	Count	0	3	0	1	4
		% within HbA1c Group 1	0.00%	75.00%	0.00%	25.00%	100.00%
		% within education_expermient	0.00%	21.40%	0.00%	20.00%	10.00%
		% of Total	0.00%	7.50%	0.00%	2.50%	10.00%
	7.9	Count	1	0	1	0	2
		% within HbA1c Group 1	50.00%	0.00%	50.00%	0.00%	100.00%
		% within education_expermient	14.30%	0.00%	7.10%	0.00%	5.00%
		% of Total	2.50%	0.00%	2.50%	0.00%	5.00%
	8	Count	0	1	1	0	2
		% within HbA1c Group 1	0.00%	50.00%	50.00%	0.00%	100.00%
		% within education_expermient	0.00%	7.10%	7.10%	0.00%	5.00%
		% of Total	0.00%	2.50%	2.50%	0.00%	5.00%
	8.1	Count	0	1	0	1	2
		% within HbA1c Group 1	0.00%	50.00%	0.00%	50.00%	100.00%

		% within education_expermient	0.00%	7.10%	0.00%	20.00%	5.00%
		% of Total	0.00%	2.50%	0.00%	2.50%	5.00%
	8.4	Count	1	0	1	0	2
		% within HbA1c Group 1	50.00%	0.00%	50.00%	0.00%	100.00%
		% within education_expermient	14.30%	0.00%	7.10%	0.00%	5.00%
		% of Total	2.50%	0.00%	2.50%	0.00%	5.00%
	8.9	Count	0	0	2	0	2
		% within HbA1c Group 1	0.00%	0.00%	100.00%	0.00%	100.00%
		% within education_expermient	0.00%	0.00%	14.30%	0.00%	5.00%
		% of Total	0.00%	0.00%	5.00%	0.00%	5.00%
	9	Count	0	2	2	0	4
		% within HbA1c Group 1	0.00%	50.00%	50.00%	0.00%	100.00%
		% within education_expermient	0.00%	14.30%	14.30%	0.00%	10.00%
		% of Total	0.00%	5.00%	5.00%	0.00%	10.00%
	9.1	Count	1	0	0	1	2
		% within HbA1c Group 1	50.00%	0.00%	0.00%	50.00%	100.00%
		% within education_expermient	14.30%	0.00%	0.00%	20.00%	5.00%
		% of Total	2.50%	0.00%	0.00%	2.50%	5.00%
	9.4	Count	0	2	0	0	2
		% within HbA1c Group 1	0.00%	100.00%	0.00%	0.00%	100.00%
		% within education_expermient	0.00%	14.30%	0.00%	0.00%	5.00%
		% of Total	0.00%	5.00%	0.00%	0.00%	5.00%
	9.6	Count	0	0	2	0	2
		% within HbA1c Group 1	0.00%	0.00%	100.00%	0.00%	100.00%
		% within education_expermient	0.00%	0.00%	14.30%	0.00%	5.00%
		% of Total	0.00%	0.00%	5.00%	0.00%	5.00%
	11	Count	1	1	0	0	2
		% within HbA1c Group 1	50.00%	50.00%	0.00%	0.00%	100.00%
		% within education_expermient	14.30%	7.10%	0.00%	0.00%	5.00%
		% of Total	2.50%	2.50%	0.00%	0.00%	5.00%
Total		Count	7	14	14	5	40
		% within HbA1c Group 1	17.50%	35.00%	35.00%	12.50%	100.00%
		% within education_expermient	100.00%	100.00%	100.00%	100.00%	100.00%
		% of Total	17.50%	35.00%	35.00%	12.50%	100.00%

HbA1c Group 2 * education_control Crosstabulation

			education_control				Total
			Secondary	**Post-Secondary**	**Graduate**	**postgraduate**	
HbA1c Group 2	6.60	Count	0	0	2	0	2
		% within HbA1c Group 2	0.0%	0.0%	100.0%	0.0%	100.0%
		% within education_control	0.0%	0.0%	10.0%	0.0%	5.0%
		% of Total	0.0%	0.0%	5.0%	0.0%	5.0%
	7.40	Count	1	0	1	0	2
		% within HbA1c Group 2	50.0%	0.0%	50.0%	0.0%	100.0%
		% within education_control	14.3%	0.0%	5.0%	0.0%	5.0%
		% of Total	2.5%	0.0%	2.5%	0.0%	5.0%
	7.50	Count	0	1	1	0	2
		% within HbA1c Group 2	0.0%	50.0%	50.0%	0.0%	100.0%
		% within education_control	0.0%	9.1%	5.0%	0.0%	5.0%
		% of Total	0.0%	2.5%	2.5%	0.0%	5.0%
	7.60	Count	1	0	1	0	2
		% within HbA1c Group 2	50.0%	0.0%	50.0%	0.0%	100.0%
		% within education_control	14.3%	0.0%	5.0%	0.0%	5.0%
		% of Total	2.5%	0.0%	2.5%	0.0%	5.0%
	8.00	Count	1	2	2	1	6
		% within HbA1c Group 2	16.7%	33.3%	33.3%	16.7%	100.0%
		% within education_control	14.3%	18.2%	10.0%	50.0%	15.0%
		% of Total	2.5%	5.0%	5.0%	2.5%	15.0%
	8.10	Count	0	1	1	0	2
		% within HbA1c Group 2	0.0%	50.0%	50.0%	0.0%	100.0%
		% within education_control	0.0%	9.1%	5.0%	0.0%	5.0%
		% of Total	0.0%	2.5%	2.5%	0.0%	5.0%
	8.40	Count	0	0	2	0	2
		% within HbA1c Group 2	0.0%	0.0%	100.0%	0.0%	100.0%
		% within education_control	0.0%	0.0%	10.0%	0.0%	5.0%
		% of Total	0.0%	0.0%	5.0%	0.0%	5.0%

	8.80	Count	0	0	3	1	4
		% within HbA1c Group 2	0.0%	0.0%	75.0%	25.0%	100.0%
		% within education_control	0.0%	0.0%	15.0%	50.0%	10.0%
		% of Total	0.0%	0.0%	7.5%	2.5%	10.0%
	8.90	Count	0	2	2	0	4
		% within HbA1c Group 2	0.0%	50.0%	50.0%	0.0%	100.0%
		% within education_control	0.0%	18.2%	10.0%	0.0%	10.0%
		% of Total	0.0%	5.0%	5.0%	0.0%	10.0%
	9.10	Count	2	1	3	0	6
		% within HbA1c Group 2	33.3%	16.7%	50.0%	0.0%	100.0%
		% within education_control	28.6%	9.1%	15.0%	0.0%	15.0%
		% of Total	5.0%	2.5%	7.5%	0.0%	15.0%
	9.90	Count	1	1	0	0	2
		% within HbA1c Group 2	50.0%	50.0%	0.0%	0.0%	100.0%
		% within education_control	14.3%	9.1%	0.0%	0.0%	5.0%
		% of Total	2.5%	2.5%	0.0%	0.0%	5.0%
	10.00	Count	1	2	1	0	4
		% within HbA1c Group 2	25.0%	50.0%	25.0%	0.0%	100.0%
		% within education_control	14.3%	18.2%	5.0%	0.0%	10.0%
		% of Total	2.5%	5.0%	2.5%	0.0%	10.0%
	12.50	Count	0	1	1	0	2
		% within HbA1c Group 2	0.0%	50.0%	50.0%	0.0%	100.0%
		% within education_control	0.0%	9.1%	5.0%	0.0%	5.0%
		% of Total	0.0%	2.5%	2.5%	0.0%	5.0%
Total		Count	7	11	20	2	40
		% within HbA1c Group 2	17.5%	27.5%	50.0%	5.0%	100.0%
		% within education_control	100.0%	100.0%	100.0%	100.0%	100.0%
		% of Total	17.5%	27.5%	50.0%	5.0%	100.0%

HbA1c Group 1 * Age Group 1 Crosstabulation

Count

		Age Group 1					Total
		14-25	26-35	36-45	46-55	56-65	
HbA1c Group 1	6.10	1	0	1	0	0	2
	7.00	2	0	2	0	0	4
	7.20	0	0	3	0	1	4
	7.30	0	1	2	0	1	4
	7.40	1	0	2	1	0	4
	7.90	0	0	0	1	1	2
	8.00	0	0	2	0	0	2
	8.10	1	1	0	0	0	2
	8.40	1	0	0	0	1	2
	8.90	0	1	1	0	0	2
	9.00	2	0	0	0	2	4
	9.10	1	0	0	1	0	2
	9.40	1	0	1	0	0	2
	9.60	1	1	0	0	0	2
	10.50	2	0	0	0	0	2
Total		13	4	14	3	6	40

HbA1c Group 2* Age Group 2 Crosstabulation

Count

Counts		Age Group 2					Total
		14-25	26-35	36-45	46-55	56-65	
HbA1c Group 2	6.60	1	0	0	1	0	2
	7.40	0	0	1	1	0	2
	7.50	0	0	1	0	1	2
	7.60	0	0	0	1	1	2
	8.00	1	0	2	1	2	6
	8.10	1	0	1	0	0	2
	8.40	0	1	1	0	0	2
	8.80	1	0	2	1	0	4
	8.90	1	2	0	0	1	4
	9.10	1	2	0	3	0	6
	9.90	1	1	0	0	0	2
	10.00	0	1	2	0	1	4
	12.50	1	0	0	0	1	2
Total		8	7	10	8	7	40