University of Alberta

Menu planning and individual counseling as strategies to improve diet quality in people with type 2 diabetes: results from a pilot study

by

Diana Cristina Soria

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Abstract

This 12-week study evaluated the effectiveness of menu planning and individual counseling in improving diet quality and health parameters among 15 type 2 diabetes patients using a pretest-posttest design. Perceived dietary adherence was measured and three-day food records were obtained to determine nutrient intakes, servings of food groups and the Healthy Eating Index (diet quality). Glycated hemoglobin, lipid parameters, weight, waist circumference and body composition were measured. There was a decrease in sodium intake (in women), and an increase in perceived dietary adherence ($p<0.05$). No significant changes were observed in diet quality. Glycated hemoglobin, weight, waist circumference, BMI and fat mass decreased, while HDL-cholesterol and fat free mass increased ($p<0.05$). Changes in health parameters were greater among participants who improved their diet quality. Menu planning was shown to be feasible and effective for diabetes management; however, more research is needed to establish the long-term benefits and feasibility of this approach.

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LIST OF ABBREVIATIONS

ADA	American Diabetes Association
BMI	Body mass index
CCHS	Canadian Community Health Survey
CDA	Canadian Diabetes Association
CHD	Coronary heart disease
CNF	Canadian Nutrient File
CVD	Cardiovascular disease
DCCT	Diabetes Control and Complications Trial
DM	Diabetes mellitus
DPP	Diabetes prevention program
EASD	European Association for the Study of Diabetes
EBMP	Exchange-based meal plan
EWCFG	Eating Well with Canada´s Food Guide
FFQ	Food frequency questionnaires
GDM	Gestational diabetes
GI	Glycemic index
GL	Glycemic load
HbA1c	Glycated hemoglobin
HDL-cholesterol	High-density lipoprotein cholesterol
HEI	Healthy Eating Index
IGT	Impaired glucose tolerance
LDL-cholesterol	Low-density lipoprotein cholesterol
MUFA	Monounsaturated fatty acids
NHANES III	Third National Health and Nutrition Examination Survey

NTG	Nutrition therapy guidelines
PDAQ	Perceived dietary adherence questionnaire
PUFA	Polyunsaturated fatty acids
RCT	Randomized clinical trial
SBT	Standard behavioral treatment
SFA	Saturated fatty acids
T1D	Type 1 diabetes
T2D	Type 2 diabetes
TC/HDL-c	Total cholesterol to HDL cholesterol ratio
TEE	Total energy expenditure
UKPDS	United Kingdom Prospective Diabetes Study
US	United States
USDA	United States Department of Agriculture

Chapter 1: Introduction

1.1. Overview

Diabetes Mellitus (DM) has become one of the most challenging health problems in the world (International Diabetes Federation [IDF], 2009). It is classified as type 1 diabetes (T1D), type 2 diabetes (T2D), gestational diabetes mellitus (GDM) and other specific types (American Diabetes Association [ADA], 2012a; Canadian Diabetes Association [CDA], 2008). However, T2D accounts for the majority of the cases (90-95%) (ADA, 2012a).

It is known that non-modifiable factors such as family history of diabetes, birth weight, ethnicity and age, influence the development of T2D. However, acquired factors such as obesity, physical inactivity and unhealthy diets are recognized as important contributors to the diabetes epidemic (Holt & Hanley, 2012; IDF, 2011).

The prevalence of diabetes is on the rise in every country, with low-and middle-income countries being disproportionally affected. In 2011, diabetes affected more than 366 million people worldwide (8.3% of the population) and this is projected to increase to 522 million (9.9%) by 2030 (IDF, 2011). In Canada, by 2009, almost 2.4 million people (6.8%) were diagnosed with diabetes, and it is expected that by 2020 there will be at least 3.7 million people living with the disease (Public Health Agency of Canada [PHAC], 2011).

Diabetes places individuals at high risk of macrovascular (i.e. stroke and heart disease), microvascular (i.e. retinopathy, nephropathy and neuropathy) and psychological complications (i.e. depression and bipolar disorder) (Holt & Hanley, 2012; PHAC, 2011). These complications cause disability and mortality, have a negative impact on quality of life and increase health-related costs (IDF, 2011; PHAC, 2011; UK Prospective Diabetes Study [UKPDS] Group, 1999).

The Diabetes Control and Complications Trial (DCCT) and the United Kingdom Prospective Diabetes Study (UKPDS) confirmed the relationship between high blood sugar levels and the development and progression of diabetes complications (The Diabetes Control and Complications Trial Research Group [DCCT], 1993; UKPDS Group, 1998). Therefore, glycemic control is one of the targets of diabetes treatment along with control of blood lipids and blood pressure (CDA, 2008). All these targets can be achieved by lifestyle modifications including changes in diet and physical activity (The Look AHEAD Research Group, 2010).

The adoption of a diet in line with the nutrition therapy guidelines (NTG) is vital for individuals with diabetes. Nutrition therapy alone leads to reductions in glycated hemoglobin (HbA1c) similar to those achieved by pharmacological agents. Therefore, nutrition therapy is recommended as the first step in T2D management (Green Pastors, Franz, Warshaw, Daly, & Arnold, 2003; Nathan, et al., 2009). Furthermore, nutrition therapy improves multiple cardiovascular risk factors such as excess body weight, waist circumference, blood pressure and lipid profile (Ash, et al., 2003; Franz, et al., 1995; Green Pastors, et al., 2003; Manley, et al., 2000; Pi-Sunyer, et al., 1999; UKPDS Group, 1990).

Evidence-based NTG such as those released by the Canadian Diabetes Association (CDA) outline the standards that individuals with diabetes should follow to have an adequate diet (CDA, 2008). However, it is consistently reported that people with T2D do not follow the nutritional recommendations on a regular basis, and have suboptimal diet quality (Asaad, 2012; Devi Durai Raj, 2012; Jarvandi, Gougeon, Bader, & Dasgupta, 2011; Muñoz-Pareja, et al., 2012; Rivellese, et al., 2008; Thanopoulou, et al., 2004; Vitolins, et al., 2009).

Nutrition therapy is considered the most challenging aspect of diabetes management (ADA, 2012b; Whittemore, Chase, Mandle, & Roy, 2002). There are several factors that affect adherence to the recommended diet including lack of knowledge and understanding of the meal plan, lack of skills to translate the recommendations into practice and lack of cultural acceptability of the diet (Galasso, Amend, Melkus, & Nelson, 2005; Marcy, Britton, & Harrison, 2011; Nagelkerk, Reick, & Meengs, 2006; Vincent, Clark, Zimmer, & Sanchez, 2006). Factors such as the accessibility and availability of the foods influence how the dietary advice is put into practice. In fact, the cost of the food items in the diet is an important barrier for dietary adherence (Jorgensen, Pollvka, & Lennie, 2002; Kearney & McElhone, 1999; Orzech, Vivian, Huebner-Torres, Armin, & Shaw, 2012; Vijan, et al., 2005). Also, personal skills and available time to select foods, plan meals and cook, limit people´s abilities to follow the recommended diet (Brown, Pope, Hunt, & Tolman, 1998; Galasso, et al., 2005; Kearney & McElhone, 1999; Rustveld, et al., 2009; Schlundt, Rea, Kline, & Pichert, 1994).

Considering the above mentioned factors when designing interventions for dietary management is fundamental. A variety of strategies can be used to assist people with diabetes to follow a diet consistent with the nutritional standards (Franz, et al., 2010). However, strategies that simplify the overall nutrition recommendations and eliminate the tasks associated with selecting and planning foods have shown to improve dietary compliance and metabolic outcomes (Metz, et al., 1997; Metz, et al., 2000; Pi-Sunyer, et al., 1999). Menu planning is such a strategy; however, it´s effectiveness in the dietary management of individuals with T2D has not been well studied.

1.2. Rationale

The number of Canadians with diabetes is on the rise and the economic burden of the disease is also expected to increase, therefore, improving diabetes management and diabetes outcomes is fundamental. The benefits of nutrition therapy in diabetes management are well known; however, adherence to the recommended diet remains a challenge. Bearing this in mind, the development of strategies that facilitate adherence to nutrition recommendations is essential. Therefore, we aimed to study the effectiveness of a 4-week menu plan that incorporated the overall recommendations of the CDA NTG and met the serving recommendations outlined in Eating Well with Canada´s Food Guide (EWCFG). Foods that are adequate for diabetes management, as well as acceptable, accessible and available to Albertans were included in the menu plan.

1.3. Purpose

The main purpose of this study was to test the effectiveness of a 4-week menu plan combined with individual counseling in improving diet quality in individuals with T2D living in the Edmonton area. Also, we wanted to assess whether this approach effectively improved glycemic control and health parameters. The goal was to demonstrate whether this approach supports healthy eating in people with T2D, and then we would work to make this menu plan part of the routine dietary management of diabetes patients in Alberta.

1.4. Hypothesis

We hypothesized that upon completion of the menu plan program, participants would improve the quality of their diets. Consequently, changes in diet quality would lead to improvements in health parameters. The specific hypotheses of the study were:

- Individuals who participated in the menu plan program would have improved diet quality.

- Individuals who participated in the program would have a decrease in glycated hemoglobin and improvements in lipid profile, body weight, waist circumference and body composition.

1.5. Specific objectives

The objectives were to evaluate changes (pre/post-intervention) in diet quality and health parameters in people with T2D who participated in the menu plan program.

- To evaluate changes in diet quality by measuring pre-and post-intervention indicators including the Healthy Eating Index score, nutrient profile of the diets and the intake of servings from EWCFG.

- To measure changes in glycated hemoglobin (glycemic control) from baseline to program completion.

- To evaluate changes in lipid profile, body weight, waist circumference and body composition from baseline to program completion.

- To determine the feasibility of menu planning by measuring recruitment, participation and retention rates.

Chapter 2: Literature review

2.1 Introduction

This chapter provides an overview of the increasing prevalence of T2D and its complications among Canadians, and underscores the importance of lifestyle modification, specifically nutrition therapy, as part of diabetes treatment. Later, a review of studies describes trends in, and factors that influence, dietary adherence. Finally, a review of strategies to facilitate dietary adherence is presented, to conclude with the evidence supporting menu planning as an approach to improve diet quality.

2.2. Definition, classification and diagnosis of diabetes mellitus

The term diabetes mellitus comprises a group of metabolic diseases characterized by elevated blood glucose levels or hyperglycemia due to defects in insulin secretion, insulin action or both. In the long term this hyperglycemia is associated with complications including retinopathy, nephropathy, neuropathy and higher risk of cardiovascular disease (CVD) (ADA, 2012a; CDA, 2008).

According to its etiology, DM is classified into T1D, T2D, GDM and other specific types (ADA, 2012a; CDA, 2008). Type 1 diabetes is usually diagnosed during childhood and adolescence and accounts for 5-10% of the cases of diabetes. It is characterized by lack of insulin production due to pancreatic beta cell destruction. On the other hand, T2D represents 90-95% of the cases of diabetes and is the result of ineffective insulin utilization in the tissues (insulin resistance) and ineffective insulin secretion. Type 2 diabetes is most common in adults, although its incidence is increasing among children and adolescents (ADA, 2012a). Gestational diabetes mellitus and other specific types of diabetes are less common than T2D and T1D. Gestational diabetes refers to high blood glucose levels first recognized during pregnancy. Finally, other specific types include those associated with genetic defects of the beta cell, infections, diseases of the pancreas and diabetes induced by drugs or chemicals (ADA, 2012a; CDA, 2008).

Diabetes Mellitus is diagnosed with any of the following: a fasting plasma glucose ≥7.0 mmol/L, a 2-hour plasma glucose in a 75 g oral glucose tolerance test ≥11.1 mmol/L, or a casual plasma glucose ≥11.1 mmol/L with classic symptoms of diabetes. Classic symptoms include polyuria, polydipsia, unexplained weight loss, polyphagia and blurred vision (ADA, 2012a; CDA, 2008). Since 2009, an HbA1c ≥6.5% is also accepted for the diagnosis of diabetes (ADA, 2012a).

2.3. Pathophysiology of type 2 diabetes

Type 2 diabetes results from the interaction of non-modifiable factors such as family history of diabetes, birth weight, ethnicity and age, and acquired factors such as obesity, physical inactivity, and unhealthy diets that negatively affect insulin secretion and insulin action (Holt & Hanley, 2012).

There are two mechanisms underlying the development of T2D: impaired insulin secretion due to pancreatic beta cell dysfunction and impaired insulin action due to insulin resistance. Insulin resistance occurs when, at physiological concentrations, insulin is not able to exert its normal effects. As a consequence, glucose uptake in the liver and skeletal muscle is reduced, the liver is not able to inhibit glucose production, and the adipose tissue loses its ability to suppress lipolysis, among other effects (Holt & Hanley, 2012). In the presence of insulin resistance, the pancreatic beta cell tries to keep blood glucose within normal range by increasing insulin secretion. When the beta cell is not able to produce higher amounts of insulin to compensate for insulin resistance, blood glucose rises and individuals develop impaired glucose tolerance (IGT). As insulin resistance and impaired insulin secretion worsen, individuals with IGT progress to T2D (DeFronzo, Bonadonna, & Ferrannini, 1992; Holt & Hanley, 2012).

2.4. Epidemiology

Economic development, increasing urbanization, aging of population, increasing prevalence of overweight and obesity, and the acquisition of negative behaviors like physical inactivity and unhealthy diets are leading the diabetes epidemic all over the world (IDF, 2011). Worldwide, diabetes affects more than 366 million people (8.3% of the population) (IDF, 2011). It is the leading cause of blindness, renal failure, and one of the leading causes of death (IDF, 2009). It is projected that by 2030, there will be approximately 552 million adults (9.9%) with diabetes in the world (IDF, 2011).

Diabetes is one of the most prevalent chronic diseases in Canada. Between 2008 and 2009, almost 2.4 million people (6.8%) were diagnosed with diabetes, from which 90-95% of the cases were T2D (PHAC, 2011). Increasing rates of overweight and obesity, migration and population aging are contributing to the prevalence of diabetes in Canada (CDA, 2008; IDF, 2011; PHAC, 2011). The proportion of people affected by diabetes increases with age, and reaches the highest prevalence in those aged 75-79 years (25.5%). However, the prevalence is increasing among younger people due to overweight and obesity. One example of this trend is the twofold increase of diabetes among adults aged 35-44 years over the past decade. If these trends continue, before 2020 there will be 3.7 million people living with diabetes in Canada (PHAC, 2011).

The story of diabetes in Alberta is not different; it is recognized as an important and growing problem that in 2009 affected 206,000 Albertans, corresponding to 5.7% of the population. Similar to what is seen nationally, the number of cases increases as people become older, therefore, the burden on the health care system is higher due to the additional health problems present in the aging population (Johnson & Balko, 2011).

2.5. Complications

Diabetes is recognized as “a chronic, debilitating and costly disease associated with major complications that pose severe risks for families, countries and the entire world” (United Nations General Assembly, 2006, p. 1).

Diabetes complications are classified into macrovascular, microvascular and psychological (Holt & Hanley, 2012). Macrovascular complications affect major blood vessels and include heart disease, stroke and peripheral vascular disease, whereas microvascular complications are those associated with damage to small blood vessels in the eyes (retinopathy), kidneys (nephropathy) and nerves (neuropathy) (PHAC, 2011).

The DCCT and the UKPDS showed that by lowering blood glucose near normal levels (HbA1c <7%), the development and progression of complications could be reduced (The DCCT Research Group, 1993; UKPDS Group, 1998). Despite the preventable nature of its complications, diabetes is the leading cause of blindness, end-stage renal disease and non-traumatic amputations in Canada (CDA, 2008; PHAC, 2011). Furthermore, CVD is the leading cause of death among people with T2D (PHAC, 2011).

Microvascular complications are highly prevalent. For example, diabetic retinopathy is present in people with T2D even before they are diagnosed with diabetes, and 20 years after diagnosis, all the individuals with T1D and 60% of those with T2D develop retinopathy. In the same manner, damage in the kidneys often begins before diagnosis of diabetes, making diabetic nephropathy a common complication and the first cause of end-stage renal disease (PHAC, 2011). Another common complication is neuropathy which affects 20-50% of people with diabetes. Neuropathy places individuals at higher risk of foot ulceration and lower-limb amputation, which increase morbidity, mortality and health care costs (Holt & Hanley, 2012). On the other hand, the risk of developing CVD is 2 to 4 times higher in individuals with diabetes. Moreover, if we consider additional risk factors such as excess body weight, dyslipidemia and high blood pressure that are very common in people with diabetes, the risk of CVD is even higher (PHAC, 2011).

Diabetes is a demanding condition in which the commitment of the patient to self-management practices is fundamental for positive outcomes (CDA, 2008). Major lifestyle changes are required as part of diabetes management, placing individuals at a high risk of emotional distress and psychological complications (Holt & Hanley, 2012). Psychological complications such as depression are associated with non-adherence to diabetes treatment, poor glycemic control and higher prevalence of microvascular and macrovascular complications (Egede & Ellis, 2010).

Macrovascular, microvascular and psychological complications of diabetes have a negative impact on quality of life, cause disability and increase the risk of death (PHAC, 2011; UKPDS Group, 1999). In fact, a study conducted by the Public Health Agency of Canada showed that diabetes is associated with a loss of life expectancy of 6 years for females and 5 years for males, living with diabetes at the age of 55 years (Loukine, Waters, Choi, & Ellison, 2012). Additionally, diabetes and its complications increase the utilization of health care services and increase health-related costs (PHAC, 2011).

2.6. Lifestyle modification in diabetes management

Besides pharmacological therapy, the adoption of a healthy lifestyle through modification of physical activity and dietary behaviors is important for diabetes prevention and treatment. Lifestyle modification in individuals at high-risk of or with T2D is an attainable goal. Individual or group-based programs are effective in helping people modify their dietary and exercise behaviors, lose weight, and delay or prevent the onset of diabetes. The Da Qing IGT and Diabetes Study was one of the first studies that targeted diabetes prevention through changes in lifestyle (Pan, et al., 1997). This study showed that group counseling focused on diet, exercise, or diet and exercise combined, could reduce the risk of diabetes by

31% ($p<0.05$), 46% ($p<0.001$), and 42% ($p<0.01$), respectively (Pan, et al., 1997), and that these benefits could persist on the long-term (Li, et al., 2008).

The results of the Da Qing IGT and Diabetes Study have been replicated in the United States (US) and Finland. The US Diabetes Prevention Program (DPP) was a multicenter, randomized clinical trial (RCT) that compared the efficacy of an intensive lifestyle intervention, a standard lifestyle intervention with metformin, and a standard lifestyle intervention with placebo, in preventing or delaying the onset of T2D. The intensive lifestyle intervention included individual coaching by a case manager, frequent contact throughout the study, and a 16-session core curriculum focused on diet, physical activity and behavioral self-management strategies. The goals for this group were to achieve and maintain a weight loss of at least 7% of initial body weight through a low-calorie, low-fat diet, and exercise, and to achieve and maintain at least 150 minutes/week of moderate intensity physical activity (The Diabetes Prevention Program Research Group [The DPP Research Group], 2002). The standard lifestyle intervention group received written recommendations and an annual session focused on the benefits of a healthy lifestyle in the prevention of diabetes. The goals for this group were similar to the intensive lifestyle intervention group (The DPP Research Group, 1999). A total of 3234 individuals were included in the 3 arms of the study and they were followed for almost 3 years. More participants in the intensive lifestyle intervention arm were able to achieve the weight loss and physical activity goals. Also they had a higher decrease in the amount of total calories (-450 kcal, $p<0.001$) and fat intake (-6.6% total daily energy, $p<0.001$). Likewise, the intensive lifestyle intervention group lost 5.6 kg or 6% of their initial body weight compared with only 0.1 kg in the placebo and 2.1 kg in the metformin groups ($p<0.001$). Incidence of diabetes was 58% lower in the intensive lifestyle intervention group compared with placebo, and 39% lower compared with metformin (The DPP Research Group, 2002). A lower incidence of diabetes in the intervention group (34%) persisted at 10 years of follow up (The DPP Research Group, 2009). Using a similar approach to lifestyle modification, the Finnish Diabetes Prevention Study showed a 58% lower incidence of diabetes in the intervention group after 3 years (Tuomilehto, et al., 2001) and 43% after 7 years of follow up compared with the control group (Lindström, et al., 2006).

A healthy lifestyle is necessary for optimal diabetes management. Weight loss, improvement of CVD risk factors (HbA1c, blood pressure, and lipid profile), psychosocial variables, as well as quality of life are among the benefits of engaging in healthy dietary and exercise behaviors (The Look AHEAD Research Group, 2010; Toobert, et al., 2007). The following section presents a review of some lifestyle modification programs and their main findings. Additional studies are included in table 2.1.

The Mediterranean lifestyle program designed by Toobert et al. (2007) was a 2-year, group-based intervention with the objective of reducing the risk of coronary heart disease (CHD) in postmenopausal women with T2D. In total, 279 women were randomized to either Mediterranean lifestyle program (n=163) or usual care (n=116). The program included a 2 ½ day retreat, weekly meetings for the first 6 months, and weekly meetings or 4 meetings plus completion of a computer program for the next 18 months. Specific behaviors known to influence CHD risk were targeted. Physical activity was promoted with the goal of exercising at least 30 minutes most days of the week; stress management strategies like yoga and meditation were also included. The dietary component of the program emphasized the principles of the Mediterranean diet such as eating more whole-grain bread, vegetables, legumes, fish and less red meat, among others. Finally, due to the influence of social support on self-management of diabetes, it was included as one of the psychosocial components of the program. Usual care included regular medical care. Compared with usual care, participants in the Mediterranean lifestyle program achieved greater long-term changes in behaviors related to diet, physical activity and stress-management, as well as in different psychosocial variables that influence diabetes management. They reduced calories from saturated fat by 4% at 6 months and maintained this reduction at 24 months ($p<0.001$). Participants in the Mediterranean lifestyle program increased significantly the frequency, duration and intensity of physical activity, as well as the number of minutes practicing stress-management techniques. They also had significant improvements in perceived social support, problem solving strategies, dietary self-efficacy, exercise self-efficacy, and confidence in overcoming challenges to diabetes management, as well as a decrease in perceived stress (Toobert, et al., 2007).

The look AHEAD (Action for Health in Diabetes) study is an ongoing RCT that includes 5145 overweight individuals with T2D. The objective is to determine the long-term impact of weight loss on cardiovascular morbidity and mortality. Individuals were assigned to intensive lifestyle intervention or diabetes support and education (usual care) and followed for a mean of 10 years. It includes a 16-session curriculum based on the DPP curriculum, ongoing group and individual support, behavioral strategies such as goal setting, self-monitoring of dietary intake and physical activity, and problem solving. The dietary approach of the intervention includes a low-calorie, low-fat diet (<30% total energy) with <10% of calories from saturated fat. Portion control strategies such as meal replacements are available to improve adherence to the dietary prescription. The physical activity component aims at increasing moderate intensity physical activity to 175 min/week, as well as increasing lifestyle activity (i.e. walking more). The objectives of the intensive lifestyle intervention are weight loss and maintenance of ≥7% of body weight and an increase in moderate-intensity physical activity. The usual care condition includes usual medical care and 3 group education sessions per year during 4 years (The Look AHEAD Research Group, 2006). At 4 years of follow up, participants in the intervention group achieved greater weight loss (-6.15 vs -0.88%, $p<0.001$) and greater improvements in physical fitness measured by % metabolic equivalents (12.74 vs 1.96%, $p<0.001$) compared with usual care. Likewise, the intervention group showed greater improvements on different CVD risk factors including a greater decrease in HbA1c (-0.36 vs -0.09%, $p<0.001$), systolic (-5.33 vs -2.97 mmHg, $p<0.001$) and diastolic blood pressure (-2.92 vs -2.48 mmHg, $p=0.01$), and triglycerides (-25.56 vs -19.75 mg/dL, $p<0.001$). They also showed a greater increase in high-density lipoprotein cholesterol (HDL) (+3.67 vs +1.97 mg/dL, $p<0.001$) (The Look AHEAD Research Group, 2010).

The Improving Control with Activity and Nutrition (ICAN) study took a different approach to lifestyle modification and compared the efficacy of a case-management intervention lead by a registered dietitian versus usual care. The case-management intervention was modestly-priced ($350 per participant/year) and included 6 individual sessions/year, 6 group sessions/year and monthly telephone contact. Sessions included assessment (i.e. anthropometry and laboratory results), goal setting, education and support. Usual care participants received educational materials. A total of 147 participants were included in the trial. Participants in the case-management strategy decreased -5.5 cm of waist circumference and lost -2.4 kg or 2.2% of initial body weight over 1 year, compared with a weight gain of +0.6 kg that occurred in the usual care group ($p<0.05$). Glycemic control improved at 4 months (HbA1c -0.57%, $p=0.008$) and 12 months (HbA1c -0.20%, $p=0.45$) (Wolf, et al., 2004).

Successful lifestyle interventions like the DPP have been translated into different settings with positive results (Matvienko & Hoehns, 2009; Mayer-Davis, et al., 2004). The pounds off with empowerment (POWER) study was a 1-year RCT designed to assess the effectiveness of an intensive lifestyle intervention, a reimbursable lifestyle intervention and usual care on weight management. A total of 187 overweight individuals with T2D were included in the study. The goal was to achieve and maintain 10% weight loss. The intensive lifestyle intervention followed a culturally relevant version of the DPP that included ongoing group and individual counseling by a nutritionist, a 16-session curriculum focused on weight loss, physical activity and behavioral strategies. The means of achieving weight loss for the intervention group were a diet providing <25% of total daily energy from fat, and an increase in physical activity to at least 150 min/week. The reimbursable lifestyle intervention was a condensed version of the intensive lifestyle intervention delivered in 3 group and 1 individual session over the 12 months. Usual care included 1 session at the beginning of the study. Positive results in weight loss (-2.2 kg, p<0.003) and glycemic control (HbA1c -1.6%, p<0.01) were observed in the intensive lifestyle intervention group. Moreover, a higher proportion of participants in the intervention group, compared with usual care, were able to lose at least 2 kg (49% vs 25%, p< 0.05) at 12 months (Mayer-Davis, et al., 2004).

The adoption of a healthy lifestyle is the cornerstone of diabetes treatment. Approaches to lifestyle modification that include behavioral strategies, ongoing support, and a diet and physical activity component are feasible and effective for diabetes management. However, the unique role of nutrition therapy on diabetes management needs to be underscored. The following sections provide an overview of the benefits of nutrition therapy and the nutrition standards recommended in Canada. Then, trends in adherence to nutrition therapy and barriers to follow a healthy diet are explored; to conclude with a review of different strategies to improve dietary adherence.

Table 2.1. Effects of lifestyle modification on different outcomes

Reference	**Study length**	**Design**	****No. subjects**	**Main findings in intervention group**
(Matvienko & Hoehns, 2009)	12 months	Pre-posttest single arm design	25	- Weight loss: -6 kg (-6%), for all p<0.05 - BMI: -2.1 kg/m^2 - Waist circumference: -5.3 cm - Hip circumference: -3.9 cm - *Total cholesterol: -21.2 mg/dL (n=28) - *LDL: -7.8 mg/dL (n=27)
(Oh, et al., 2010)	12 months	RCT (therapeutic lifestyle modification (TLM) vs control)	TLM, n=27 Control, n=21	- Weight loss: -4.3 kg (-7%), for all p<0.05 - BMI: -1.4 kg/m^2 - Waist circumference: -9.4 cm

(Gallagher, et al., 2012)	16 weeks	RCT (lifestyle intervention (LI) vs control)	LI, n=75 Control, n=58	- Weight loss: -2.19 kg (-3.2%), for all $p<0.05$ - Waist circumference: -2.83 cm - BMI: -0.74 kg/m^2 - Days/week of exercise: +1.07 - Minutes/week of exercise: +119
*6 months follow up ** Subjects that completed the intervention				

2.7. Nutrition therapy in diabetes management

Nutrition therapy is an essential component of diabetes management (ADA, 2008; ADA, 2012b; CDA, 2008). The goals of nutrition therapy are to improve and maintain nutritional and health status, quality of life and to prevent or slow the rate of complications (ADA, 2008; CDA, 2008).

Maintenance of blood glucose within normal or near-normal range slows and decreases the development of complications and is one of the objectives of overall diabetes management (ADA, 2008; ADA, 2012b; The DCCT Research Group, 1993; UKPDS Group, 1998). In this regard, nutrition therapy is as effective as pharmacological agents and leads to reductions on HbA1c of 1-2% (Franz, et al., 1995; Green Pastors, et al., 2003; Kulkarni, et al., 1998; Nathan, et al., 2009; Pi-Sunyer, et al., 1999; UKPDS Group, 1990). Besides glycemic control, a diet in line with the NTG has benefits on different CVD risk factors that could otherwise be achieved with multiple strategies (i.e. multiple medications). Among these benefits are weight loss, changes in body composition such as decrease in waist circumference, and improvements on blood pressure and lipid profile (Ash, et al., 2003; Franz, et al., 1995; Green Pastors, et al., 2003; Manley, et al., 2000; Pi-Sunyer, et al., 1999; UKPDS Group, 1990).

2.7.1. Canadian Diabetes Association Nutrition Therapy Guidelines

The CDA NTG outline the standards that individuals with diabetes should follow in order to have an adequate diet and take advantage of the benefits previously described (CDA, 2008). According to the CDA, nutrition therapy should be individualized to suit the person´s needs, culture and preferences. People with diabetes are encouraged to meet their nutritional requirements by following a healthy diet such as EWCFG (Health Canada, 2007). By choosing a variety of foods and appropriate servings from the 4 food groups (vegetables & fruits, grain products, milk & alternatives, meat & alternatives), individuals can ensure they are meeting their nutritional needs (CDA, 2008; Health Canada, 2007). Table 2.2 includes a summary of the food guide servings recommended for adults with and without diabetes (Health Canada, 2007).

Table 2.2. Eating Well with Canada´s Food Guide: recommended number of food guide servings

	19-50 years		51 + years	
	Female	Male	Female	Male
Vegetables & Fruits	7-8	8-10	7	7
Grain Products	6-7	8	6	7
Milk & Alternatives	2	2	3	3
Meat & Alternatives	2	3	2	3
Oils and fats	*2 to 3 tablespoons of unsaturated fat- for cooking, salad dressings or spreads.*			

Adapted from Health Canada, 2007.

The macronutrient composition of the diabetic diet falls within the acceptable distribution ranges for the general population (Health Canada, 2010). Carbohydrates represent 45-60% of total daily energy, fat <35% and protein 15-20%. Specific recommendations regarding carbohydrate intake include spacing carbohydrates evenly throughout the day and including low-glycemic index (GI) foods, whole grains and high-fiber carbohydrates. Due to its benefits on glycemic control and cardiovascular disease risk factors, individuals with diabetes need to consume more fiber than the rest of the population (25-50 g/day). Furthermore, added sucrose should be limited to <10% of total daily energy to prevent negative effects on blood glucose and lipids. In regards to fat intake, monounsaturated fatty acids (MUFA) should be favored in the diet while the intake of saturated fatty acids (SFA) and polyunsaturated fatty acids (PUFA) should be limited to <7% and <10% of total daily energy, respectively. Meal plans should include sources of omega-3 fatty acids (i.e. fatty fish) and plant oils (CDA, 2008). As excess body weight, dyslipidemia and high blood pressure are very common among people with T2D and contribute to cardiovascular morbidity and mortality, reductions in caloric intake, as well as trans fatty acids, cholesterol and sodium consumption are desirable (ADA, 2008; CDA, 2008). Table 2.3 presents a summary of the CDA NTG.

Table 2.3. Canadian Diabetes Association: nutrition therapy guidelines

Nutrient	Recommendations
Total Carbohydrate	45-60% total daily energy
Fiber	25-50 grams/day
Sucrose	<10% total daily energy
Fructose	<60 grams/day
Sugar Alcohols	Up to 10 grams/day
Sweeteners	Those approved for use in diabetes by Health Canada in limited amounts
Protein	15-20% total daily energy
Total Fat	<35% total daily energy
Saturated Fat	<7% total daily energy
Trans Fat	Minimize
Polyunsaturated Fat	<10% total daily energy
Monounsaturated Fat	Choose most often
Cholesterol	Limit in the presence of dyslipidemia
Alcohol	<1-2 drinks/day
[1]Sodium	<1500 mg/day

Adapted from CDA, 2008; [1]Health Canada, 2010.

2.8. Dietary adherence in diabetes

Although the benefits of nutrition therapy are well known, following the dietary recommendations is considered the most challenging aspect of diabetes management (ADA, 2012b; Whittemore, et al., 2002). Integrating a new diet behavior into a preexisting lifestyle has been described as a complex process whereby the person with diabetes needs to translate the advice received into something meaningful, workable and applicable in his own life (Whittemore, et al., 2002).

It is well known that people with T2D are more successful in taking medications, performing self-monitoring of blood glucose and keeping their medical appointments than following their diet (Peyrot, et al., 2005; Ruggiero, et al., 1997; Vijan, et al., 2005). Travis (1997) studied adherence to the meal plan in a sample of 75 subjects with T2D. Although the importance of diet in diabetes management had been explained to virtually all the participants and most of them (75%) reported understanding how to follow their meal plan, only 27% followed it every day and 39% followed it from 4-6 days/week (Travis, 1997). Orzech et al. (2012) reported that the proportion of people who often or always adhered to the diet plan differed among ethnicities and was as low as 33% for white, 57% for black and Latino, and 91% for Vietnamese (Orzech, et al., 2012). Similar findings were reported in other studies in which complete adherence to the recommended diet went from 22% to 42% (Broadbent, Donkin, & Stroh, 2011; Jorgensen, et al., 2002).

Several studies have been conducted to determine the level adherence to the nutrition guidelines of the American Diabetes Association (ADA), CDA and the European Association for the study of Diabetes (EASD) among people with T2D. Overall, ≤60% of the participants in these studies were able to meet the recommendations for total fat, saturated fat and sodium (Jarvandi, et al., 2011; Muñoz-Pareja, et al., 2012; Rivellese, et al., 2008; Thanopoulou, et al., 2004; Vitolins, et al., 2009). The level of adherence was different between countries; for example, for fat and saturated fat the lowest level was seen in the US (<15%) while the highest was seen in Italy (60%) (Rivellese, et al., 2008; Vitolins, et al., 2009). For sodium, the lowest adherence was reported in the US (8%) and the highest in Canada (50%) and Spain (55%) (Jarvandi, et al., 2011; Muñoz-Pareja, et al., 2012; Vitolins, et al., 2009). The percentage of people meeting the recommendations for fiber was even lower ranging from 3-25% (Jarvandi et al., 2011; Muñoz-Pareja, et al., 2012; Rivellese, et al., 2008; Thanopoulou, et al., 2004; Vitolins, et al., 2009). For protein, MUFA and PUFA, the majority of participants were able to meet the recommendations, with percentages ranging from 62-70%, >80% and >96%, respectively (Muñoz-Pareja, et al., 2012; Rivellese, et al., 2008). Adherence to the recommendations of carbohydrates was as low as 32% in 6 Mediterranean countries and as high as 70% in Italy (Rivellese, et al., 2008; Thanopoulou, et al., 2004). The range for adherence to cholesterol intake was quite wide as well, and went from 48% in Spain to 85% in Italy (Muñoz-Pareja, et al., 2012; Rivellese, et al., 2008). Thanopoulou et al. (2004) reported that only 12% of the participants were able to meet the recommendations for macronutrients (i.e. protein, carbohydrates and fat) and fiber. However, Rivellese et al. (2008) reported lower levels of adherence (3%) when they considered the percentage of participants meeting the recommendations for macronutrients, saturated fat, MUFA, PUFA and cholesterol.

Rivellese et al. (2008) evaluated adherence to the nutritional recommendations of EASD in a sample of 540 Italian patients with T2D. Using a 3-day weighed food record they showed that caloric intake was higher than recommended (+250 kcal/day), while fiber intake was lower (12.5 g/1000 kcal). Macronutrients were within the recommended range except for saturated fat that was higher (10±3%) (Rivellese, et al., 2008).

Muñoz-Pareja et al. (2012) conducted a cross-sectional study to evaluate adherence to the EASD and ADA nutritional recommendations in subjects with T2D (n=609). Intakes of total fat (36.7%), saturated fat (11.2%), cholesterol (322 mg/day), total sugars (16.9%) and sodium (3100 mg/day) were higher than recommended while intakes of carbohydrate (41.1%) and fiber (23.8 g/day) were lower (Muñoz-Pareja, et al., 2012).

The above mentioned studies show that lack of adherence to the nutritional recommendations is a problem even in countries such as Italy and Spain that follow a Mediterranean dietary pattern. Therefore, we can expect to see similar tendencies in western countries.

Nelson et al. (2002) used data from the Third National Health and Nutrition Examination Survey (NHANES III) to evaluate diet and exercise patterns in diabetic subjects (n=1,480). They reported that more than 60% of the sample followed a diet that included less than 5 servings of fruits and vegetables per day, >30% of daily calories from fat and >10% from saturated fat (Nelson, Reiber, & Boyko, 2002).

Baseline evaluation of the look AHEAD trial confirms that people with diabetes in the US do not consume healthy diets. Food frequency questionnaires (FFQ) from 2,757 participants were analyzed. Most of the sample (82%) ate the recommended servings of meat; however only 7% of the participants had the recommended servings of grains and ≤40% ate the recommended servings for fruits, vegetables and dairy. What is of concern is the small proportion of participants (28%) able to meet the recommendation for fats, oils and sweets, which should be limited in the diet. As participants in this study were not making the best food choices, the intake of some nutrients was also inadequate. Sodium intake was high (2474 mg/day), whereas fiber intake was low (≤18 g/day). The contribution of carbohydrates to total daily energy was lower than recommended (44%), while the contribution of fat (40%) and saturated fat (13%) were higher (Vitolins, et al., 2009).

Data from the 2004 Canadian Community Health Survey (CCHS) - Nutrition suggest that Canadian adults (diabetic and non-diabetic) are not making the best food choices. In 2004, the ´other foods´ category provided 22% of daily calories and contributed to almost 30% of fat intake. This group includes foods high in fat, sugar and salt that should be limited in the diet (i.e. soft drinks, salad dressings, syrups and sugars, among others). Despite high consumption of ´other foods´, the overall contribution of fat to the diet was within the recommended range except for 20% of adults who ate more than 35% of calories from fat. On the other hand, about half of adults ate less than 5 servings of fruits and vegetables per day

(Garriguet, 2007a). It is expected that diabetic adults modify their diet and have healthier diets than the general adult population; however, the evidence supporting this is not convincing (Chen, Cheskin, Shi, & Wang, 2011; Muñoz-Pareja, et al., 2012). Bearing this in mind, data from the CCHS may be suitable for Canadians with diabetes.

Recent evidence supports the notion that Canadians with diabetes are not following the recommendations for healthy eating. The purpose of this study conducted in Montreal was to identify gaps in adherence to the nutritional guidelines in obese (n=95) and non-obese (n=105) participants with T2D. Data were obtained using FFQ. The diets were analyzed using the Canadian Nutrient File (CNF) and EWCFG. Overall, the sample had inadequate consumption of the food guide servings recommended in EWCFG with no differences between obese and non-obese subjects. Intake of fruits and vegetables (5 servings/day), grains (5.5 servings/day), and milk and alternatives (1.7 servings/day) were low, while intake of meat and alternatives was high (3.5 servings/day) (Jarvandi, et al., 2011). Similar intakes of food guide servings were reported in the CCHS (Garriguet, 2007b). Participants in this study had inadequate nutrient intakes. For example, intake of fiber was low (17.3 g/day), while intake of sodium was high (2,500 mg/day). Likewise, fat and saturated fat contributed to 38% and 11.4% of the daily calories, respectively, which is more than recommended (Jarvandi, et al., 2011).

Our research group has reported similar findings. Using information from 3-day food records, Devi Durai Raj (2012) reported that the diet of 48 Albertans with T2D was high in SFA (10% total daily energy) and sodium (2866 mg/day). Approximately 30% of the participants were able to meet the recommendation for sodium, less than 20% for SFA and less than 10% of the participants met the recommendations for calories, MUFA and sugar. When overall adherence to the CDA recommendations was assessed (energy, total fat, SFA, MUFA, PUFA, carbohydrates, sugars, protein, cholesterol, fiber and sodium), most of the participants (73%) were able to meet 4 to 6 recommendations, however, no one was able to meet 9, 10 or the 11 recommendations (Devi Durai Raj, 2012).

Asaad (2012) reported that senior citizens with T2D (n=16) were not meeting the food guide servings recommended in EWCFG. Servings of grains, fruits and vegetables, milk and alternatives and meat and alternatives were low: 4.1, 3.4, 1.4 and 2.1 servings/day, respectively. Compared with the CDA NTG, intake of fiber was low (16.2 g), while the calories from SFA and sodium were higher than recommended with 9.6% of the total daily energy and 1984 mg, respectively. Using information from the food guide servings and the intake of selected nutrients, the Healthy Eating Index (HEI) was calculated as an indicator of overall diet quality. Using this indicator, 87.5% of the participants were classified as "diet needs improvement" (Asaad, 2012).

There is a gap between the nutritional recommendations for diabetes and what people really do on a daily basis. Patients with diabetes are not making optimal food choices as is suggested by the low inclusion of grains, milk, and fruits and vegetables in the diet, and the presumably high inclusion of foods that should be limited (oils, fats and sweets). As a consequence, the quality of the diet is suboptimal: high in total fat, saturated fat and sodium, as well as low in carbohydrates and fiber. Moreover, only few people are able to achieve the overall nutrient recommendations. Therefore, understanding the difficulties that people face to follow the recommended diet and designing interventions to decrease these barriers is fundamental.

2.9. Factors affecting dietary adherence

Although patients understand that maintaining a healthy diet is important for their overall health, most of them fail to make healthy food choices and meet the nutrition recommendations. Adopting a healthy diet usually involves changing a long-standing behavior. The ability to make this change is influenced by people´s knowledge and skills, lifestyle, personal preferences, cultural factors, and environmental factors such as availability and cost of the foods. Also the complexity of the changes required in the diet influence the ability to adopt them (Sherman, et al., 2000). In the case of diabetes there are multiple recommendations that need to be integrated into the diet plan to completely benefit from it (CDA, 2008).

There are several obstacles for dietary adherence that people face on a daily basis. Identifying these obstacles among people with T1D (n=12) and T2D (n=14) was the main objective of the study conducted by Schlundt et al. (1994). Negative emotions (i.e. stress), resisting temptation (i.e. cravings), eating out, social events, offers of inappropriate foods from others and planning meals were some of the challenges experienced on a daily basis for this group (Schlundt, et al., 1994). Other obstacles suggested in the literature are portion control and the lack of variety in the diet (Rustveld, et al., 2009; Vijan, et al., 2005; Wycherley, Mohr, Noakes, Clifton, & Brinkworth, 2012).

The accessibility and availability of foods influence how the dietary advice is put into practice (Orzech, et al., 2012). The cost of complying with the diet has been identified as an important barrier (Jorgensen, et al., 2002; Kearney & McElhone, 1999; Orzech, et al., 2012; Vijan, et al., 2005). In a cross-sectional study of people with low income and T2D diabetes (n=98), most of the sample (70%) rated taste and cost of foods as very important factors when choosing what to eat. These factors were considered more important than the macronutrient composition of the foods (Marcy, et al., 2011). Likewise, Galasso et al. (2005) identified the cost of foods as a major barrier for adherence to medical nutrition therapy in black women with T2D. This suggests the need for meal plans that include food options that are accessible and available for people with T2D.

Lack of knowledge and understanding of the meal plan, as well as lack of skills to translate the recommendations into practice are frequently cited as barriers for healthy eating among people with T2D (Galasso, et al., 2005; Marcy, et al., 2011; Nagelkerk, et al., 2006; Vincent, et al., 2006). Vijan et al. (2005) conducted focus groups (n=6) to explore participant´s barriers to follow the recommended self-care. In this study, participants expressed their lack of understanding of elements of the diet such as portion sizes and how to put together different recommendations (Vijan, et al., 2005). Similar results were found in a study conducted to explore beliefs and attitudes towards the diet in Hispanic men with T2D (n=34). Through focus group interviews participants expressed the challenge of translating the nutrition recommendations of the ADA into practice. They manifested difficulty understanding and applying specific recommendations such as portion sizes to their meals. Also, establishing structure on the diet by eating several meals throughout the day and eating at specific times were identified as barriers (Rustveld, et al., 2009). Therefore, simplifying the overall nutritional recommendations may be a good strategy to help people adopt healthier diets.

It has been reported that people with diabetes experience feelings of frustration and deprivation while following their diet and this has a negative impact on adherence to the meal plan. Feelings of deprivation are related to the perception that they have to give up their preferred foods in order to comply with the diet (Marcy, et al., 2011; Rustveld, et al., 2009; Vijan, et al., 2005; Vincent, et al., 2006). Dietary preferences are, in many cases, culturally rooted yet the nutrition recommendations are not culturally specific. Vincent et al. (2006) conducted a study to identify factors that facilitate or hinder diabetes self-management. Six focus groups were conducted with 20 diabetic patients (Hispanic) and 20 caregivers. Participants expressed the challenge of incorporating the generic advice of the ADA into their traditional diet. For example, they struggled to comply with the recommendation for carbohydrate intake because their traditional diet is based on carbohydrates. Furthermore, they expressed their desire of having nutritional information tailored to their culture and their willingness to try low-fat adaptations of their traditional foods (Vincent, et al., 2006). Considering the personal and cultural acceptability of the foods included in the meal plan are necessary to improve dietary adherence.

In the same way that lack of knowledge limits people´s abilities to follow the diet, skills to select foods, plan meals, and cook influence dietary patterns (Galasso, et al., 2005; Rustveld, et al., 2009). Also, the time available for this plays an important role. Time constraints including a busy lifestyle and work hours are factors that affect adherence to the diet (Brown, et al., 1998; Galasso, et al., 2005; Kearney & McElhone, 1999; Schlundt, et al., 1994). In the study of Maxwell (2011), working hours were negatively correlated with diet quality among middle- and high-income Albertans with T2D (Maxwell, 2011). Likewise, younger patients perceive their schedule as a barrier to follow the diet, and are more likely to have a high intake of fat and saturated fat, and low intake of fruits and vegetables (Nelson, et al., 2002; Travis, 1997). Strategies that eliminate the tasks and time associated with planning and preparing foods have shown to improve dietary compliance (Metz, et al., 1997).

Considering some of the above mentioned factors when designing interventions for diabetes management may reduce the challenge of integrating new dietary behaviors into patients' lifestyle and facilitate adherence to the nutrition recommendations.

2.10. Dietary intervention in diabetes management

Compliance with dietary recommendations is fundamental for achieving good glycemic control and cardiovascular benefits (Metz, et al., 1997). A variety of interventions can be used to assist people with diabetes to follow a diet consistent with the nutritional standards. Intensive lifestyle modification programs with a dietary component, exchange lists, simplified meal plans, healthy food choices, food provision, meal replacements and menu plans are some of the approaches to nutrition therapy commonly utilized (Franz, et al., 2010).

As was previously described, intensive lifestyle modification programs are effective means for changing specific dietary behaviors such as energy, fat and saturated fat intake, as well as for achieving weight loss, glycemic control and improvements on CVD risk factors (The Look AHEAD Research Group, 2010).

On the other hand, programs that consider key factors for dietary adherence such as the cultural competence of the nutritional recommendations are an effective way to increase knowledge, enhance decision making skills and modify dietary behaviors (Galasso, et al., 2005; Song, et al., 2010). In the study of Galasso et al. (2005), 86 women with T2D were enrolled in a culturally competent program for diabetes self-management education. Overall, the program was directed towards improving their skills to make healthy food choices on a daily basis and towards achieving modest dietary modifications. It followed a non-prescriptive approach that emphasized healthy food choices (i.e. including more fruits, vegetables and whole grains) and the adoption of low-fat preparation techniques for their traditional foods, which were usually high in fat. As a result of the intervention, participants adopted low-fat preparation techniques including baking, broiling, steaming, stewing, and roasting. They improved their food choices, for example, they changed the use of high-fat dairy products for low-fat, and refined grains for whole grains. Also, they bought fewer sweets and more vegetables, decreased serving sizes of food and read more food labels (Galasso, et al., 2005). Although, results of the diet composition were not presented, it is likely that by making better food choices they had, to some extent, improved the quality of the diet.

A hands-on approach to nutrition therapy was taken by the program entitled Kitchen Creations: a cooking school for people with diabetes and their families. This program included 4 cooking sessions (3 hours each) with a curriculum focused on food groups, meal planning, food labels, portion control, carbohydrate-containing foods and healthy cooking techniques. The program aimed to help individuals adopt healthier diets by enhancing food preparation skills, teaching adequate serving sizes and types of foods, providing accurate nutrition information and emphasizing that a diabetic diet can be acceptable and delicious. Three-day food records were mailed to attendees before and after the program. Data of 117 participants with T2D were analyzed to determine the effectiveness of the program on changing dietary intake. Improvements in the overall diet composition were observed after program completion. The intakes of calories, fat, saturated fat and carbohydrate decreased by -142 kcal/day ($p<0.001$), -8 g/day or -2% of total daily energy ($p<0.01$), -3 g/day ($p<0.001$) and -13 g/day ($p=0.01$), respectively. On the other hand, the percentage of calories from protein increased by +1% ($p=0.02$). Intakes of important nutrients such as cholesterol and sodium decreased by -26 mg/day (p=0.008) and -217 mg/day (p=0.002), respectively (Archuleta, et al., 2012).

Some studies have demonstrated that by following the traditional exchange-based meal plan (EBMP) patients with diabetes can improve their nutritional intake. However, alternative strategies have shown to be equally, or even more effective, in improving nutrient intake and metabolic outcomes with the advantage of being more simple to implement (Ash, et al., 2003; Metz, et al., 2000; McCarron, et al., 1997; Pi-Sunyer, et al., 1999). For example, one study compared the effectiveness of an EBMP with a simple meal plan that emphasized healthy food choices in African Americans with T2D. The EBMP (n=359) was individualized according to each individual´s energy requirement and had an emphasis on weight loss, if this was required. Patients in this group were instructed on portions sizes and food exchanges. The healthy food choices (n=289) plan didn't emphasize restriction of foods or weight loss. Participants were instructed to limit sweets, fats and saturated fats and to use the food guide pyramid as an aid tool. At 6 months, both groups decreased their intake of fat and sugar ($p<0.01$). Glycemic control improved in both groups as demonstrated by a decrease in HbA1c (-1.9%, $p<0.0001$) and fasting plasma glucose (EBMP -28.8 mg/dL and healthy food choices -16.2 mg/dL, $p<0.0001$). In both groups, 53% of the participants were able to lose some weight. There were no changes in total cholesterol or LDL-cholesterol (low-density lipoprotein cholesterol), however, triglyceride levels decreased by -22.2 mg/dL in the EBMP and by -48.0 mg/dL in the healthy food choices group ($p<0.001$ for both). Furthermore, HDL-cholesterol (high-density lipoprotein cholesterol) increased by +2.3 mg/dL in both groups ($p<0.005$) (Ziemer, et al., 2003).

Although following an EBMP confers some benefits, self-selecting a diet with adequate quantities of total fat, saturated fat, cholesterol, fiber and sodium is a challenging task (Metz, et al., 1997). However, intakes of these nutrients and adherence to the overall nutritional recommendations can be improved by using alternatives that simplify the recommendations (Metz, et al., 1997; Metz, et al., 2000). This approach was taken by Pi-Sunyer et al. (1999) who designed a comprehensive prepared meal plan that incorporated the overall nutritional recommendations of the ADA, American Heart Association, National Cholesterol Education Program and the Food and Nutrition Board of the National Academy of Sciences into a simple program. In a 10-week RCT, they compared the effectiveness of the comprehensive prepared meal plan (n=100) and a traditional EBMP (n=102) in improving glycemic control and cardiovascular disease risk factors in individuals with T2D. The comprehensive prepared meal plan consisted of prepackaged breakfast, lunch, dinner and snack options that were provided for free to the participants in this group. They had to consume one breakfast, lunch and dinner as well as one serving of fruit, vegetable and low-fat dairy product. Subjects in the EBMP were prescribed a fixed number of servings of breads and starches, fruits, vegetables, low-fat dairy products and lean meats; they had to select their food options from an exchange list. Caloric intake and cholesterol intake decreased significantly in both groups, while the energy from carbohydrates and protein increased ($p<0.001$ for all). The percentage of energy from fat and saturated fat decreased ($p<0.01$) in the comprehensive prepared meal plan group to levels consistent with the nutritional recommendations (<30% and <7% total daily energy, respectively). In this group, fiber intake increased to 34 g/day and sodium intake decreased to 2500 mg/day ($p<0.001$ for both). The improvements observed in the comprehensive prepared meal plan group were greater than those in the EBMP ($p<0.05$). In both groups, significant weight loss was observed, as well as a significant decrease on fasting plasma glucose, HbA1c, total and LDL-cholesterol ($p<0.05$) (Pi-Sunyer, et al., 1999).

Simplifying the overall nutritional recommendations into one single approach is effective for improving dietary adherence and metabolic outcomes (Pi-Sunyer, et al., 1999). Moreover, food provision, as in the comprehensive prepared meal plan, eliminates the tasks and time associated with meal selection, meal planning and preparation. Also, increasing structure in the meals and portion control (i.e. what and how much to eat) seem to be some of the mechanisms underlying the greater benefits of this approach (Metz, et al., 1997; Wing & Jeffrey, 2001).

2.10.1. Menu planning as a strategy to improve diet quality

Providing individuals with the foods they should eat, in appropriate portion sizes is a good strategy to improve dietary intake, metabolic outcomes and to promote weight loss (Pi-Sunyer, et al., 1999; Wing & Jeffrey, 2001). As noted above, this approach simplifies the dietary regimen, increases the structure and portion control in the diet and helps to modify food cues by changing the food environment (Wing & Jeffrey, 2001; Metz, et al., 1997). However, simpler and less costly alternatives such as providing menu plans with grocery lists are as effective and acceptable as providing foods (Wing, et al., 1996; Cunningham, et al., 2006).

Wing et al. (1996) conducted a 6-month RCT to examine the mechanisms associated with the effectiveness of food provision. Overweight women (n=163) were randomly assigned to standard behavioral treatment (SBT); SBT plus structured menu plans and weekly grocery lists (menu plan); SBT plus menu plans and food provided with copayment (buy food) or SBT plus menu plans plus food provided for free (free food). Overall, this study demonstrated that providing structured menu plans and grocery lists was sufficient to achieve positive outcomes. In other words, food provision did not have further impact to that conferred by the menu plan. Therefore, I will only describe the outcomes achieved for the participants in the menu plan group. Dietary behaviors were significantly improved in the menu plan condition compared with SBT ($p<0.01$ for all). Participants decreased their perceived barriers to the diet, improved the quality of foods stored at home (i.e. more fruits and vegetables, low fat meat, breads and cereals), and decreased their difficulty estimating portion sizes, finding time to plan meals and controlling eating when not hungry. Also, this strategy led to more regular eating patterns: increased frequency of eating breakfast and lunch, and decreased frequency of snacking. Participants in the menu plan condition had a lower energy intake compared with the SBT group and achieved greater weight loss at 6 months (12 kg vs 8 kg, $p<0.003$) and at 1 year of follow up (6.9 kg vs 3.3 kg, $p<0.02$) (Wing, et al., 1996). In summary, this strategy reduced some barriers associated with non-adherence to the diet (i.e. planning meals and estimating portions), conferred structure in the diet (i.e. types of foods, quantities and frequency of meals), and changed the quality of foods stored at home, which may, consequently, impact food intake.

Cunningham et al. (2006) evaluated the acceptability and usefulness of a 2-week menu plan with grocery lists in people with T2D (n=10). The menu plan was designed to simplify decision making regarding the types and amounts of foods consumed, to provide support in the acquisition of a new dietary pattern, to help develop self-efficacy and decision making skills, as well as to increase awareness of purchase patterns by using grocery lists. Each subject was assigned an energy allowance based on his weight. Then, menus and grocery lists were tailored to each individual situation (i.e. individual preferences, foods available at home). Alternatives to the menus and recipes were provided if requested. Semi-structured interviews and food diaries were used to obtain information. Using the menus helped participants to estimate portion sizes, monitor their food intake and increase awareness of the food-blood glucose relationship. Although the length of the study was only 2 weeks, all the participants were able to lose some weight (range 1-3.5 kg) (Cunningham, et al., 2006).

Besides being an acceptable and effective strategy to reduce barriers for dietary adherence, the use of menu plans and recipes as part of the dietary intervention has shown to improve nutrient intakes. The LOADD (Lifestyle Over and Above Drugs in Diabetes) study was a 6-month RCT that investigated the effectiveness of an intensive dietary intervention on glycemic control and cardiovascular risk factors in individuals with T2D. Intensive dietary intervention (n=52) included a nutrition prescription with 10-20% of total energy from protein, <30% from fat, <10% from saturated fat and <10% from polyunsaturated fat, 45-60% from carbohydrate and 40 g/day of fiber. A deficit of calories was considered for individuals who were overweight or obese. These dietary allowances were translated into foods, meals and recipes to emphasize food choices and quantities. Usual care participants (n=52) continued management with their health care provider. Participants in the intervention group showed improvements in the overall diet composition while control participants did not. In the intervention group caloric intake, total fat and SFA decreased by -278 kcal/day, -2.2% and -1.5% of total daily energy, respectively. On the other hand, the intake of protein increased by +2.4% of total daily energy. Compared with usual care, intensive dietary intervention participants improved their food choices as demonstrated by a higher proportion of total energy from low fat dairy products (8% vs 6% total daily energy) and nuts (5% vs 1% total daily energy), and a lower proportion of calories from high fat dairy products (3% vs 7% total daily energy). Some significant differences in anthropometric and metabolic outcomes were observed between the groups. Glycated hemoglobin at 6 months was significantly lower in the intervention group compared with control (-0.4%, $p<0.01$). In parallel with this, there were significant differences between intervention and usual care participants for weight (-1.3 kg, $p<0.05$), body mass index (BMI) (-0.5 kg/m2, $p<0.05$) and waist circumference (-1.6 cm, $p<0.05$) (Coppell, et al., 2010).

2.11. Summary

Nutrition therapy is the cornerstone of T2D. The CDA NTG outline the standards that individuals should follow in order to have an adequate diet. However, people with diabetes face difficulties following the nutritional recommendations on a daily basis and have suboptimal diet quality. Strategies that simplify the overall recommendations and help people put them into practice may improve diet quality, glycemic control and health parameters. Menu planning is such a strategy. Therefore, our goal was to test the effectiveness of implementing a four-week menu plan combined with individual counseling in improving diet quality and health parameters in individuals with T2D. The menu plan incorporated the recommendations of the CDA NTG and met the serving recommendations from EWCFG, using foods that are adequate for diabetes management, as well as acceptable, accessible and available to Albertans.

Chapter 3: Methodology

3.1. Introduction

The following section presents the methods used to address the objectives of the research. It starts by introducing how the menu plan that we are testing in this program was developed, followed by the study design and characteristics of the study population. Later, the data collection process, questionnaires, assessments, and approaches used to evaluate diet quality are described, concluding with the data analysis procedures.

3.2. Development of the menu plan

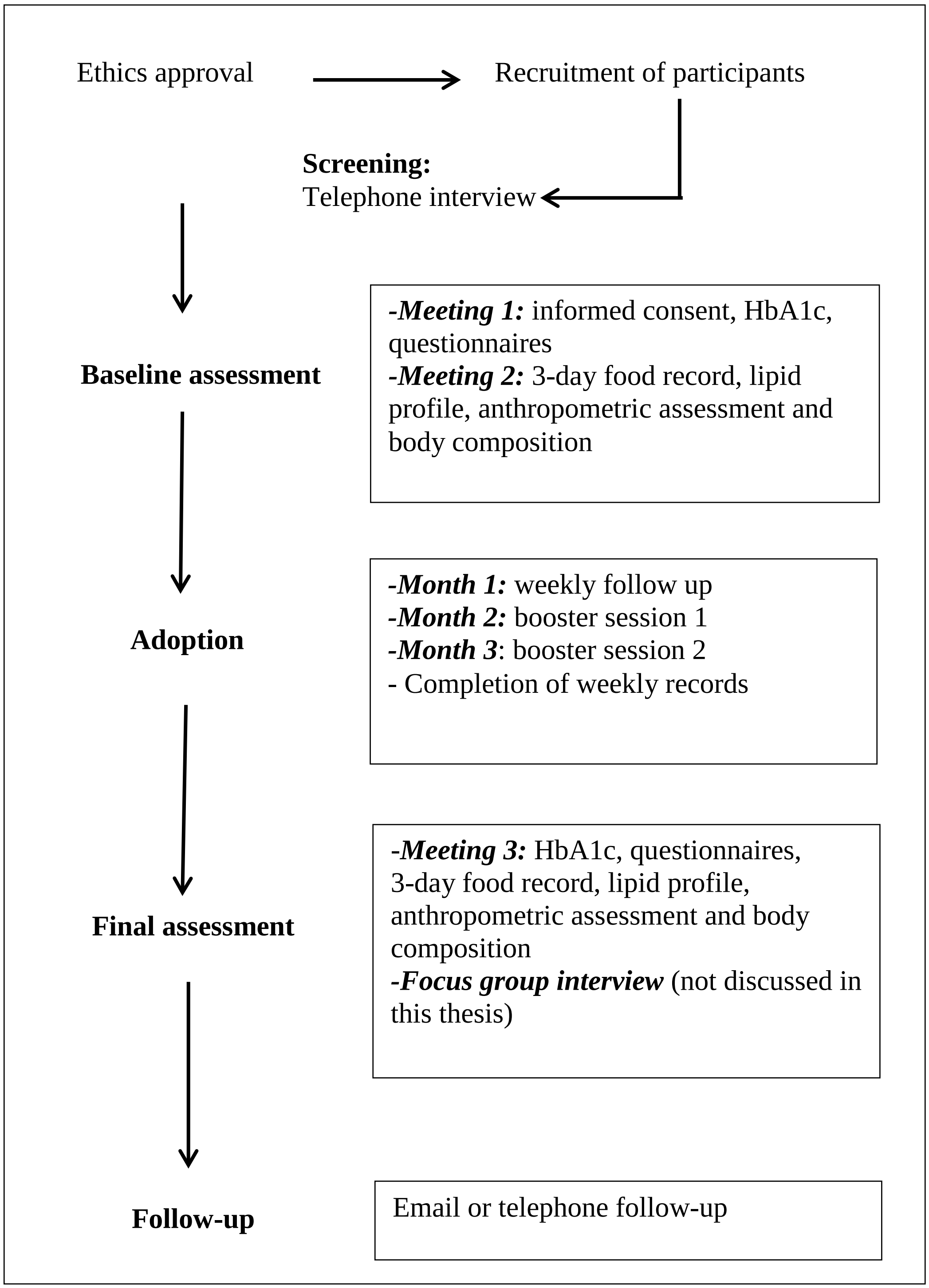
In this study we tested the effectiveness of a 4-week menu plan titled “Eating healthy with T2D: a smart menu plan for Albertans”. This menu plan was previously developed for our research group and is part of the nutrition component of the “Physical Activity and Nutrition for Diabetes in Alberta” (PANDA) project.

The menu plan was designed with the objective of helping Albertans with T2D to improve adherence to the recommended diet by reducing barriers such as lack of knowledge, flexibility and lack of cultural acceptability of the diet. This menu plan features 4 weeks of menus that translate the nutrient recommendations of the CDA NTG (CDA, 2008) and meet the food guide servings outlined in EWCFG (Health Canada, 2007). The 4-A framework, adapted from the food security literature (Riely, et al., 1999), was used to develop the menu plan. The 4-A framework stipulates that foods included in the menu plan should be adequate for diabetes management as well as accessible, available and acceptable for Albertans. *Adequacy* is defined as “food satisfying dietary needs, taking into account the individual’s age, living conditions, health, occupation, sex, etc.” (United Nations Human Rights, 2008, p. 2). For people with T2D, in order to be adequate, the diet should meet guidelines for health and facilitate dietary improvements that lead to better primary (blood glucose control) and secondary outcomes (complications, e.g. kidney failure). *Accessible* summarizes the factors associated with financial (i.e. affordability of foods) and physical accessibility (i.e. distance to the market and available transportation) of foods. Foods must be *Acceptable* from multiple perspectives: hedonic qualities, culture, traditions and consumption habits. Finally, foods must also be generally *Available* to the consumer population of interest (i.e. locally grown or regularly imported) (United Nations Human Rights, 2008). The menus provide an average of 2055 kcal/day. Meals incorporated three to four food groups while snacks included at least two. Furthermore, consideration was given to important recommendations such as choosing low-GI foods and spacing carbohydrates throughout the day, and emphasis was placed on incorporating foods produced in Alberta. Besides being a practical tool that simplifies the NTG, it is simple to understand, and includes resources that facilitate adherence to the menus such as recipes, cooking tips, weekly grocery lists, and a list of Alberta-produced foods and places to obtain them. Another important feature of the menu plan is that it does not include "specialty" foods for people with diabetes such as artificial sweeteners; therefore, it is also appropriate for people without diabetes. A one-day sample menu is included in appendix A.

3.3. Study design

To address the objectives of the research, we conducted a 12-week pilot study with a pretest-posttest single arm design. Pilot studies are important to assess whether a new intervention (in this case dietary intervention) is feasible. Furthermore, the results obtained from pilot studies are used to guide the design of larger studies; therefore, they represent an important step before large-scale implementation of a program (Griffiths, 2009). The study was divided into 3 different phases and follow-up (Figure 3.1). Participants followed the menu plan for 12 weeks, completed questionnaires, 3-day food records and underwent repeated assessments at baseline and post-intervention. The details of study procedures and assessments will be described in the following sections. The study was approved by the University of Alberta Research Ethics Board (approval number: Pro00022167).

Figure 3.1. Study flow chart



3.4. Study population

We aimed to recruit 20 individuals with T2D living in the Edmonton area. Purposive sampling was used to determine the best subjects for this research (Griffiths, 2009). Twenty-three participants consented to participate, and 15 (65%) completed the 12-week program. Personal reasons and time constraints were the main reasons for dropping out of the study. Participants were given a 50-dollar gift card for a grocery store of their choice for taking part in the study.

3.4.1. Inclusion criteria

- Participants had to self-report being diagnosed with T2D.
- To minimize recruitment of people with T1D, we included volunteers at least 35 years of age or older.
- Participants could have any treatment for diabetes (diet and exercise, hypoglycemic agents or insulin).

3.4.2. Exclusion criteria

- We excluded participants with severe gastrointestinal or renal problems that would preclude them eating according to a diet plan outlined in the Nutrition Therapy Guidelines for Diabetes.
- Also, we excluded people unable to read and write English because the menu plan and questionnaires were written in English.
- We excluded participants unable to provide written informed consent.

3.4.3. Recruitment

Participants were recruited from January through June 2012. Posters containing a brief description of the study, inclusion criteria and contact information of the study coordinator were advertised at strategic locations and websites (appendix B). Posters were placed on bulletin boards at the University of Alberta hospital, Alberta Diabetes Institute and University of Alberta; however, no participants were recruited from these locations. Later, consent was obtained to put up posters at 2 branches of a diagnostic laboratory services clinic near the University. From these places we recruited 6 participants. We also obtained consent from a supermarket to put up some posters at the pharmacy area and to distribute the information among their diabetes educators. From this strategy we recruited 1 participant. We advertised the study in the Alberta Diabetes Institute website and were able to recruit 8 additional participants. At the beginning of March, the study coordinator obtained permission to give information about the study at the “taking charge of your diabetes” class offered by Alberta Health Services as part of the regional diabetes program. Five participants were recruited from this class. The rest of the participants (3) were recruited by “word of mouth” and other sources. Posters were also sent to different hospitals in the Edmonton area but no participants were recruited from these places.

Interested persons contacted the study coordinator by email or by phone. After this initial contact, we conducted telephone interviews with prospective participants to screen for eligibility and provide an overview of the study (purpose, procedures and benefits). An initial meeting was scheduled if respondents met the inclusion criteria and were interested in participating. At this initial meeting participants were explained the purpose, procedures and benefits of participating in the study. They received the information letter of the study, had time to read through it and ask questions. After this, participants provided written informed consent to participate in the study and completed part of the baseline assessment. Examples of the information letter and consent form are included in appendix C.

3.5. Data collection

Data were collected February through October 2012. The research was conducted at the Human Nutrition Research Unit at the University of Alberta. Figure 3.1 depicts the 3 different phases into which this 12-week pilot study was divided: baseline assessment, adoption and final assessment. Additionally, a follow-up was conducted 2 months after study completion to document if participants continued to use the menu plan.

3.5.1. Baseline assessment

The initial assessment was divided into 2 different meetings. In the first meeting, once written consent was obtained, HbA1c was measured using a finger prick method. Questionnaires were applied to gather information about participants´ demographic characteristics, diabetes treatment, self-care activities, physical activity and perceived adherence to the diet. Participants were instructed to complete a 3-day food record and bring it to the next meeting, held within one week. The questionnaires and assessments are described in the following section. The self-rated health, self-efficacy, accessibility, acceptability and availability of foods questionnaires were also applied but will not be discussed in this thesis.

At the second meeting the 3-day food records were reviewed, portions sizes were clarified and participants were asked for further description of the food items if necessary. Fasting blood samples were collected to measure lipid profile. Height, weight, waist circumference and body composition were also measured.

3.5.2. Adoption

Participants were asked to follow the menu plan for 12 weeks and keep weekly records of its use by filling out a booklet designed for this study. In their weekly records (one for each month), participants set a goal on how many days they would follow the menu plan and were encouraged to monitor the achievement of their goals. They were also asked to fill out a set of questions every week (included in the weekly records).

During the first month of this phase, the study coordinator held one-on-one weekly meetings with the participants. The duration of the meetings was approximately 40 to 60 minutes with some exceptions in which the meetings lasted for up to 120 minutes. The general purpose of these meetings was to provide nutrition counseling and education focused on the menu plan. In all the sessions, difficulties or obstacles faced by the participants and possible solutions or strategies to overcome them were discussed, and goal setting and goal achievement were reviewed. Furthermore, behaviors and/or activities that helped or affected the use of the menu plan were identified. Additionally, during the first and second follow-up sessions, the food groups and servings from EWCFG were reviewed to help participants make appropriate substitutions of foods in the menus and to increase the flexibility of the meal plan. The content of the third and fourth follow-up sessions was individualized according to each participant´s situation: interests, difficulties experienced, goals, among others. For the second and third month, only one meeting was scheduled (booster session 1 and 2, respectively). The purpose and agenda of the booster sessions were the same as for the third and fourth weekly follow-ups held during the first month. At the last booster session, the dates for the final assessment and focus group interview, which is not addressed in this thesis, were established and participants were instructed to complete the final 3-day food record during the last week of the study. Email and telephone contact were used as necessary.

3.5.3. Final assessment

The third study meeting corresponded to the final assessment, and was conducted within 1 week of study completion. At this meeting, HbA1c, weight, waist circumference and body composition were measured. Also, a fasting blood sample to measure lipid profile was collected. Some of the initial questionnaires were repeated: diabetes treatment, perceived adherence to the diet and an exit survey about the menu plan. The final 3-day food record was reviewed. Additional questionnaires not discussed in this thesis include: self-rated health, self-efficacy, accessibility, acceptability and availability of foods.

The last meeting consisted of the focus group interview. The purpose of the interview was to gather information about participants´ experience, perceived benefits of, and barriers and facilitators to follow the menu plan. Also we were interested in getting feedback from the participants about the utility of the menu plan in helping them to follow a healthy diet and changes or suggestions to improve it. The information obtained from the focus groups will not be included in this thesis; however, it is an important piece of information that will help us to improve the menu plan for future research projects, and to understand the possible mechanisms that facilitate dietary change using this approach.

3.5.4. Follow-up

Email or telephone follow-up was conducted 2 months after study completion to document whether participants continued to use the menu plan as a reference for healthy eating. This information was important to assess the feasibility of the program.

3.6. Questionnaires

3.6.1. Demographic information

Demographic descriptors such as age, gender and years with diabetes, as well as information about ethnicity, education, employment, annual household income and financial situation were collected using a questionnaire (appendix D). This questionnaire was previously developed and used by our research group (Asaad, 2012; Devi Durai Raj, 2012). Descriptive statistics (mean ± standard deviation, range, frequencies and proportions) were used as appropriate to describe participants' characteristics.

3.6.2. General health and diabetes treatment

Information about participants´ current diabetes treatment and medications used on a regular basis was collected using this questionnaire (appendix E). Also, information about the presence of comorbidities such as CVD, high blood pressure and high cholesterol, among others, was collected. Some questions about smoking status and the use of supplements were included. This questionnaire was adapted from a previous study conducted by our group (Watanabe, 2009). Descriptive statistics were used to describe diabetes treatment and comorbidities.

3.6.3. Diabetes self-care activities

The diabetes self-care activities questionnaire (appendix F) was developed based on the summary of diabetes self-care activities measure (Toobert, Hampson, & Glasgow, 2000). This questionnaire asks whether participants are aware and/or have received advice from their health care team regarding different components of diabetes treatment including diet, physical activity, self-monitoring of blood glucose and medications. The diabetes self-care activities questionnaire was modified to reflect the CDA recommendations. For example, the guideline of following EWCFG was added to the questionnaire. Also, the servings of fruits and vegetables were modified from 5 to 7 to be consistent with EWCFG, and a low-GI diet option was included along with the option of following a complex carbohydrate diet. No modifications were made to other components. Descriptive statistics were used to summarize self-care activities.

3.6.4. Physical activity

Physical activity was assessed only at baseline using the questionnaire developed by Godin and Shephard (1985) (appendix G). This questionnaire asks the times per week that participants spent on strenuous, moderate or mild physical activity during the preceding week (at least 15 minutes per session). It also queries the presence of heart rate changes and perspiration. Using this information participants are classified as having strenuous, moderate or mild physical activity. For example, if most days of the week they engaged in physical activities without experiencing changes in heart rate or sweating they were classified as having mild physical activity. If most days of the week they engaged in activities and experienced light perspiration and elevated heart rate (not exhausting) they were classified as having moderate activity. Finally, if most days of the week they practiced physical activities and experienced elevated heart rate (exhausting) and sweating they were classified as having strenuous physical activity. Descriptive statistics were used.

3.6.5. Perceived adherence to the Canadian Diabetes Association nutrition therapy guidelines

Perceived adherence to the recommended diet was assessed using the perceived dietary adherence questionnaire (PDAQ) adapted from Toobert et al. (2000) to reflect the CDA NTG (appendix H). The PDAQ contains 9 questions that query the frequency that participants followed specific recommendations from the CDA NTG during the preceding week (0 to 7 days). Higher scores reflect higher adherence to the diet except for the following items where higher scores reflect lower adherence: on how many of the last 7 days did you eat foods high in sugar (i.e. cakes, cookies, desserts, candies)?; on how many of the last 7 days did you eat foods high in fat (i.e. high fat dairy products, fatty meat, fried or deep fried foods)? For these items the scores were inverted. For example, a person who ate foods high in sugar 7 days/week received a score of 0, for 6 days he/she received a score of 1 and so on. Scores for individual items were calculated and then added to obtain an overall adherence score (range 0-63). In a previous study conducted by our group the total score of the PDAQ was negatively correlated with HbA1c and individual components were correlated with nutrient intakes from 3-day food records (Devi Durai Raj, 2012). Descriptive statistics were used to summarize questionnaire items and overall score. Comparison of the PDAQ score at pre-and post-intervention was done using wilcoxon signed-rank test.

3.6.6. Weekly records: menu plan usage

The 3 weekly records (1 for each month) were used to guide the meetings with the participants during the adoption phase (appendix I). They contain questions related to participants´ use of the menu plan. Participants were instructed to fill out these records every week and bring them to the study meetings. At the end of every month participants handed or mailed the records to the study coordinator. Information on the use of the menu plan (days/week) throughout the study was obtained from the records and summarized using descriptive statistics. Additional information collected in the weekly records but not discussed in this thesis includes: questions about participants´ enjoyment of the menu plan, difficulties or obstacles faced while following the menu plan, information on goal setting and perceived dietary adherence (collected on week 4, 8 and 12 using the PDAQ).

3.6.7. Exit survey

This was a survey designed to gather information about the aspects of participants´ diet that were influenced by following the menu plan (appendix J). Participants had to respond in a 5-point Likert scale whether they strongly disagreed, disagreed, were neutral, agreed or strongly agreed with the statements. Descriptive statistics were used.

3.6.8. Other questionnaires

The self-rated health and self-efficacy questionnaires (Stanford University, 2012) were applied but are not discussed in this thesis. Additional questionnaires not addressed in this thesis include: the accessibility, acceptability and availability of foods questionnaires, which were previously developed by our research group (Asaad, 2012; Devi Durai Raj, 2012) (appendices K-O).

3.7. Diet quality

The following section outlines the different methods used to evaluate changes in the participants´ diet. First, we used a three-day food record to obtain information of the nutrient profile and consumption of food groups. Then, using this information we calculated a measure of diet quality, the HEI. Finally, we calculated the glycemic load (GL) and GI of the diets.

3.7.1. Three-day dietary intake record

There are several advantages in using food records to assess dietary intake that need to be highlighted. First, using this method we can obtain a detailed description of participants´ eating habits and dietary intake. Second, this method does not rely on memory (i.e. compared with 24 hour dietary recall) because the participant records his consumption at the time of eating. Furthermore, data from multiple days is more representative of usual intake than 1 single day (Lee & Nieman, 2010). Therefore, a 3-day dietary intake record was used twice during the study: meeting 1 (baseline assessment) and 1 week prior to study completion (Appendix P). To reduce variation, participants were assigned recording days (2 weekdays, 1 weekend day), which were the same for both recording occasions. For example, if a participant completed Sunday, Monday and Tuesday at baseline he completed the same days for the final record. They were instructed to record everything they ate and drank, to estimate portion sizes using household measures and to provide information about the time and eating occasion when the items were consumed, as well as information of brands, cooking methods and recipes, and to bring food labels if possible. The study coordinator reviewed the food records, probed for additional eating occasions, clarified potions sizes and asked for additional description of food items if necessary. Food records were analyzed using the Food Processor Software SQL (version 10.9.0). The CNF (Health Canada database) was the first choice to calculate nutrient intake, then the United States Department of Agriculture (USDA) database. A codebook was kept throughout the study to ensure consistency in selection of food items and measures. Food processor entries were double checked by a graduate student and a registered dietitian to ensure consistency.

3.7.1.1. Nutrient profile

Intakes of macro-and micronutrients were obtained from the Food Processor software and compared with the CDA NTG (CDA, 2008) and the Canadian/US Recommended Dietary Allowances (Health Canada, 2010). Energy intake was compared against each individual´s energy requirement, which was obtained with the formula outlined by the Institute of Medicine (Food and Nutrition Board. Institute of Medicine of the National Academies., 2005). Grams of carbohydrates, proteins and fats were respectively multiplied by 4, 4 and 9 kcal to obtain total calories from these nutrients. In the same way, grams of alcohol were multiplied by 7 kcal to obtain their caloric contribution. Calories from carbohydrates, proteins, fats and alcohol were then added to obtain total daily caloric intake.

Sucrose intake was manually calculated using a data base developed at the University of Alberta. This data base contains the sugar content of different foods and was developed using data from the food processor, the CNF and information from manufacturers (Bell et al., unpublished data). Energy and nutrient intakes over the 3 days were averaged and summarized using descriptive statistics. Two-tailed, paired samples t-test and Wilcoxon signed-rank test were used as appropriate to compare changes in the nutrient profile.

3.7.1.2. Food groups from Eating Well with Canada´s Food Guide

Besides evaluating nutrient intakes and their adequacy we wanted to assess other aspects such as the inclusion of different foods in the diet. From the 3-day food records we manually calculated the servings of the food groups outlined in EWCFG: fruits and vegetables; grain products, milk and alternatives and meat and alternatives (Health Canada, 2007). To be consistent with EWCFG we calculated the amount of unsaturated fat added in the foods (i.e. oils, salad dressing). The amount of calories from the "other foods" category was calculated to compute the HEI. The "other foods" category includes fats and oils other than unsaturated fat, such as butter, cream, cream cheese, among others. This category also includes confectionaries and sugars such as cakes, pastries, frozen desserts, pies, chocolate, candies, coated cookies and granola bars, alcoholic and non-alcoholic beverages, salty snacks and high fat snacks, condiments and spices. In general this category includes all the foods that cannot be classified into the 4 main categories, and foods that should be limited in the diet (high salt, sugar and fat). Mixed dishes were broken down into their basic ingredients. No food was classified into the 4 food groups and the "other foods" category at the same time. For example, if a cheeseburger was broken down into grains (i.e. bun), milk & alternatives (i.e. cheese) and meat & alternatives (i.e. patty), it was not classified as "other foods" as well. A code book was kept to ensure consistency.

The average of the 3 days was used to evaluate intake of the food groups. The information was summarized using descriptive statistics (mean and standard deviation). Intakes at baseline and post-intervention were compared using two-tailed, paired samples t-test.

3.7.2. Healthy Eating Index

Nutrients and foods are not consumed in isolation, therefore considering the complexity of dietary behaviors and evaluating the overall dietary pattern as opposed to the intake of single components is important. Considering the above-mentioned factors, the USDA developed the HEI, an indicator that incorporates information of food groups and nutrients to evaluate the overall quality of a diet (Kennedy, Ohls, Carlson, & Fleming, 1995). Recently, the HEI was adapted to conform to the Dietary Guidelines for Americans 2005 (HEI-2005) and to emphasize important aspects of the diet such as the inclusion of whole grains, dark vegetables, and saturated fat, among others. It includes 9 adequacy components: total fruit, whole fruit, total vegetables, dark green and orange vegetables and legumes, total grains, whole grains, milk, meat and beans, and oils; and 3 moderation components: saturated fat, calories from solid fats, alcoholic beverages and added sugars, and sodium. All the components are reported in relation to energy consumption (amounts per 1000 kcal or % daily energy). Each component is awarded from 0 to 5, 10 or 20 points for a total range of 0-100 points, where 0 is the “poorest diet” and 100 represents the “greatest” diet (Guenther, Reedy, & Krebs-Smith, 2008).

Different authors have used the HEI within the Canadian context (Asaad, 2012; Garriguet, 2009; Glanville & McIntyre, 2006; Woodruff & Hanning, 2010). Using data from the 2004 CCHS, Garriguet (2009) adapted the HEI-2005 to evaluate diet quality in Canada. In this adaptation, foods were classified into fruits and vegetables, grain products, milk and alternatives and meat and alternatives, and the “other foods” category as outlined in EWCFG. The HEI-Canada includes 8 adequacy and 3 moderation components. Recommendations in the Canadian adaptation are expressed as food guide servings according to age and gender, as g or mg, and as % daily energy. Table 3.1 shows the components and scoring system of the HEI-Canada. Total vegetables and fruits, whole fruits, dark green and orange vegetables, total grain products, whole grains, milk and alternatives, meat and alternatives and unsaturated fat make up the adequacy components of the HEI-Canada. These components receive from 0 to 5-10 points. The lowest score (i.e. 0) is awarded to persons whose intake is 0 servings (or grams), while the highest score of 5 or 10 is awarded to those meeting the recommendations of EWCFG. Proportional scores are awarded to persons with intakes between the minimum and maximum. Saturated fat, sodium and calories from “other foods” make up the moderation components. In the case of these 3 components, persons with lower intakes are awarded more points (i.e. 10 or 20) and those with greater intakes are awarded less points. Proportional scores are awarded to those between the minimum and maximum intakes. The index score ranges from 0 to 100. More than 80 points represent good diet quality, 51-80 points mean diet needs improvement and less than 50 points represents a poor diet (Garriguet, 2009).

The HEI has been used to evaluate the diets of adults with chronic diseases including T2D in Canada and the US (Asaad, 2012; Chen, Cheskin, Shi, & Wang, 2011). Moreover, it has been adapted to the recommendations of EWCFG and the Canadian Recommended Dietary Allowances for saturated fat and sodium (Garriguet, 2009) which apply for people with T2D (CDA, 2008), therefore we decided to use the HEI-Canada to evaluate diet quality in the present study. The HEI-Canada was computed using the servings of food groups and nutrient intakes previously calculated, following the scoring criteria proposed in table 3.1. Data were summarized using descriptive statistics and pre-and-post-intervention scores were compared using two-tailed, paired samples t-test.

Table 3.1. Components and scoring criteria of the HEI-Canada		
Component	**Range of points**	**Scoring criteria**
***Adequacy** Total vegetables and fruit	0-10	**Minimum: 0** **Maximum:** Females 19+ y: ≥7 svg Males 19-50 y: ≥8 svg Males 51+ y: ≥7 svg
Whole fruit *21% recommendation for total vegetables and fruit*	0-5	**Minimum: 0** **Maximum:** Females 19+ y: ≥1.5 svg Males 19-50 y: ≥1.7 svg Males 51+ y: ≥1.5 svg
Dark green and orange vegetables *21% recommendation for total vegetables and fruit*	0-5	**Minimum: 0** **Maximum:** Females 19+ y: ≥1.5 svg Males 19-50 y: ≥1.7 svg Males 51+ y: ≥1.5 svg
Total grains	0-5	**Minimum: 0** **Maximum:** Females 19+ y: ≥6 svg Males 19-50 y: ≥8 svg Males 51+ y: ≥7 svg
Whole grains *50% recommendation for total grains*	0-5	**Minimum: 0** **Maximum:** Females 19+ y: ≥3 svg Males 19-50 y: ≥4 svg Males 51+ y: ≥3.5 svg
Milk & alternatives	0-10	**Minimum: 0** **Maximum, females and males:** 19-50 y: ≥ 2 svg 51+ y: ≥ 3 svg
Meat & alternatives	0-10	**Minimum: 0** **Maximum:** Females 19+ y: ≥2 svg Males 19+ y: ≥3 svg
Unsaturated fat	0-10	**Minimum: 0** **Maximum:** Females 19+ y: 30 g Males 19+ y: 45 g
****Moderation** Saturated fats	8-10 0-8	**Minimum:** ≤7-10% total daily energy **Maximum:** 10- 15%
Sodium	8-10 0-8	**Adequate intake to upper limit** 31-50 y: ≤1500-2300 mg 50-70 y: ≤1300-2300 mg >70 y: ≤1200-2300 mg **Upper limit to twice upper limit** All: 2300-4600 mg
"Other foods"	0-20	**Minimum:** ≤5% total daily energy **Maximum:** ≥40%

Abbreviations: SVG: servings
***Adequacy:** 0 points for minimum, 5 or 10 for maximum or more, proportional scores between minimum and maximum.
****Moderation:** 0 or 20 points for minimum or less, 0 points for maximum or more, proportional scores between minimum and maximum
Adapted from Garriguet, 2009, Health Canada, 2007, Health Canada, 2010.

3.7.3. Dietary glycemic load and glycemic index

The glycemic index is a measure of the effect of carbohydrate-containing foods in postprandial blood glucose levels, compared with a standard (i.e. white bread or glucose). It is considered a measure of carbohydrate quality. On the other hand, the GL measures the overall glycemic effect of a portion of food by taking into account the quality and quantity of carbohydrates. The higher the GL, the greater effect in blood glucose and insulin response (Foster-Powell, Holt, & Brand-Miller, 2002).

The GI and GL have been used as dietary strategies to optimize glycemic control in individuals with T2D. Two meta-analyses showed that individuals who followed a low-GI diet had an HbA1c -0.4% lower than those who followed a high-GI or control diet (Brand-Miller, Hayne, Petocz, & Colagiuri, 2003; Thomas & Elliot, 2010). Low-GI diets have shown to improve glucose utilization, total cholesterol and LDL-cholesterol levels in people with T2D (Rizkalla, et al., 2004). Also, there is evidence that low-GI/GL diets induce a greater decrease in body weight, fat mass and BMI compared with high-GI/GL or control diets (Thomas, Elliott, & Baur, 2007).

The CDA recommends that individuals with T2D include 45-60% of their total daily energy from carbohydrates; however they also endorse the use of low-GI carbohydrates to optimize glycemic control (CDA, 2008). Taking this into account, we gave preference to low-GI carbohydrates to be included in our menu plan.

Changes in the quantity and quality of carbohydrates were assessed by calculating the GI and GL of the diets at baseline and post-intervention. Glycemic index and GL were calculated using the formulas described by Sahyoun et al. (2005). First, a GI value was assigned to each of the carbohydrate-containing foods in the 3-day food records. GI values compared with glucose as standard were obtained from two databases (Foster-Powell, Holt, & Brand-Miller, 2002; The University of

Sydney, 2012). Then, the GL per serving of food was calculated using the formula:

$$\text{GL per serving} = \text{GI} \times \frac{\text{available carbohydrate}}{100}$$

Available carbohydrate= total carbohydrates – total fiber

To obtain daily GL, GL values of all the foods consumed in a day were summed.

Then, daily GI was calculated using the formula:

$$\text{Daily GI} = \frac{\text{daily GL}}{\text{available carbohydrate}} \times 100$$

Daily GI values were classified as low (<55.0), medium (56–69), or high (≥70) (The University of Sydney, 2012).

Daily GI and GL values were averaged over the 3 days and summarized using descriptive statistics. Pre-and-post intervention values were compared using two-tailed, paired samples t-test.

3.8. Biochemical assessment and anthropometric measures

3.8.1. Glycated hemoglobin and lipid profile

Glycated hemoglobin was obtained from a finger prick blood sample using an autoanalyser (DCA 2000®+, Siemens Diagnostics). Quality control procedures were performed routinely to ensure appropriate functioning of the equipment. The concentrations of selected lipid parameters were assessed using commercially available enzymatic colorimetric assays. Fasting blood samples (≥8 hours) were collected by a trained nurse at the Human Nutrition Research Unit. Samples were kept at room temperature for 10-15 minutes, and then centrifuged (3500 rpm) to obtain serum which was subsequently stored at -80°C until assays were performed. Triglycerides, total- and HDL-cholesterol, were measured using direct colorimetric chemical enzymatic reactions (Wako Chemicals USA, Inc). Low-density lipoprotein cholesterol levels were estimated using the following equation:

LDL-c= total cholesterol − HDL-cholesterol – triglycerides/5 (Friedewald, Levy, & Fredrickson, 1972). The ratio of total cholesterol to HDL cholesterol (TC/HDL-c) was calculated. Samples were analyzed in triplicate using assay kits from a single lot and performed in one batch at the University of Alberta. Descriptive statistics were used to summarize biochemical measures. Two-tailed, paired samples t-test and wilcoxon signed-rank test were used as appropriate to compare changes from baseline to program completion.

3.8.2. Anthropometric measures

Anthropometric assessment included height, weight, BMI, waist circumference and body composition. Height was measured without shoes and head gear, with the participant standing straight against a wall-mounted stadiometer (Quick Medical Heightronic digital stadiometer, Northbend, WA), touching the wall with heels, buttocks and back. Heels were together and head was oriented in the Frankfort plane (the upper border of the ear opening and the lower border of the eye socket on a horizontal line). The subject was instructed to stretch upward and take and hold a full breath, and then the headboard of the stadiometer was lowered until it touched the head vertex. Weight was measured with light clothing and without shoes using a digital scale (Health-o-Meter Professional Series digital scale, Sunbeam, Boca Raton, FL). Body mass index was calculated using the formula weight (kg) divided by height squared (m). Waist circumference was measured at the midpoint between the lower border of the rib cage and the iliac crest, directly over the skin, at the end of a normal expiration, with arms relaxed at the sides and weight evenly distributed across both feet. A steel flexible tape was used (Rosscraft anthrotape®). All the measurements were taken in triplicate, averaged and recorded to the nearest 0.1 cm or 0.1 kg. Body composition was measured through air displacement plethysmography (Bod Pod®) wearing tight clothing (i.e. bathing suit for females and shorts for males) and a swim cap, and having jewelry, glasses and socks removed. The Bod Pod was calibrated before use and all the subjects were fasting for the assessment. Descriptive statistics were used to summarize anthropometric measures and changes from pre-to-post-intervention were compared using paired samples t-test.

3.8.3. Health parameters according to changes in diet quality

Changes in HbA1c, lipid profile and anthropometric measures were explored according to whether participants increased or decreased their diet quality as measured by the HEI-Canada. Changes from baseline to post-intervention within the study groups were assessed using a two-tailed, paired samples t-test, whereas differences between the groups were explored using independent samples t-test.

3.9. Data analysis

All the information was recorded on paper, then it was coded and inputted into Microsoft Excel, and analyzed using IBM SPSS statistics 20 and GraphPad Prism 5. All data and informed consent materials were kept in a secure cabinet. Data were cleaned by removing outliers (mean ± 2SD). Descriptive statistics were used to describe characteristics of the population and variables of interest. Mean and standard deviation, and median and range were used for continuous variables. Frequencies and percentages were used for categorical variables. Comparison of continuous variables at pre- and post-intervention was done using two-tailed, paired samples t-test for variables with normal distribution, and Wilcoxon signed-rank test for skewed distribution. Categorical variables were compared using chi square test or Fisher's exact test. A p value <0.05 was considered significant and $p<0.10$ was considered a trend, which we noted because of the pilot nature of the study. Data tabulations and bar graphs were used to illustrate the findings.

Chapter 4: Results

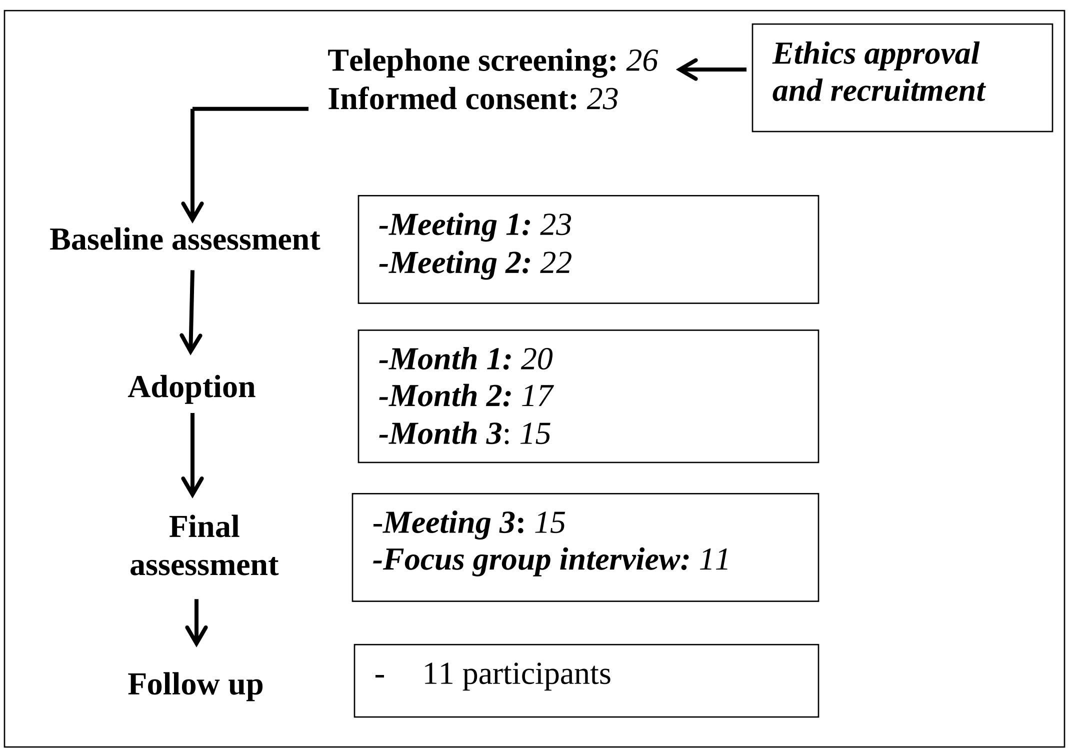
4.1. Introduction

The following section begins by describing the number of participants that completed the study procedures, followed by their demographic characteristics, diabetes treatment and self-care activities, concluding with the findings of our study as they relate to the objectives.

4.2. Participants

Twenty-six participants were screened for eligibility; 23 met the inclusion criteria and consented to take part in the study (Figure 4.1). Twenty-two participants completed the baseline assessment but 2 of them did not return the 3-day dietary intake record. The first, second and third months of the study were completed by 20, 17 and 15 participants, respectively. Fifteen participants completed the final assessment, 11 took part in the focus group interviews and 11 were contacted for follow-up two months after study completion.

Figure 4.1. Participants completing study procedures



As was previously described, 6 follow-up sessions were held during the adoption phase of the program: 4 weekly sessions during the first month, and 1 booster session the second and third month. The duration of the sessions was approximately 40 to 60 minutes with few exceptions in which the meetings lasted for approximately 120 minutes. Participants attended an average of 4 (range 2-6) follow-up sessions throughout the 12-week program.

4.3. Demographic information

Table 4.1 displays demographic characteristics of participants who completed (completers) and those who did not complete the study (non-completers). Sixty percent of the participants who completed were male. The average age of completers was 59.3±9.9 (SD) years and they had had T2D for a mean of 8.1±8.3 (SD) years. Most of the participants were white (80%) and 20% were Aboriginal, South Asian or Latin American. Half of the sample (53%) had completed college or university, 33% had some, not completed, post-secondary education and 13% graduated from high school. Regarding employment, 33% were employed with wages and salaries, 13% were self-employed and 20% lived from retirement income, while the remaining 33% received income from a combination of the above-mentioned categories. On the other hand, non-completers (n=8) were younger (52.6±8.3 years) and had had diabetes for only 4.3±4.7 years. Most of the participants in this group were women (62%), all of them were white and the majority (75%) had completed college or university. Sixty-two percent were employed with wages and salaries and 38% were self-employed.

Table 4.1. Demographic characteristics of study participants

Variable	Completers (n=15)	Non-completers (n=8)
Age (mean±SD) Range	59.3±9.9 years 36-74 years	52.6±8.3 years 41-62 years
Years with diabetes (mean±SD) Range	8.1±8.3 years Less 1-26 years	4.3±4.7 years Less 1-15 years
Gender (n, %)		
Male	9, 60.0 %	3, 37.5 %
Female	6, 40.0 %	5, 62.5 %

Ethnicity (n, %)		
White	12, 80.0 %	8, 100 %
Aboriginal	1, 6.7 %	
South Asian	1, 6.7 %	
Latin American	1, 6.7 %	
Education (n, %)		
High school graduate	2, 13.3 %	
Some college or university (have some post-secondary education, but not completed)	5, 33.3 %	2, 25 %
College or university graduate or above	8, 53.3 %	6, 75 %
Employment (n, %)		
Wages and salaries	5, 33.3 %	5, 62.5 %
Income from self-employment	2, 13.3 %	3, 37.5 %
Retirement income (pensions, old age security and GIS, etc.)	3, 20.0 %	
[1]Other	5, 33.3 %	
[1]Includes different combinations of wages and salaries, income from self-employment and retirement income.		

Table 4.2 displays income and financial situation of study participants. Thirteen percent of completers had an income lower than $30,000 per year and 40% had an income from $30,000 to $59,999 or higher than $60,000. Most of the sample (67%) described their financial situation as good enough to meet their needs and have money left to do most of the things they wanted. On the other hand, 57% of non-completers had an income higher than $60,000 and 43% from $30,000 to $59,999.

Table 4.2. Income and financial situation of study participants

Variable	Completers (n=15)	Non-completers (n=8)
[1]Household income (n, %)		
$ 10,000- $ 14,999 (1 or 2 people)	1, 6.7 %	
$ 15,000- $ 29,999 (1 or 2 people)	1, 6.7 %	
$ 30,000-$ 59,999 (1 or 2 people)	6, 40.0 %	3, 42.9 %
$ 40,000-$ 79,999 (3 or 4 people)	1, 6.7 %	
>$ 60,000 (1 or 2 people)	5, 33.3 %	2, 28.6 %
>$ 80,000 (≥ 3 people)	1, 6.7 %	2, 28.6 %

Financial situation (n, %)		
I can meet my needs and still have enough money left to do most of the things I want	10, 66.7 %	5, 62.5 %
I have enough money to meet my needs and to do many of the things I want if I budget carefully	3, 20.0 %	2, 25 %
I have enough money to meet my needs but have little left for extras	1, 6.7 %	1, 12.5 %
I can barely meet my needs and have nothing left for extras and I am solely responsible for my treatment financially	1, 6.7 %	
[1] Non-completers household income n=7		

4.4. General health and diabetes treatment

Table 4.3 describes diabetes treatment, comorbidities and medications used by the participants. The majority of the participants (60%) used anti-diabetic drugs combined with diet and/or exercise to manage their diabetes. Metformin was the medication most commonly used by the participants (93%). Besides T2D, participants had a mean of 3 concurrent illnesses of which high blood pressure had the highest prevalence (67%), followed by high cholesterol (47%). Also, back problems and allergies affected 33% the participants. Likewise, 67%, 47% and 40% reported taking medications to treat high blood pressure, dyslipidemia and for cardiovascular prevention, respectively. A minority of the sample (13%) were current smokers.

During the 12-week program most of the participants (72%) did not change the dose or type of medication used for diabetes or concurrent illnesses. On the other hand, 1 participant (7%) discontinued glicazide, 1 (7%) discontinued metformin and the medication for hyperlipidemia, and 1 (7%) discontinued high blood pressure medication. Only 1 participant (7%) increased the dose of the metformin

.

Table 4.3. General health and diabetes treatment		
Variable	**Number (n=15)**	**Proportion**
Diabetes treatment		
Lifestyle (diet and/or exercise) + anti-diabetic agent + insulin	5	33.3 %
Lifestyle + anti-diabetic agent	9	60.0 %
Lifestyle + insulin	1	6.7%
[1]**Diabetes medications**		
Metformin	14	93.3%
Basal insulin	6	40.0%
Glicazide	6	40.0%
Prandial insulin	2	13.3%
Other: victoza, repaglinide and sitagliptin	4	26.7%
[1]**Concurrent illness**		
High blood pressure	10	66.6 %
High cholesterol	7	46.6 %
Back problems	5	33.3 %
Allergies	5	33.3 %
Heart problems	4	26.7 %
Trouble seeing	4	26.7 %
Arthritis	3	20.0 %
Trouble hearing	3	20.0 %
Other medical problems	3	20.0 %
Chronic asthma, emphysema, or bronchitis	2	13.3 %
Foot problems	2	13.3 %
Bladder control	1	6.7 %
Poor or increased appetite	1	6.7 %
Balance problem, osteoporosis, neuropathy, kidney problems	0	0%
[1]**Other medications**		
Hypertension	10	66.6 %
Hyperlipidemia	7	46.6 %
Cardiovascular prevention (aspirin)	6	40.0 %
Antidepressant	3	20.0 %
Acid reflux	2	13.3 %
Digestive disorders	2	13. 3%
Analgesic/antipyretic	1	6.7 %
Bone disease	1	6.7 %
Birth control	1	6.7 %
Eye problems	1	6.7 %
Smoking		
Current	2	13.3 %
Former smoker	5	33.3 %
Non-smoker	8	53.3 %
[1]More than 1 option was possible		

As shown in table 4.4., vitamin and mineral supplements were taken by 80% of the participants and herbal supplements by 33%. The most common supplements were multivitamins (53%) and Vitamin D (40%) followed by omega 3 fatty acids and vitamin C (each 33%).

Table 4.4. Supplements use among the participants		
Variable	**Number (n=15)**	**Proportion**
Supplements use		
Vitamin and minerals	12	80.0 %
Herbal supplements	5	33.3 %
[1]Supplements used		
Multivitamin	8	53.3 %
Vitamin D	6	40.0 %
Omega 3 fatty acid	5	33.3 %
Vitamin C	5	33.3 %
Calcium	4	26.7 %
Fish oil	3	20.0 %
Cinnamon	2	13.3 %
Folic acid	2	13.3 %
B complex	2	13.3 %
B12	1	6.7 %
Bilberry	1	6.7 %
Magnesium	1	6.7 %
Other	11	73.3 %
[1]More than 1 option was possible		

4.5. Diabetes self-care activities

Participants were asked about the self-care activities that their health care team (doctor, nurse, dietitian, or diabetes educator) had advised them to do as part of their diabetes treatment. Table 4.5 displays participants´ answers for the 4 aspects of diabetes self-care explored: diet, physical activity, self-monitoring of blood glucose and medication taking. Eighty percent of the participants had been advised to follow EWCFG, whereas around 60% had been advised to reduce the number of calories they ate to lose weight, to eat lots of fruits and vegetables and very few sweets. Around 50% had been advised to eat foods high in fiber and to avoid foods high in fat. On the other hand only 20% were advised to follow a diet high in complex carbohydrates or low in GI. Regarding exercise, all the participants had been advised to get physical activity on a daily basis (i.e. walking), almost 70% had been advised to fit physical activity into their routine (i.e. taking the stairs instead of elevator) and to exercise continuously for at least 30 minutes 5 times per week. On the other hand, only a few participants (20%) had received specific instructions of the amount, type, duration and level of exercise they should take. Participants were also asked about the methods that had been recommended to self-monitor their blood glucose. Most of the participants (93%) had been advised to test their blood sugar using a meter and 7% had not received any advice. Finally, when they were asked about the medications prescribed by their doctor, 87% had been prescribed diabetes pills, 27% an insulin shot 1 or 2 times per day, and 7% had been prescribed an insulin shot 3 times per day or more.

Table 4.5. Recommended self-care activities for diabetes treatment

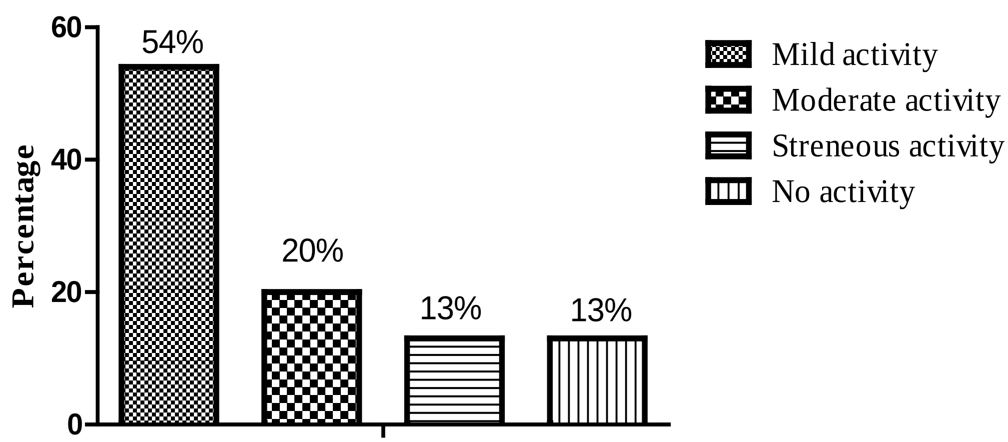
[1]**Self-care activity**	**Number (n=15)**	**Proportion**
Diet		
Follow Canada's Food Guide	12	80.0 %
Follow a low glycemic index diet	3	20.0 %
Reduce the number of calories	9	60.0 %
Eat foods high in dietary fiber	8	53.3 %
Eat lots of fruits and vegetables	10	66.7 %
Eat very few sweets (e.g. desserts)	9	60.0 %
Avoid foods high in fat	8	53.3 %
Have not received any advice	0	0 %
Physical activity		
Get regular physical activity on a daily basis	15	100.0 %
Fit physical activity into your daily routine	11	73.3 %
Exercise continuously for 30 minutes/5 times a week	10	66.7 %
Engage in a specific amount/ type/duration or level of exercise	3	20.0 %
Other	1	6.7 %
Have not received any advice	0	0 %

Self-monitoring of blood glucose Test blood sugar using a color chart Test blood sugar using a meter Test your urine for sugar Have not received any advice	 1 14 2 1	 6.7 % 93.3 % 13.3 % 6.7 %
Medications Insulin shot 1 or 2 times/day Insulin shot ≥3 times/day Diabetes pills Other Have not received any advice	 4 1 13 2 0	 26.7 % 6.7 % 86. 7% 13.3 % 0 %
[1]More than 1 option was possible for all items		

4.6. Physical activity

As shown in figure 4.2 most of the participants (87%) reported being physically active at baseline. Half of the sample (54%) reported taking part in mild physical activity (i.e. easy walking), 20% in moderate physical activity (i.e. fast walking) and 13% in strenuous physical activity (i.e. running). On the other hand, 13% reported no physical activity.

Figure 4.2. Participation in regular physical activity at baseline (n=15)



The physical activity questionnaire was not applied at program completion. However, during the follow-up sessions participants reported minimal changes in physical activity: those with no activity and with mild physical activity at baseline did not report an increase in exercise during the program, except for one person who started to walk every day after joining the program. Those with moderate and strenuous physical activity did not report a change in activities.

4.7. Perceived adherence to the Canadian Diabetes Association nutrition therapy guidelines

Table 4.6 shows participants´ perceived adherence to the dietary recommendations at baseline and post-intervention. Responses to individual items of the PDAQ were grouped into 0-2, 3-5 and 6-7 days per week. At baseline, 33% of the participants reported following EWCFG 6-7 days/week and after the program the percentage increased to 54%. The percentage of participants who reported eating ≥7 servings of fruits and vegetables 6-7 days/week did not change, while the percentage following the recommendation 3-5 days/week increased from 40% to 47%. At baseline, 47% of participants reported eating foods high in sugar 0-2 days/week and after the program 60% of the participants reported doing so. In a similar way, 40% and 67% reported eating foods high in fat 0-2 days/week at baseline and post-intervention, respectively. Forty percent of the participants spaced carbohydrates throughout the day 6-7 days/week at baseline compared with 47% post-intervention. The percentage of participants eating foods high in omega 3 fatty acids 6-7 days/week did not change, while the percentage following the recommendation 3-5 days/week increased from 27% to 47%. Finally, the percentage eating foods which contained plant oils 6-7 days/week increased from 27% to 54%. The overall dietary adherence measured by the PDAQ score increased significantly from baseline to program completion (Median (range) 43.0 (18.0-57.0) vs 46.0 (22.0-58.0), p=0.01).

Table 4.6. Participants´ perceived adherence to dietary recommendations at baseline and at program completion

Variable	Baseline (n=15)	Post-intervention (n=15)
Follow Eating Well with Canada´s Food Guide (n, %)		
0-2 days	3, 20.0%	2, 13.0%
3-5 days	7, 47.0%	5, 33.0%
6-7 days	5, 33.0%	8, 54.0%

Eat the recommended servings of fruits & vegetables (n, %)		
0-2 days	3, 20.0%	2, 13.0%
3-5 days	6, 40.0%	7, 47.0%
6-7 days	6, 40.0%	6, 40.0%
Eat foods with low glycemic index (n, %)		
0-2 days	1, 6.0%	2, 13.0%
3-5 days	7, 47.0%	9, 60.0%
6-7 days	7, 47.0%	4, 27.0%
Eat foods high in sugar (n, %)		
0-2 days	7, 47.0%	9, 60.0%
3-5 days	6, 40.0%	5, 33.0%
6-7 days	2, 13.0%	1, 7.0%
Eat foods high in fiber (n, %)		
0-2 days	0	0
3-5 days	3, 20.0%	6, 40.0%
6-7 days	12, 80.0%	9, 60.0%
Space carbohydrates evenly throughout the day (n, %)		
0-2 days	4, 27.0%	3, 20.0%
3-5 days	5, 33.0%	5, 33.0%
6-7 days	6, 40.0%	7, 47.0%
Eat foods high in omega 3 fatty acids (n, %)		
0-2 days	9, 60.0%	6, 40.0%
3-5 days	4, 27.0%	7, 47.0%
6-7 days	2, 13.0%	2, 13.0%
Eat foods prepared with vegetable oils (n, %)		
0-2 days	5, 33.0%	2, 13.0%
3-5 days	6, 40.0%	5, 33.0%
6-7 days	4, 27.0%	8, 54.0%
Eat foods high in fat (n, %)		
0-2 days	6, 40.0%	10, 67.0%
3-5 days	8, 53.0%	5, 33.0%
6-7 days	1, 7.0%	0
No significant differences from baseline to program completion compared by chi-square test and Fisher´s exact test		

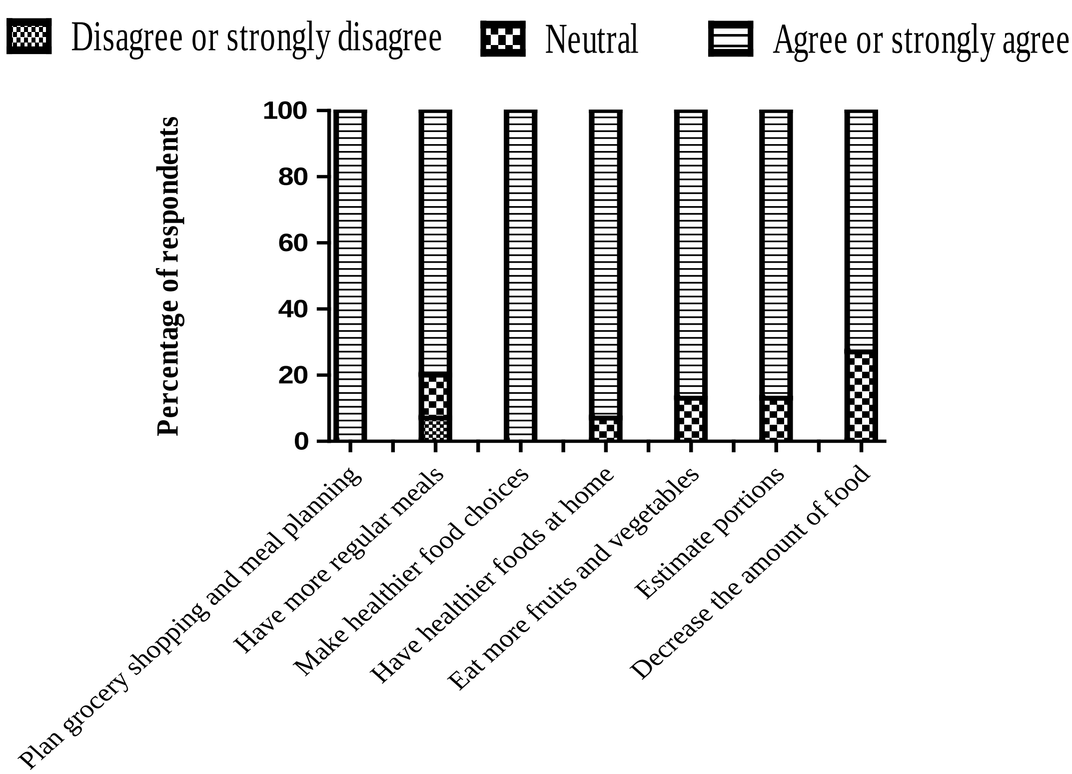
4.8. Weekly records: menu plan usage

Information of the menu plan usage was obtained from the weekly records. Participants (n=14) reported following the menu plan an average of 5.0±1.9 days per week throughout the 12 weeks. One participant did not complete the weekly records.

4.9. Exit survey

Figure 4.3 displays participants´ perception of the influence of the menu plan program on different aspects of their diets. All the participants agreed or strongly agreed that following the menu plan helped them to initiate habits such as planning grocery shopping and meal planning, as well as to make healthier food choices. Approximately, 75% of the participants agreed or strongly agreed that the menu plan helped them to establish structure in their meals (i.e. schedule and frequency of meals) and to decrease the amount of food consumed. Almost all the participants (90%) agreed or strongly agreed that the menu plan helped them to have healthier foods available at home, to increase the amount of fruits and vegetables consumed and to estimate portions of foods in their meals.

Figure 4.3. Influence of the menu plan in selected aspects of participants´ diets (n=15)



4.10. Diet quality

4.10.1. Nutrient profile

Table 4.7 describes the intake of nutrients and calories at baseline and after the program. Median caloric intake at baseline was 1960 kcal/day. Intakes of carbohydrates, sucrose, fiber, protein, fat, monounsaturated fat and polyunsaturated fat were 48.2%, 5.3%, 26 g, 19.6%, 29.9%, 10.6% and 5.9%, respectively, all within the recommendations of the CDA NTG. On the other hand the intakes of saturated fat, cholesterol and sodium were higher than recommended with 9.6%, 299 mg and 2480 mg, respectively. Alcohol intake was less than 0.3% of total daily energy. The CDA recommends that individuals with T2D limit their intake of cholesterol but does not provide an upper limit; therefore cholesterol intake was compared with the recommendations of the ADA (ADA, 2008).

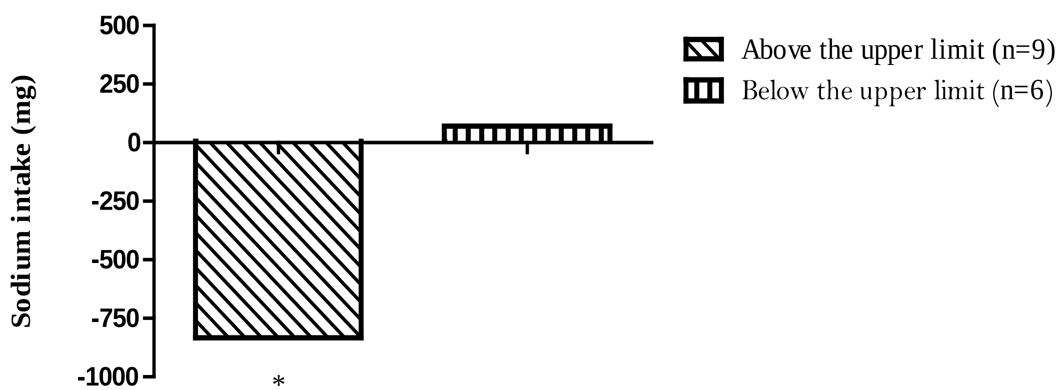
Table 4.7. Caloric and nutrient intakes at baseline and post-intervention

Variable	Pre-intervention (n=15)	Post-intervention (n=15)	CDA Nutrition therapy guidelines	p value
***Total calories (kcal)**	1960 (913-2802)	1617 (974-3245)		ǂp=0.60
Carbohydrates (%)	48.2±6.7	48.3±7.9	45-60% TDE	p=0.97
Total sugars (%)	16.8±5.6	18.1±3.8		p=0.51
Sucrose (%)	5.3±3.9	5.6±2.3	<10% TDE	p=0.67
Fiber (g)	26.0±9.4	25.3±7.9	25-50 g	p=0.75
Fat (%)	29.9±7.9	29.9±6.9	<35% TDE	p=0.98
Saturated fat (%)	9.6±3.2	9.1±3.0	<7% TDE	p=0.47
MUFA (%)	10.6±3.3	11.9±3.0		p=0.24
PUFA (%)	5.9±2.4	5.9±1.8	<10% TDE	p=0.93
***Protein (%)**	19.6 (14.9-33.5)	21.6 (16-26.6)	15-20% TDE	ǂp=0.98
***Cholesterol (mg)**	299 (104-755)	313 (17-492)	[1]<200 mg	ǂp=0.72
Sodium (mg)	2480±1039	2008±905	[2]<1500 mg/day	p=0.11
Alcohol (%)	0.30±1.2	0.61±1.4		p=0.36

Abbreviations: MUFA: monounsaturated fatty acids; PUFA: polyunsaturated fatty acids; TDE: total daily energy.
Data are means ± SD unless otherwise indicated. All the participants were included in the analysis. P value is based on two-tailed, paired samples t-test unless otherwise indicated. *Median (range). ǂ P value based on two-tailed, Wilcoxon signed-rank test
[1] American Diabetes Association, [2] Dietary Reference Intakes Canada

No significant changes were observed in caloric intake and nutrient intakes after the program except for sodium, which decreased significantly in women (2059±475 mg vs 1317±298 mg, p=0.04). Also, as figure 4.4 shows we observed a trend towards decreased sodium intake in individuals who had an intake above the upper limit (2300 mg) at baseline (3068±889 mg vs 2235±1092 mg, p=0.06).

Figure 4.4. Changes in sodium intake in participants above or below 2300 mg at baseline



*p<0.10, compared with two-tailed, paired samples t-test.

Two participants who dropped out of the study provided a final 3-day food record for us to take as a comparison group. They did not change their caloric intake and nutrient intakes except for sucrose that increased from baseline to their final food record (15.7±9.8 g vs 27.3±10.7 g, p=0.035).

Although caloric intake did not change significantly during the study, participants reported an energy intake significantly lower compared to their estimated total energy expenditure (TEE) ($p<0.05$). Those who had an energy intake within ±5% of their TEE (n=2) or above their TEE (n=1) at baseline decreased their caloric intake by 15.2% and 34.1%, respectively at post-intervention. Those who had an energy intake below their TEE at baseline kept a similar intake after the program.

4.10.2. Food intake analyzed by food groups from Eating Well with Canada's Food Guide

Table 4.8 describes the mean number of servings that participants consumed pre- and post-intervention. At baseline, intakes of fruits and vegetables, grain products, milk & alternatives and meat & alternatives were 6.5 servings/day, 5.4 servings/day, 1.7 servings/day and 3.2 servings/day. At program completion, non-significant changes in the intake of food guide servings were observed: participants increased their intake of fruits and vegetables and milk & alternatives by +1.0 serving/day and +0.2 servings/day, respectively. On the other hand they decreased their intake of grain products and meat and alternatives by -1.0 serving/day and -0.2 servings/day, respectively.

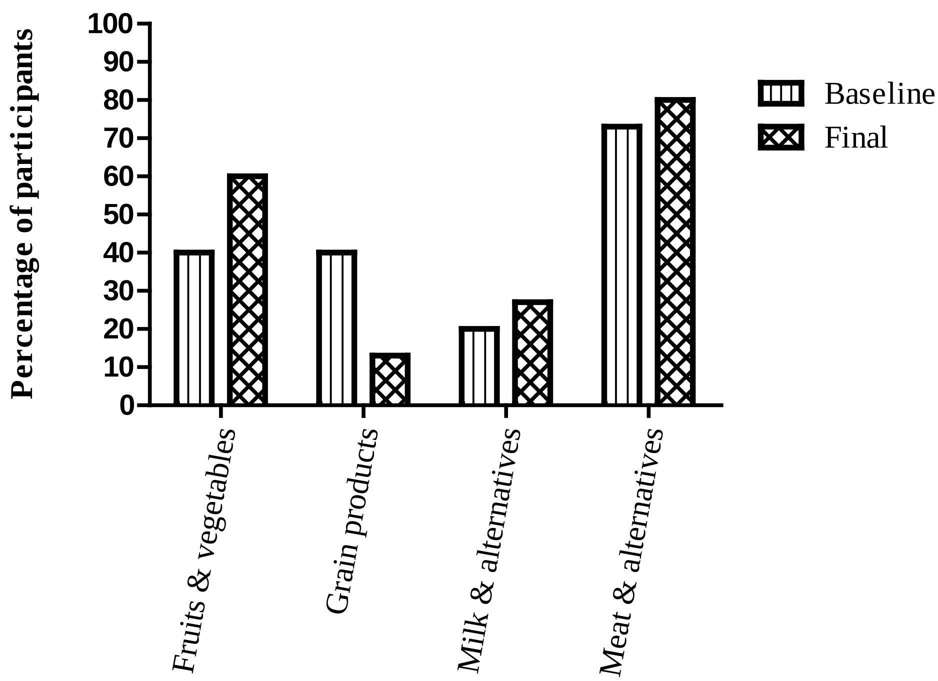
Table 4.8. Mean number of food guide servings at baseline and post-intervention

Variable	Pre-intervention (n=15)	Post-intervention (n=15)	[1] Recommendation
Fruits & vegetables	**6.5±2.6**	**7.6±4.3**	
Women	6.0±2.5	9.0±5.8	7
Men	6.9±2.8	6.7±3.1	7
Grain products	**5.4±2.2**	**4.4±1.8ǂ**	
Women	4.1±2.1	3.4±1.9	6
Men	6.2±1.9	5.1±1.3	7
Milk & alternatives	**1.7±1.0**	**1.9±1.4**	
Women	1.7±0.4	1.3±0.5ǂ	3
Men	1.7±1.3	2.3±1.6	3
Meat & alternatives	**3.2±1.4**	**3.0±1.4**	
Women	2.9±0.7	2.4±0.7	2
Men	3.5±1.7	3.4±1.6	3

Data represent servings per day and are expressed as means ± SD. All the participants were included in the analysis. ǂ $p<0.10$ based on two-tailed, paired samples t-test.
[1]Eating Well with Canada´s Food Guide.

As figure 4.5 shows, the percentage of participants meeting the recommendation for fruits and vegetables increased from 40% at baseline to 60% at program completion. In the same way the percentage meeting the recommendations for milk & alternatives and meat & alternatives increased from 20% to 27%, and 73% to 80%, respectively. On the other hand the percentage meeting the recommendation for grain products decreased from 40% to 13%. All changes were non-significant, however.

Figure 4.5. Percentage of participants meeting the food groups recommendations at baseline and post-intervention (n=15)



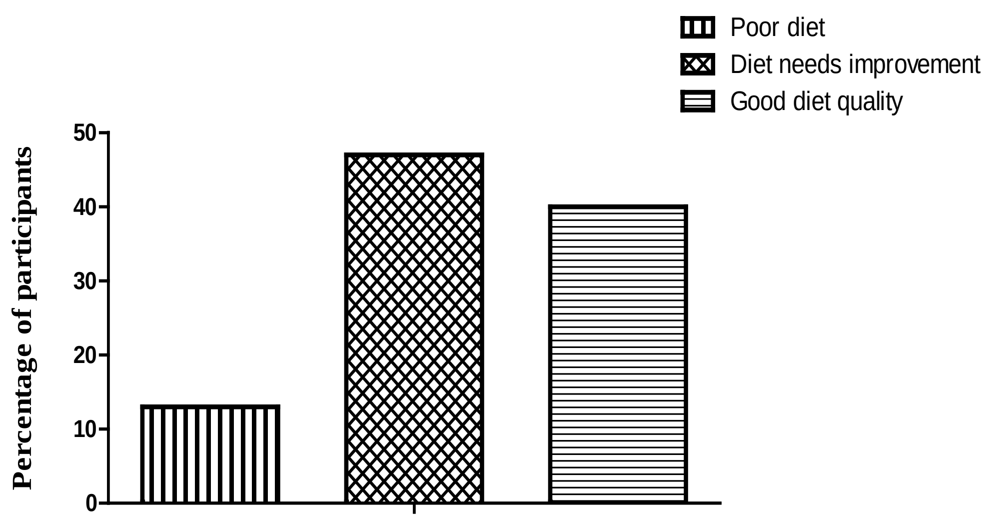
No significant differences compared by Fisher´s exact test.

4.10.3. Healthy Eating Index

The HEI-Canada was computed as an indicator of overall diet quality. The HEI score of our participants did not change from baseline (71.6±14.2) to program completion (73.6±13.9) (Table 4.9).

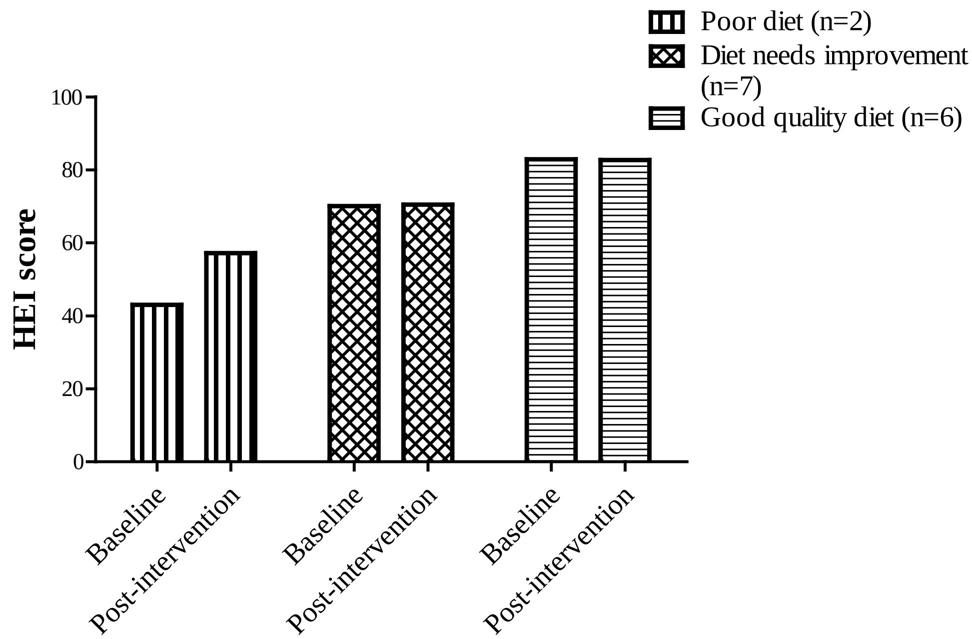
A HEI ≤50 was considered poor diet quality, whereas a HEI between 51 and 80, and higher than 80 were considered diet needs improvement and good diet quality, respectively. As figure 4.6 describes 13% of the participants were classified as having poor diet quality, 47% were classified as diet needs improvement and 40% as having good diet quality. The percentage of participants in each category did not change from baseline to program completion. As figure 4.7 shows those who were initially classified as having poor diet quality (n=2) increased their HEI score from 43.0 to 57.2, whereas those initially classified as diet needs improvement (n=7) and good diet quality (n=6) maintained a HEI score of 70 and 83, respectively.

Figure 4.6. Overall diet quality at baseline and post-intervention (n=15)



No significant differences from baseline to program completion compared by chi-square test.

Figure 4.7. Changes in HEI score according to baseline diet quality



No significant differences based on two-tailed, paired samples t-test.

4.10.4. Dietary glycemic load and glycemic index

Dietary GL and GI are important to optimize glycemic control in T2D. As table 4.9 shows, GL changed from 84.7 at baseline to 80.5 at program completion, whereas GI changed from 43.1 to 42.4. The changes did not reach statistical significance. All the subjects were classified as having a low-GI diet at baseline and after the program.

Table 4.9. Changes in diet quality, glycemic index and glycemic load

Variable	Pre-intervention (n=15)	Post-intervention (n=15)
Healthy eating index score	71.6±14.2	73.6±13.9
Glycemic load	84.7±33.1	80.5±31.5
Glycemic index	43.1±7.2	42.4±4.6

Data are presented as means ± SD. All the participants were included in the analysis. No significant differences based on two-tailed, paired samples t-test.

4.11. Biochemical assessment and anthropometric measures

4.11.1. Glycated hemoglobin and lipid profile

Table 4.10 describes the changes in glycemic control measured by HbA1c and lipid parameters. At baseline participants had an HbA1c of 8.2%, which indicated poor glycemic control. After the 12 weeks of study they were able to significantly decrease their HbA1c by -1.4% (p=0.006) reaching a level of 6.9% which is within recommended target of the CDA (CDA, 2008). When an outlier (participant with a difference greater than the mean plus 2 SD) was removed from the analysis, the decrease in HbA1c remained significant (7.9±1.6 vs 6.9±1.3, p=0.0007). There were no gender differences in the change in HbA1c.

After the program participants achieved a more favorable lipid profile. Triglycerides at baseline were slightly over the ideal range with 150.9 mg/dL and after the program they decreased to 113.0 mg/dL reaching borderline significance (p=0.06). Likewise, there was a significant increase in HDL-cholesterol of +5.9 mg/dL (p=0.04). In contrast, there was a non-significant decrease in total cholesterol, LDL cholesterol and the total cholesterol/HDL ratio of -5.6 mg/dL, -3.9 mg/dL and -0.9 units respectively. There were no significant gender differences in the changes in lipid parameters.

Table 4.10. Changes in glycated hemoglobin and lipid parameters

Variable	Pre-intervention (n=15)	Post-intervention (n=15)	Mean difference	p value
Glycated hemoglobin (%)	8.2±2.0	6.9±1.3	-1.4±0.7	p=0.006
Triglycerides mg/dL (mmol/L)	150.9±73.7 (1.7±0.8)	113.0±46.6 (1.3±0.5)	-37.9±71.0 (-0.43±0.8)	p=0.06
Total cholesterol mg/dL (mmol/L)	174.1±39.4 (4.5±1.0)	168.5±26.8 (4.4±0.7)	-5.6±36.9 (-0.1±1.0)	p=0.57
HDL cholesterol mg/dL (mmol/L)	36.4±7.7 (0.9±0.2)	42.2±9.8 (1.1±0.3)	+5.9±10.2 (+0.2±0.3)	p=0.04
LDL cholesterol mg/dL (mmol/L)	107.5±37.4 (2.8±1.0)	103.7±26.8 (2.7±0.7)	-3.9±36.8 (-0.1±0.9)	p=0.69
*Total cholesterol/ HDL ratio	4.2 (3.2-7.8)	3.5 (2.8-7.1)	-0.9 (-4.4-2.4)	ǂp=0.15

Data are means ± SD unless otherwise indicated. All the participants were included in the analysis. P value is based on two-tailed, paired samples t-test unless otherwise indicated. *Median (range). ǂ P value based on two-tailed, Wilcoxon signed-rank test.

4.11.2. Anthropometric measures

Table 4.11 shows mean changes in anthropometric measures. At baseline participants´ weight was 99.3 kg, mean BMI was 34.6 kg/m^2 and 80% were classified as obese, 13% as overweight and 7% as normal weight (figure 4.8). Waist circumference was higher that recommended with 114.4 cm, fat mass was 41.2 kg or 41.1 % and fat free mass was 58.1 kg or 58.9%. After the program, there were significant improvements in weight status and body composition ($p<0.05$ for all). Participants decreased their weight by -2.6 kg, BMI by -0.9 kg/m^2 and waist circumference by -2.8 cm. Furthermore, fat mass decreased by -2.5 kg or -1.4% and the percentage of fat free mass increased by +1.4%. As shown in figure 4.8, after the study 74% of participants were classified as obese, 13% as overweight and 13% as normal weight. There were gender differences in the changes in anthropometric measures. Changes in weight, BMI, fat mass (kg and %) and percentage of fat free mass were only statistically significant in men. Women had a significant decrease in waist circumference and in men this was only a trend ($p<0.10$).

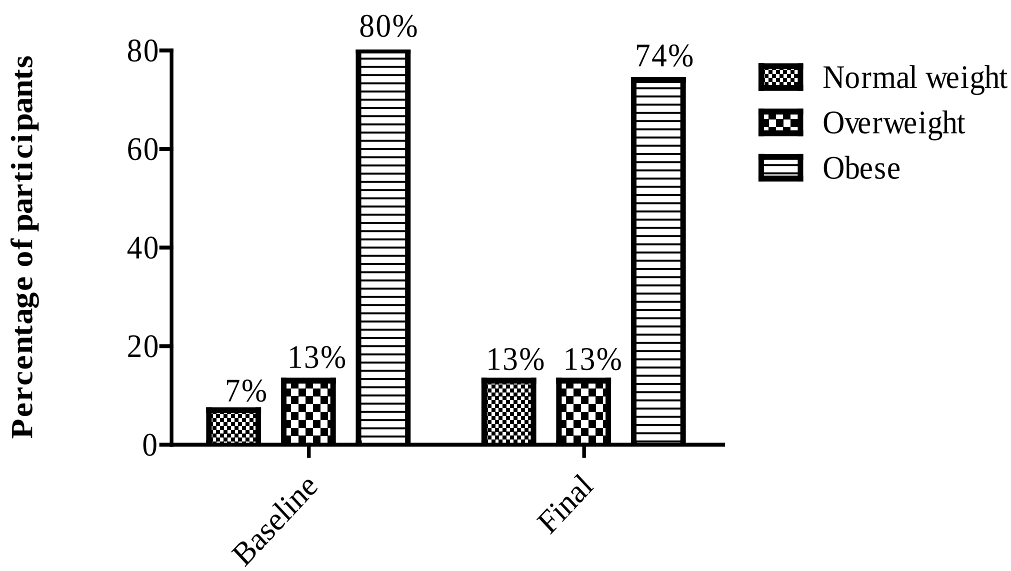
Table 4.11. Changes in weight, waist circumference and body composition

Variable	Pre-intervention (n=15)	Post-intervention (n=15)	Mean difference	p value†
Weight (kg)	99.3±19.3	96.7±19.1	-2.6±3.8	p=0.02
Women	87.9±13.1	86.1±12.2	-1.8±3.8	
Men	106.9±19.5	103.7±20.2	-3.2±3.9*	
Waist circumference (cm)	114.4±15.2	111.6±15.2	-2.8±3.7	p=0.009
Women	108.3±12.9	105.6±11.8	-2.7±2.4*	
Men	118.6±16.0	115.6±16.6	-3.0±4.5ǂ	
Body mass index (kg/m^2)	34.6±5.7	33.7±5.6	-0.9±1.4	p=0.02
Women	34.2±4.9	33.4±4.1	-0.7±1.6	

Men	34.9±6.5	33.8±6.6	-1.1±1.3*	
Fat mass (kg)	41.2±12.2	38.7±11.9	-2.5±3.4	p=0.01
Women	41.2±9.1	39.8±7.9	-1.4±3.8	
Men	41.2±14.5	38.0±14.4	-3.2±3.2*	
Fat mass (%)	41.1±7.6	39.7±8.1	-1.4±2.3	p=0.03
Women	46.5±4.4	45.9±4.0	-0.6±2.0	
Men	37.5±7.2	35.5±7.5	-2.0±2.5*	
Fat free mass (kg)	58.1±11.3	58.0±11.7	-0.1±1.4	p=0.71
Women	46.6±5.1	46.3±5.4	-0.3±0.5	
Men	65.8±6.5	65.7±7.2	-0.02±1.8	
Fat free mass (%)	58.9±7.6	60.3±8.1	+1.4±2.3	p=0.03
Women	53.5±4.4	54.1±4.0	+0.6±2.0	
Men	62.5±7.2	64.5±7.5	+2.0±2.5*	

Data are means ± SD. All the participants were included in the analysis.
† Significance of the mean difference for both genders based on two-tailed, paired samples t-test. * $p<0.05$ and ǂ $p<0.10$

Figure 4.8. Participants classified as normal weight, overweight or obese pre-and post-intervention (n=15)



No significant differences compared by chi-square test.

4.11.3. Health parameters according to changes in diet quality

According to the HEI-Canada changes during the study, participants were divided into those who improved their diet quality (i.e. increased HEI) and those who did not (i.e. decreased HEI). Sixty-seven percent of the participants improved their diet quality and 33% reported worse diet quality. Glycated hemoglobin, lipid parameters and anthropometric measures were not significantly different between the 2 groups at baseline (compared by independent samples t-test). Compared with baseline, those individuals who improved their diet quality significantly decreased their HbA1c (p=0.007), triglycerides (p=0.03) and waist circumference (p=0.02) (table 4.12). Also, this group showed a strong trend towards decreased body weight (p=0.051) and BMI (p=0.054), as well as kilograms of fat mass (p=0.08). In contrast, individuals who worsened their diet quality had no significant improvements in any of the parameters; however this group showed a trend towards increased HDL cholesterol (p=0.06), decreased fat mass (kg p=0.10 and % p=0.08) and increased percentage of fat free mass (p=0.08). When the 2 groups were compared with each other, there were no significant differences in the final parameters or in the mean changes.

Table 4.12. Mean changes in glycated hemoglobin, lipid parameters and anthropometric measures in participants according to whether they improved or worsened diet quality

	Improved diet quality (n=10)			Worsened diet quality (n=5)		
Variable	**Baseline**	**12-weeks**	**Mean Change**	**Baseline**	**12-weeks**	**Mean change**
HbA1c (%)	7.7±1.4	6.7±1.0	-1.0±0.9*	9.3±2.7	7.2±1.8	-2.1±2.6
TGs (mg/dL)	149.1±56.8	109.9±46.7	-39.1±48.9*	154.5±108.3	119.2±51.2	-35.2±110.8
Total-c (mg/dL)	175.3±35.6	167.8±28.0	-7.5±32.9	171.6±50.7	169.9±27.3	-1.7±47.9
HDL-c (mg/dL)	37.4±8.8	43.8±10.7	+6.4±12.4	34.4±5.1	39.2±7.8	+4.8±4.0ǂ
LDL-c (mg/dL)	108.1±32.3	102.1±24.7	-6.1±35.1	106.4±50.6	106.9±33.4	+0.5±43.9
Total-c/HDL	5.0±1.7	4.1±1.4	-0.9±2.1	5.1±1.6	4.6±1.7	-0.5±1.8

Weight (kg)	94.7±16.9	91.5±16.3	-3.1±4.4ǂ	108.6±22.2	106.8±22.1	-1.7±2.4
WC (cm)	112.9±14.4	109.5±13.5	-3.4±3.9*	117.5±18.1	115.8±19.1	-1.6±3.0
BMI (kg/m²)	33.9±5.4	32.8±5.1	-1.1±1.6ǂ	36.0±6.8	35.4±6.6	-0.6±0.8
FM (kg)	38.6±11.2	36.1±11.0	-2.5±3.9ǂ	46.4±13.8	44.0±12.9	-2.4±2.5ǂ
FM (%)	40.5±8.4	39.1±8.9	-1.4±2.7	42.3±6.5	40.8±6.9	-1.5±1.5ǂ
FFM (kg)	56.1±11.3	55.5±11.1	-0.6±1.4	62.2±11.3	62.9±12.4	+0.7±1.2 †
FFM (%)	59.5±8.4	60.9±8.9	+1.4±2.7	57.7±6.5	59.2±6.9	+1.5±1.5ǂ

Abbreviations: HbA1c: glycated hemoglobin; TGs: triglycerides; Total-c: total cholesterol; HDL-c: HDL cholesterol; LDL-c: LDL cholesterol; Total-c/HDL: total cholesterol/HDL ratio; WC: waist circumference; BMI: body mass index; FM: fat mass; FFM: fat free mass.
*$p<0.05$ and ǂ $p<0.10$ within the study group, based on two-tailed, paired samples t-test.
† $p<0.10$ for the difference between groups compared with two-tailed, independent samples t-test.

4.12. Feasibility of menu planning

The pilot study drew the attention of several persons that called or emailed us to receive more information. The time commitment required was one of the main reasons why people were no longer interested after receiving more information about the study. Twenty-six subjects were screened for eligibility, 3 (12%) did not meet the inclusion criteria, and 23 (88%) consented to take part in the study. One out of the 23 participants did not complete the baseline assessment, 2 participants completed the baseline assessment but did not return the 3-day food record. Twenty (87%) participants completed all the baseline assessment including the 3-day food record, commenced the study and completed the first month of follow up. During the second month of study 3 participants (13%) dropped out and later during the 3rd month 2 (9%) participants more dropped out. Fifteen subjects or 65% completed the study. Personal reasons were mentioned as reasons for drop-out by 5 participants followed by time constraints (2 participants). One participant was lost to follow-up.

The 15 subjects that completed the study were highly participative in all the study procedures: 93% attended at least one follow-up session during the first month and 80% and 73% attended the booster sessions in the 2^{nd} and 3^{rd} months, respectively. Participants attended an average of 4 (range 2-6) out of 6 possible follow-up sessions. Also, the weekly records were completed and returned by 87% of the participants during the 1^{st} and 2^{nd} months and 93% during the last month. Furthermore, 11 (73%) participants took part in the focus group interviews and 11 (73%) were contacted for follow-up two months after study completion.

In spite of the high drop-out rates (35%), participation among those who completed the study and some other indicators support the feasibility of this strategy in people with T2D. Participants reported using the menu plan an average of 5 days per week throughout the 12 weeks. Also, results from the exit survey show that participants perceived the menu plan to have an influence in different aspects of their diets, for example they perceived it was useful to have more regular meals, to make healthier food choices and to have healthier foods available at home, among other benefits. Finally, 7 out of the 11 participants who were contacted for follow-up reported that they were still using the menu plan as a resource for healthy eating and 2 participants reported that although they were not using the menu plan, they were definitely making healthier food choices.

Chapter 5. Discussion

Diet quality

Nutrient profile

Nutrient intakes at baseline were within the recommendations of the CDA NTG, except for saturated fat (9.6%), cholesterol (299 mg) and sodium (2480 mg), which were higher. Several studies have reported that recommended intakes of saturated fat, cholesterol and sodium are difficult to achieve for people with T2D. In addition, adequate intakes of total fat and fiber have also been reported as difficult to meet (Jarvandi et al., 2011; Muñoz-Pareja, et al., 2012; Rivellese, et al., 2008; Thanopoulou, et al., 2004; Vitolins, et al., 2009). However, our participants had intakes of these nutrients of 29.9% and 26 g, respectively, which are within the recommended limits. On the other hand, the intake of carbohydrates was in the lower end of the recommendation (48.2%) which may explain the higher inclusion of protein (19.6%) in the diet.

No significant changes were observed in caloric or nutrient intakes after following the menu plan for 3 months, except that sodium decreased significantly in women (2059 mg vs 1318 mg, $p=0.04$), and in the subgroup of participants with intakes above the upper limit at baseline (3068 mg vs 2235 mg, $p=0.06$). Similar results were observed in the program titled Kitchen Creations: a cooking school for people with diabetes and their families. After 4 cooking sessions, participants decreased their median sodium intake by -217 mg ($p<0.05$) and the change was greater in those individuals who had the highest intakes at baseline (median 3,594 mg vs 2,696 mg) (Archuleta et al., 2012). The benefits of menu planning on sodium intake may be related to a change in food selection and cooking techniques. For example, preparing more foods following the menus and recipes instead of eating processed foods (which are usually higher in sodium), might lead to a decrease in sodium intake. Similar benefits were reported in 2 studies that included cooking lessons as part of their curriculum. In these studies participants reported improvements in nutrition knowledge, cooking skills, and food selection behaviors (Abbott, Davison, Moore, & Rubinstein, 2012; Archuleta, VanLeeuwen, Halderson, Wells, & Bock, 2012).

After the study, the overall sample and the subgroup of participants with the highest intake at baseline achieved sodium intakes below the upper tolerable limit, 2008 mg/day and 2235 mg/day, respectively. Although these levels are still above the adequate intake for sodium (i.e. 1500 mg), this improvement may have positive health benefits, for example in blood pressure (Sacks, et al., 2001); however, blood pressure was not measured in our participants. Also the levels achieved are consistent with the objectives of the Sodium Reduction Strategy for Canada which establishes as a long-term objective achieving a sodium intake below 2300 mg/day for most of Canadians (Barr, 2010).

Food intake analyzed by food groups from Eating Well with Canada's Food Guide

At baseline, intakes as measured by food guide servings were below the recommendations of EWCFG except for meat and alternatives: fruits and vegetables (6.5 servings/day), grain products (5.4 servings/day), milk and alternatives (1.7 servings/day), and meat and alternatives (3.2 servings/day). Similar results have been reported for Canadians with and without diabetes (Garriguet, 2007b; Jarvandi et al., 2011), except for the consumption of fruits and vegetables, which was higher in our sample (~1 serving/day).

Since the menu plan was based on the recommendations of EWCFG some improvements in intakes of food group servings were expected. At program completion, participants achieved an intake of fruits and vegetables consistent with the recommendations (7.6 servings/day), and this improvement mainly reflected an increase in vegetables (~1 serving). However, surprisingly, participants decreased their intake of grain products by 1 serving. A study in Japanese elderly with T2D showed that grain intake decreased progressively with an increase in vegetable intake (Takahashi, et al., 2012). One possible explanation may be that participants were concerned about the effect of a higher intake of carbohydrates on blood sugar levels. Thus, as they increased their intake of fruits and vegetables, they decreased grain product servings and maintained a similar carbohydrate intake throughout the study. Other authors have observed that people with T2D focus on reducing the amount of carbohydrates, regardless of the type and quality, to control blood sugar levels and to lose weight (Vitolins, et al., 2009; Raynor, et al., 2008).

Even though the change from baseline to post-intervention was not statistically significant, achieving an intake of more than 7 servings of fruits and vegetables may have health benefits for the participants. In the study of elderly Japanese with T2D, participants with higher intakes of total vegetables (i.e. ≥200 g) and green vegetables (i.e. ≥70 g) had lower HbA1c and triglycerides (Takahashi, et al., 2012), suggesting a possible benefit of increased vegetable intake in metabolic outcomes. On the other hand, diets rich in fruits and vegetables (i.e. 5 servings/day) have been associated with lower risk of CVD, the leading cause of death in individuals with T2D (Hung, et al., 2004; PHAC, 2011). Furthermore, it has been suggested that a higher intake of fruits and vegetables is negatively correlated with long-term weight gain (Mozaffarian, Hao, Rimm, Willet, & Hu, 2011).

The increased consumption of vegetables and decreased intake of grain products at the end of the study along with the sustained intakes of carbohydrates and fiber, suggested the possibility of a change in carbohydrate quality. Therefore, we calculated the GI and GL of the diets and observed non-significant changes in both parameters. However, it is important to note that these parameters were also low at baseline.

Healthy Eating Index

The HEI has been used by other authors to evaluate diet quality in people with and without diabetes. Chen et al. (2011) evaluated diet quality in a sample of Americans with T2D using the HEI-2005. In this study, participants had a mean HEI of 56.1. Garriguet (2009) reported that the HEI for Canadian adults was 59.5, and 84.7% of the participants were classified as diet needs improvement. Similar results were reported by our research group in a sample of elderly with T2D, for whom the mean HEI score was 64.4 and 87.5% of the participants were classified as diet needs improvement (Asaad, 2012). In these 3 studies, less than 3% of the participants were classified as having good diet quality.

In the current study, the HEI score was higher than in the above-mentioned studies, 71.6 at baseline and 73.6 at program completion (p=0.4). Contrary to what has been reported, 47% of our participants were classified as diet needs improvement and 40% were classified as having good diet quality at baseline and at program completion. The fact that almost half of the participants were classified as having good diet quality at baseline, as well as our small sample size may have influenced our ability to observe a significant change in the HEI score.

Another possible reason why we did not observe a significant change in the HEI score may be that it was not specifically developed to evaluate diet quality in T2D. Although, the food groups and nutrient intakes included in the HEI apply for people with diabetes as well as healthy individuals, there are specific recommendations for people with T2D that are not captured using the HEI (CDA, 2008). These recommendations include the distribution of carbohydrate-containing foods evenly throughout meals, the inclusion of low GI foods, avoiding foods high in sugar and fat, and emphasizing foods high in fiber, foods rich in omega 3 fatty acids and the use of vegetable oils for cooking. However, all these aspects were considered in the PDAQ score, which increased significantly at program completion (median 43.0 vs 46.0, p=0.01).

It is expected in dietary interventions that some participants will have better outcomes than others. In this study, 67% of the participants improved their HEI score. Moreover, this approach showed to be more beneficial for those who were initially classified as having poor diet quality since they increased their HEI score from 43 to 57, thus, they changed from poor diet quality to diet needs improvement. A higher HEI score has been associated with lower BMI and lower risk of CVD (Chiuve, et al., 2012). Also, modest improvements in dietary behaviors have been associated with better health outcomes in subjects at risk of T2D (Kontogianni, et al., 2012). Furthermore, it was recently proposed that a small-changes approach in which people are helped to make small, conscious lifestyle changes at a population level could reverse the trends of diabetes and CVD (Hill, 2009). Therefore, considering the pilot nature of the study and the implementation in free-living individuals, helping more than half of the participants to make small changes in their dietary habits is something that deserves attention. A study with a larger sample size will help determine the true benefits of this approach to improve diet quality.

Biochemical assessment and anthropometric measures

Previous research has shown that nutrition therapy leads to significant improvements in weight status, HbA1c and lipid parameters over 3 months (Franz, et al., 1995; Manley, et al., 2000).

After 3 months of following the menu plan, there were significant changes in biochemical measures in the participants. Glycated hemoglobin decreased by -1.4% from 8.2% at baseline (-1.0% when an outlier was removed from the analysis), there was a trend towards decreased triglycerides (-37.9 mg/dL from 150.9 mg/dL) and a significant increase in HDL-cholesterol (+5.9 mg/dL from 36.4 mg/dL). Perhaps because of the use of lipid-lowering medications by almost half of the sample, there were no differences in total cholesterol and LDL-cholesterol. Our results are consistent with findings from other studies of similar duration. Ash et al. (2003) showed that a 12-week dietary intervention could decrease HbA1c by -1.0 % and triglycerides by -26.7 mg/dL independently of the type of intervention (i.e. meal replacement, meal provision or self-selected diet) (Ash, et al., 2003). Ziemer et al. (2003) reported that a simple meal plan emphasizing healthy food choices was as effective as an exchange-based meal plan in improving glycemic control and lipid parameters. At 6 months, there was a significant decrease in HbA1c (-1.9 %), triglycerides (-48.0 mg/dL) and an increase in HDL-cholesterol (+2.3 mg/dL). There were no changes in the rest of the lipid parameters (Ziemer, et al., 2003). Another study showed that consuming either a prepared meal plan (i.e. food provision) or a self-selected diet based on the ADA NTG for 10 weeks led to a significant decrease in HbA1c (-0.8%) and triglycerides (-19.6 mg/dL) (only for the self-selected diet) (Pi-Sunyer, et al., 1999).

Different factors influence metabolic parameters. In the exit survey conducted at the end of the study, most of the participants agreed or strongly agreed that the menu plan helped them to make healthier food choices, to decrease the amount of food consumed and to have more regular meals. Also, as a result of having recipes along with the menus, the participants may have changed some of their food preparation techniques. Ziemer et al. (2003) reported that by making healthier food selections (i.e. lower in fat and sugar) participants decreased their HbA1c, triglycerides and increased HDL-cholesterol without major improvements in weight status (Ziemer, et al., 2003). Also, data from our research group showed a negative association between the frequency of choosing recommended foods and HbA1c (Devi Durai Raj, 2012). Furthermore, participants in our study reported improvements in basic eating practices such as consuming foods high in sugar and fat with less frequency, and spacing carbohydrates evenly throughout the meals more often. It has been suggested that these basic practices along with meal planning, portion control and regularity in meal consumption and in carbohydrate intake are associated with better glycemic control (CDA, 2008; Savoca, Miller, & Ludwig, 2004; Vallis, Higgins-Bowser, Edwards, Murray, & Scott, 2005; Wolever, et al., 1999). Also, changes in the source of carbohydrates, for example more vegetables and less grain products, are related to lower HbA1c and triglyceride levels (Savoca, et al., 2004; Takahashi, et al., 2012).

Medication use and physical activity are factors that influence metabolic parameters. In this study, medication use did not change in most of the participants (72%), some others discontinued medications (20%) and only one participant increased the dose of a prescribed anti-diabetic drug. In the case of physical activity, it was recently reported that behavioral interventions targeting free-living individuals with T2D decreased HbA1c by -0.32% (Avery, Flynn, van

Wersch, Sniehotta, & Trenell, 2012); however, in the present study, only one participant reported an increase in physical activity.

Acute changes in caloric intake (12-16 weeks) and weight loss are associated with better glycemic control (Ash, et al., 2003; Wing, et al., 1987). For example, in the study of Ash et al. (2003) a reduction in body weight of 6.5% was associated with a decrease in HbA1c of 1.0% among men with T2D (Ash, et al., 2003). Also, weight loss is associated with lower triglyceride levels and higher HDL-cholesterol levels (Wing, et al., 1987). Even though caloric restriction was not emphasized in our study, participants were able to significantly improve their weight status and body composition: weight decreased by -2.6 kg (-2.6%) from 99.3 kg at baseline, waist circumference decreased by -2.8 cm from 114.4 cm, BMI decreased by -0.9 units from a mean of 34.6 kg/m2. Also, fat mass decreased by -1.4% and fat free mass increased by 1.4%. Moreover, the proportion of participants classified as obese decreased by 6%.

The changes in anthropometric measures observed in our study are similar or modest compared with other studies. One study showed that moderate caloric restriction led to a weight loss of -6.4 kg (6.5%), as well as to a decrease in the percentage of body fat of -1.9% and waist circumference of -8.1 cm over 12 weeks (Ash, et al., 2003). Also, in the study of Pi-Sunyer et al. (1999) participants decreased their body weight by -3.4 kg and -2.9 kg after following a prepared meal plan or a self-selected diet, respectively, for 10 weeks (Pi-Sunyer, et al., 1999). Wing et al. (1996) showed that menu planning was effective for achieving weight loss in obese subjects. After 26 weeks, participants decreased significantly their weight by -12 kg (Wing, et al., 1996). Finally, a short study evaluating the acceptability and usefulness of a 2-week menu plan in 10 subjects with T2D showed modest weight losses ranging from 1-3.5 kg (Cunningham, et al., 2006).

The effectiveness of menu planning in weight loss has been associated with changes in the food environment and increased structure in dietary patterns. For example, in the study of Wing et al. (1996) participants reported positive changes in the type of foods stored at home, more regular eating patterns and less difficulty estimating portion sizes. Furthermore, they were more likely to report having a plan for their meals (Wing, et al., 1996). As reported by the majority of our study participants in the exit survey, these aspects of their diets were influenced by using the menu plan.

Other dietary behaviors have been related with weight status in subjects with T2D. For example, greater frequency of fast food consumption per week has been associated with higher BMI, while more regular eating patterns such as a greater number of days consuming breakfast have been related with lower BMI (Raynor, et al., 2008). In the same way, eating food away from home has been associated with higher caloric intake and long-term weight gain (Mancino, Todd, & Lin, 2009). Therefore, if participants cooked more at home instead of eating out, or if they managed to make healthier food selections in their meals, we could expect to see some benefits in weight status. Also, as reported in the exit survey, having more regular meals and decreasing the amount of food consumed (i.e. portion control) may have led to improvements in weight status. In fact, a study in obese subjects with T2D in Canada showed that portion control strategies such as a calibrated dinner plate and a breakfast bowl led to greater weight loss at 6 months compared with usual care (-2.1 kg vs -0.1 kg, $p<0.05$) (Pedersen, Kang, & Kline, 2007).

The above mentioned changes in dietary behaviors may promote weight loss by decreasing daily caloric intake, although this was not an intervention goal in our study. In fact, the menus included in the menu plan provided an average of 2055 kcal/day. At program completion daily caloric intake of our participants was significantly lower compared to their TEE, therefore, weight loss was physiologically plausible. Moreover, we observed a modest decrease in caloric intake of 343 kcal/day (median). It has been proposed that the discrepancy between energy intake and energy expenditure responsible for long-term weight gain in the US could be eliminated by changes in energy expenditure and/or caloric intake of around 100 kcal/day (Hill, 2009). Therefore, the importance of modest changes in caloric intake on weight loss cannot be dismissed. Also, the possibility of increased energy expenditure due to changes in physical activity as a contributor to the observed weight loss cannot be ruled out. However, during the follow-up sessions, only one person reported changes in physical activity.

Finally, those participants who improved their diet quality (i.e. increased HEI) had significant improvements in HbA1c, triglycerides and waist circumference. Also, this group showed a trend towards decreased body weight, BMI and kilograms of fat mass. Therefore, these results highlight the importance of adherence to dietary guidelines (i.e. as measured in the HEI) for achieving optimal glycemic control and health outcomes (Chiuve, et al., 2012; Kontogianni, et al., 2012; Metz, et al., 1997). A study with a larger sample size will help to establish the benefits of menu planning in metabolic parameters.

Ambivalent results were observed regarding changes in dietary and biochemical and anthropometric variables: improvements in weight, waist circumference, body composition, HbA1c, triglycerides and HDL-cholesterol occurred, while the dietary variables remained unchanged with the exception of the PDAQ score. The accuracy of biochemical and anthropometric variables was assured by following standard protocols described in the methodology section. Briefly, anthropometric measurements were taken in triplicate following the protocol, the Bod Pod® was calibrated before use and participants wore appropriate clothing and were fasting for the assessment, the auto analyzer for the HbA1c measurement was calibrated before use and quality control procedures were performed routinely. Furthermore, as was previously noted, minimal changes in medication use and physical activity occurred during the program, therefore these variables are unlikely to have played a major role in anthropometric and biochemical outcomes. In contrast, all the dietary information from this study (except the PDAQ) was derived from a 3-day dietary intake record applied at pre-and-post intervention. It is known that under-reporting of dietary intake is a common source of error when using 3-day food records (Gibson, 2005). Moreover, accuracy of the data depends on the subject´s ability to estimate portions of food (Gibson, 2005); this ability might have changed as a result of participating in the program. Therefore, underestimation of portions of food at baseline may have influenced the accuracy of the data collected at this point; then observing significant differences from baseline to program completion would be more difficult. In summary, the biases associated with the food records are greater than those associated with the anthropometric and biochemical measures; therefore, anthropometric and metabolic outcomes more accurately reflect the effect of the program than dietary variables.

Feasibility of menu planning

The results obtained from this pilot study add to the body of literature supporting the feasibility of menu planning for the dietary management of obesity and T2D (Cunningham, et al., 2006; Wing, et al., 1996). First, 88% of the persons who were screened for eligibility met the inclusion criteria and agreed to take part in the study. Furthermore, the program was acceptable for most of the participants as 65% of them completed the study. Similar retention rates have been reported in other pilot studies (Kluding, et al., 2010). Moreover, compared with completers, participants that dropped-out were younger, currently employed and most of them had high income. All these factors have been related with lower dietary adherence and poor diet quality among people with T2D (Maxwell, 2011; Nelson, et al., 2002; Travis, 1997), therefore, a different strategy for program delivery may be necessary for these specific groups.

For the subjects who did complete the program, adherence to study procedures was acceptable. First, participants reported using the menu plan an average of 5 days/week throughout the study, and all of them completed the 3-day food records, biochemical and anthropometric assessments. Furthermore, participants attended an average of 4 out of 6 possible follow-up sessions. Also, the weekly records were returned by approximately 90% of the participants during the 12 weeks. Moreover, 73% of the participants took part in the focus group interviews and 73% were contacted for follow-up two months after study completion. Sixty-four percent of the participants contacted for follow-up reported that they were still using the menu plan as a resource for healthy eating. All these results indicate that the program itself was acceptable and feasible.

On the other hand, the usefulness of this strategy to modify dietary behaviors was confirmed in the exit survey where participants expressed different aspects of their diets that changed by following the menu plan. For example, they perceived it was useful to have more regular meals, to make healthier food choices and to control the portions of food consumed, among other benefits. Despite the above-mentioned results, the acceptability, feasibility and effectiveness to the larger population remain to be established.

Chapter 6. Conclusion, limitations and implications

Conclusion

As was previously suggested, integrating the multiple dietary recommendations for T2D into a single approach may be a good strategy to improve diet quality. Therefore, we took a simple, non-expensive, and common clinical practice and developed a resource that simplified the overall recommendations of the CDA NTG. Our menu plan includes 4 weeks of menus along with different resources to facilitate their use such as recipes, weekly grocery lists and cooking tips. Importantly, it took into account aspects of the food environment in Alberta, such as food acceptability, accessibility and availability when choosing the menu items and recipes.

We hypothesized that upon completion of the menu plan intervention, participants would improve the quality of their diets. Consequently, changes in diet quality would lead to improvements in glycemic control and health parameters. From the results obtained we can conclude the following:

- The results of this study suggest that menu planning may induce changes in food selection and food preparation techniques, thus, it may contribute to improvements in the intake of selected nutrients such as sodium. Moreover, this approach was useful to improve consumption of fruits and vegetables. However, the decrease in grain products suggests the need for including concepts such as the GI of the foods in the education component of the program to help participants focus on carbohydrate quality and not only on carbohydrate quantity. In line with these changes in food selection, there were no significant changes in the GI and GL of the diets. However, these parameters were also low at baseline, reflecting the borderline intake of carbohydrates and high intake of fiber in our sample.

- Overall diet quality measured by the HEI score did not change significantly. However, 67% of the participants increased their HEI score, and those initially classified as having poor diet quality were able to improve their score and change to ‘diet needs improvement’. A larger sample size and a larger number of participants with poor diet quality or diet in need of improvement, which are more representative of people with T2D, would help to establish whether this approach positively impacts diet quality. On the other hand, although the HEI is an indicator of food and nutrient intakes, it may not capture all the dietary behaviors that influence glycemic control and health parameters. Therefore, we included a measure of dietary adherence that was specifically designed to account for the recommendations of the CDA NTG, the PDAQ, and observed a significant improvement. Further development and validation of the PDAQ is warranted.

- Consistent with what is usually seen in patients with T2D, glycemic control, triglycerides, LDL-cholesterol and HDL-cholesterol levels at baseline were suboptimal. At program completion, there was an important decrease in HbA1c, triglycerides and an increase in HDL-cholesterol. These improvements seem to be related to changes in specific dietary behaviors and to weight loss (adipose tissue). On the other hand, the effects of medications and exercise in these parameters cannot be ruled out, although medication use stayed constant for most of the participants (72%) and minimal changes in physical activity were reported.

- According to their BMI, 80% of our participants were obese at baseline and, as it would be expected, had high fat mass and abdominal fat (waist circumference). At program completion, there was a significant decrease in weight, waist circumference, BMI, fat mass and a significant increase in fat free mass. Changes in dietary behaviors such as decreasing portions of food and having more regular meals may have promoted weight loss by decreasing daily caloric intake. The possibility of increased energy expenditure due to changes in physical activity as a contributor to the observed weight loss cannot be ruled out; but only one participant reported changes in physical activity after joining the program.

- Participants who improved their diet quality had significant improvements in HbA1c, triglycerides and waist circumference.

- Finally, considering the recruitment and retention rates in this pilot study, as well as the overall adherence to the study procedures, menu planning was shown to be an acceptable and feasible strategy for the dietary management of T2D. The acceptability and feasibility to the larger population needs to be further studied.

Menu planning combined with individual counseling was demonstrated to be effective for improving specific dietary behaviors, adherence to the CDA NTG, glycemic control and health parameters, however, its effectiveness in diet quality measured by the HEI needs to be further studied.

Limitations

The present study has several limitations:

- The sample size is the first methodological limitation of the study that must be acknowledged. First, due to the small sample size we may not have had enough power to detect significant differences in some of the variables such as the HEI score. Furthermore, the results in which the variables were stratified for analysis (i.e. changes in diet quality according to baseline HEI, and changes in metabolic parameters according to whether participants increased or decreased their HEI), need to be studied in a larger group of participants.

- The inclusion of volunteers who were highly motivated to manage their disease and thus may not be representative of the general population with T2D. This assumption is supported by the fact that 40% of participants had good diet quality at baseline. Also, this may have influenced our ability to detect significant differences in the diet quality score. The acceptability, feasibility and effectiveness of this strategy in people with poorer diet quality need to be further studied.

- Eighty percent of the participants were white, thus, more information is needed to establish the acceptability of this strategy among people from different ethnic backgrounds.

- We used one-on-one meetings for the delivery of the program; therefore, contact time may have influenced the results. Nevertheless, simple correlations showed no association between the number of meetings that participants attended and changes in diet quality or health parameters.

- We used 3-day food records to obtain a representative account of participants' diet. The challenges of collecting highly accurate food records without extensive monitoring need to be acknowledged, as well as the possibility of participants´ modifying their usual intake for the recording process and the possibility of underestimating portions of food, especially at baseline.

- We analyzed the amount of sodium present in processed and natural foods but not salt added at the table or during preparation; therefore, we are providing a conservative estimate of sodium intake.

- The HEI has not been validated in people with T2D and as was mentioned before it does not capture some dietary behaviors that may impact glycemic control.

- In a previous study, the items of the PDAQ were correlated with nutrient intakes from 3-day food records and the total PDAQ score was correlated with HbA1c. Although these results suggest the PDAQ may be a good measure of dietary adherence in diabetes, the limitations of self-reporting questionnaires must be acknowledged. One of the limitations is the possibility of participants reporting higher adherence to the recommended diet to impress the researcher. Furthermore, the PDAQ has not been validated.

- Participants reported minimal changes in medication type and dose during the study (3 participants discontinued medications and 1 increased the dose of metformin); however, it is unknown whether changes had occurred in the weeks immediately preceding joining the program.

- Since the physical activity questionnaire was not applied at program completion, information of changes in physical activity during the program was obtained from the records that the study coordinator kept during the follow-up sessions.

Implications and future directions

Bearing in mind the growing prevalence of T2D in Canada and the importance of nutrition therapy in its management, the development of strategies that facilitate changes in dietary behaviors is essential.

The results of this study can be seen as further support for the idea that menu planning may be a good strategy to improve diet quality and health outcomes, however, the true benefits of this approach will be demonstrated in our next study. This study will involve a larger number of participants, and it will include nutrition education and a revised version of the menu plan as the main components. Also, instead of one-on-one meetings, it will be delivered in small groups of participants to reinforce the concepts of peer and social support.

After we demonstrate whether this approach supports healthy eating in people with T2D, we will work to make this menu plan part of the routine dietary management of diabetes patients in Alberta.

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Appendices

Appendix A One day sample menu

Menu plan	Servings	
Breakfast Yogurt Parfait (see recipe, pg. 26)	¾ cup Yogurt* ½ cup Strawberries* (frozen) ¼ cup Granola* ½ cup Orange Juice 1 cup Coffee (or Tea) 2 tbsp 1% Milk* 1 tsp Sugar*	***3 ½ carbohydrate choice***
Morning Snack Honey Whole Wheat Muffin (see recipe, pg. 26)	1 small Muffin 1 tsp Margarine ¼ cup Unsweetened Applesauce*	***1 ½ carbohydrate choice*** ***1 fats choice***
Lunch Greek Tuna Salad Pita (see recipe, pg. 27)	3 oz Tuna 1 pita Whole Wheat Pita ½ cup Romaine Lettuce* ½ cup Cucumber* ¼ cup Tomato* 4 olives Black Olives 1 tbsp Feta Cheese 1 tbsp Olive Oil & Balsamic Vinegar dressing 1 cup 1% Milk* ½ cup Canned Peaches (in water)	***3 ½ carbohydrate choice*** ***1 ½ meat & alternatives choice*** ***2 fats choice***
Afternoon Snack Hummus & Crackers (see recipe, pg. 27)	⅓ cup Hummus 6 crackers Melba Toast	***1 carbohydrate choice*** ***1 meat & alternatives choice***
Dinner Pork Tenderloin (see recipe, pg. 28)	4 ½ oz. Pork Tenderloin* ½ cup Roasted Potatoes* ½ cup Green Beans* 1 small Whole Grain Dinner Roll* 1 tsp Margarine ½ cup 1% Milk*	***2 ½ carbohydrate choice*** ***4 ½ meat & alternatives choice*** ***1 fats choice***
Evening Snack Cinnamon Raisin Toast (see recipe, pg. 28)	2 slices Raisin Bread* 2 tsp Margarine 1 tsp Cinnamon Pinch Sugar* ½ cup 1 % Milk*	***2 ½ carbohydrate choice*** ***2 fats choice***

Appendix B Recruitment poster

UNIVERSITY OF ALBERTA
EDMONTON, ALBERTA, CANADA

PANDA
Physical Activity & Nutrition for Diabetes in Alberta

Pilot testing of the Alberta Diet

Researchers at the University of Alberta are conducting a study to evaluate a new nutrition guide called ***Eating Healthy with Type 2 Diabetes: a Smart Menu Plan for Albertans.*** This guide includes a 4-week menu plan, recipes for all menu items, shopping lists and cooking tips.

Your participation will consist in using the menu plan during 3 months and assisting to 4 different meetings.
For your participation you will receive a small cash gift.

If you:

- ✓ Have **type 2 Diabetes.**
- ✓ Are 35 years of age or older.
- ✓ Are able to read and write English.
- ✓ Don't have gastrointestinal problems (colitis, gastritis).
- ✓ Don't have any kidney problems.

You may be eligible to participate!

If you are interested in participating, please contact:
Study coordinator, Diana Soria at **albertadiet@gmail.com** or 780-492-9964.

albertadiet@gmail.com	780-492-9964
albertadiet@gmail.com	780-492-9964
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albertadiet@gmail.com	780-492-9964

Appendix C Information letter and consent form

Information Sheet

Title of Project

Pilot testing of the Alberta Diet

Principle Investigator: Dr. Cathy Chan 780-492-9939 Cathy.Chan@ualberta.ca
Co-investigator: Dr. Rhonda Bell 780-492-7742 Rhonda.Bell@ualberta.ca

Purpose of this study

The purpose of this study is to find out how people use and like a new nutrition resource called Eating Healthy with Type 2 Diabetes: a Smart Menu Plan for Albertans. This resource features a 4-week menu plan, recipes for all menu items, shopping lists and cooking tips that were put together by nutrition experts. All the menus meet the Nutrition recommendations for Diabetes, therefore, by following them and using the other information in the book, people may find it easier to follow the recommended diet for diabetes. This menu plan is part of a larger study called Physical Activity and Nutrition for Diabetes in Alberta (PANDA).

Background

Following an appropriate diet is important for good glucose control in Type 2 Diabetes, yet diet is sometimes thought to be difficult to change and maintain over the long term. There are different factors that affect what people choose to eat including their ethnic and cultural background, economic factors (e.g. how much money they have to spend on food), their personal likes and dislikes, how much time they have to prepare foods – and many other factors.

Procedures

If you agree to participate in the study, you will meet with the Study Team 4 times. The schedule will be:

Meeting 1, approximately 2 ½ hours total.

Your Hemoglobin A1c (A1c) level (a test that measures your long term blood sugar control) will be measured using a finger-prick method (like when you check your blood sugar at home). The normal value for A1c is less than 6.5%. To be eligible to participate in this study your A1c must be at least 6.0%. If you agree to be in the study, we will take a blood sample to measure the amount of fat and cholesterol in your blood (lipid profile). We will measure your height, weight and waist circumference, as well as the amount of muscle and fat in your body (body composition) with a special machine called the Bod Pod. The Bod Pod consists in a test chamber where you will be sitting for approximately 2 minutes. The entire test procedure takes about 5 minutes and for this, you will be asked to change into tight clothing (available at our lab). This is necessary in order to accurately assess the amount of muscle and fat in your body. This test is completely safe. At this meeting, you will complete some questionnaires related to what you eat, your grocery buying, health status and your diabetes treatment, information about your age, ethnicity, income level and other general information. You will complete questionnaires with information on how confident you feel to follow a diet for your diabetes and the support that you receive from your family, friends and significant others. Finally, you will be asked to record everything you eat and drink for 3 days and to bring it back your next visit.

Meeting 2, about 2 hours total

About 1 week after the first meeting, we will ask you to come to a group meeting (with other research participants and study staff) where we will explain all about the menu plan. A Registered Dietitian (RD) will conduct this meeting. You will look through the book and you will have the opportunity to discuss how to use it and for any questions you have about the menu plan. We would like you to try using this menu plan for 3 months and to keep weekly records of its use by filling out a special booklet that we will provide you. At the end of each week in the booklet, you will record information on how many days you used the menu plan in one week, how you enjoyed the meals and how useful you found it to follow a healthy diet. This booklet also includes some questions about your diet and who helps you to follow it. Completing this record will take you 10-15 minutes every week. We will provide you with a self-addressed stamped envelope so you can mail this booklet back to the research team at the end of every month.

Meeting 3, about 2 hours total

This meeting will be held at the end of 3 months. One week before the meeting, you will record everything you eat and drink for 3 days. We will look through these records during your third visit.

At this meeting, you will be asked to complete some of the questionnaires that were initially filled. These include questionnaires related to what you eat, your grocery buying, confidence to follow your diet and health status .We will also measure your Hemoglobin A1c, the amount of fat and cholesterol in your blood (lipid profile), weight, waist circumference and the amount of muscle and fat in your body (body composition) using the Bod Pod machine.

Meeting 4, about 2 hours total

We will ask you to come to a group meeting (with other research participants and study staff) to get your general feedback about the menu plan. The conversation of this meeting will be audio recorded. This is necessary in order to capture and then, transcribe the interview accurately.

Telephone Follow-up

Two months after the 3rd meeting we will call you to ask a few follow-up questions. This will take you around 10 minutes.

Additional procedures

Each week during the first month, the study coordinator will contact you to know how you are feeling following the menu plan. You can decide whether you want to be contacted by telephone or to have a face-to-face meeting with the study coordinator. Optional group meetings will be held in the 2nd and 3rd months, at these meetings you can share your experiences and ask questions. During the 3 months, you can contact the study team by phone or by email.

Confidentiality

Only people associated with the research study (Dr. Chan, Dr.Bell and the study coordinator) will have access to your records. Records from the study are confidential and securely stored in locked filing cabinets. Your records will be listed according to your identification number rather than your name. Published reports (thesis, research articles and presentations) resulting from this study will be summarized as group findings. We will not identify you in any report. We will not give your name or phone number to anyone or use them for any other purpose apart from the study. Other participants may know that you took part in the study, but they will never see your reports. Study data will be securely stored for 5 years after the study is over, at which time it will be destroyed. Data obtained through this study will be used to refine the menu plan and include it in future diabetes treatment studies (this will have to be approved by a Research Ethics Board).

Possible Risks

There are no known risks for participating in this study. You may get a sore finger from the finger prick blood sample taken to determine your Hemoglobin A1c, which should be minor because the test is the same as the finger prick that you do to test your blood glucose. You could present some minor discomfort or bruising with providing the blood sample to measure the amount of fat and cholesterol in your blood (lipid profile). It will take time for you to attend the meetings and to fill out the questionnaires and weekly records. If you get tired during the meetings, you can take a break whenever you want.

Possible Benefits

The menu plan meets the recommendations from the Canadian Diabetes Association and it may be helpful in following the recommended diet for diabetes. If you wish, you can receive information about your nutritional assessment, as well as your Hemoglobin A1c level, the amount of fat and cholesterol in your blood (lipid profile), weight, height and waist circumference. You can have access to study staff, including a Registered Dietitian, who are there to answer questions about diet and diabetes. We will pay for the parking costs at the University for your attendance to the meetings, and at the end of the study, you will receive a $50 grocery card as a thank you gift.

Withdrawal from the study

Participation in the study is voluntary. You may refuse to participate, refuse to answer any questions or withdraw from the study at any time without risking any aspect of your health care now or in the future.

Contact Information

If you have any questions about this study, please contact:

Catherine Chan, Principal Investigator	780-492-9939	Cathy.Chan@ualberta.ca
Rhonda Bell, Co-Investigator	780-492-7742	Rhonda.Bell@ualberta.ca

Diana Soria, Study Coordinator 780-492- 4496 or 9964 soria@ualberta.ca

If you have any questions or concerns about your rights as a project participant, please contact:
The University of Alberta, Research Ethics Officer 780-492-2615

CONSENT FORM

Title of Project: Pilot testing of the Alberta Diet

Principal Investigator: Dr. Cathy Chan Phone Number(s):780-492-9939

	Yes	No
Do you understand that you have been asked to be in a research study?	☐	☐
Have you read and received a copy of the attached Information Sheet?	☐	☐
Do you understand the benefits/risks involved in taking part in this research study?	☐	☐
Have you had an opportunity to ask questions and discuss this study?	☐	☐
Do you understand that you are free to withdraw from the study at any time, without having to give a reason?	☐	☐
Has the issue of confidentiality been explained to you?	☐	☐
Do you understand who will have the access to the study information you provide?	☐	☐

Who explained this study to you?______________________________

I agree to take part in this study YES ☐ NO ☐

Signature of the participant____

Printed name of the participant____

I believe that the person signing this form understands what is involved in the study

and voluntarily agrees to participate.

Signature of Investigator or Designee__________________________________Date________________

Appendix D Demographic information questionnaire

DEMOGRAPHIC QUESTIONNAIRE

Please write or mark the appropriate answer for the following questions.

Date: ___________________
Age: _____________________
Date of birth: ________________
Gender: Male / Female
Years with diabetes diagnosis:___________________

Ethnicity:
Please put a checkmark in the appropriate answer(s).

- ☐ White
- ☐ Chinese
- ☐ West Asian (e.g., Afghan, Iranian)
- ☐ Aboriginal (First Nations, Metis or Inuit)
- ☐ South Asian (e.g. East Indian, Pakistani, Sri Lankan)
- ☐ Southeast Asian (e.g. Cambodian, Indonesian, Laotian, Vietnamese)
- ☐ Latin American
- ☐ Japanese
- ☐ Korean
- ☐ Arab
- ☐ Black
- ☐ Filipino
- ☐ Other ( )

Please put a checkmark in the box
Education:

- ☐ Less than high school
- ☐ High school graduate
- ☐ Some college or university (have some post secondary education, but not completed)
- ☐ College or university graduate or above

Employment :
- ☐ Wages and salaries
- ☐ Income from self-employment
- ☐ Retirement income (pensions, old age security and GIS, etc.)
- ☐ Unemployed (not including retirement)
- ☐ Other ( )

Household annual income:
- ☐ < $ 10,000 if 1 to 4 people
- ☐ < $ 15,000 if ≥ 5 people
- ☐ $ 10,000 to $ 14,999 if 1 or 2 people
- ☐ $ 10,000 to $ 19,999 if 3 or 4 people

☐ $ 15,000 to $ 29,999 if ≥ 5 people
☐ $ 15,000 to $ 29,999 if 1 or 2 people
☐ $ 20,000 to $ 39,999 if 3 or 4 people
☐ $ 30,000 to $ 59,999 if ≥ 5 people
☐ $ 30,000 to $ 59,999 if 1 or 2 people
☐ $ 40,000 to $ 79,999 if 3 or 4 people
☐ $ 60,000 to $ 79,999 if ≥ 5 people
☐ ≥ $ 60,000 if 1 or 2 people
☐ ≥ $ 80,000 if ≥ 3 people

Financial situation: (How would you describe your financial situation?)
☐ I can meet my needs and still have enough money left to do most of the things I want
☐ I have enough money to meet my needs and to do many of the things I want if I budget carefully
☐ I have enough money to meet my needs but have little left for extras
☐ I can barely meet my needs and have nothing left for extras
☐ I am solely responsible for my treatment financially

Appendix E General health and diabetes treatment questionnaire

GENERAL HEALTH AND DIABETES TREATMENT QUESTIONNAIRE

Please put a checkmark in the box.

Diabetes Treatment:

- ☐ None
- ☐ Diet only
- ☐ Diet + Exercise
- ☐ Diet + oral antidiabetic drugs
- ☐ Diet + oral antidiabetic drugs + Exercise
- ☐ Diet + Insulin
- ☐ Diet + Insulin + Exercise

Please list all medications you take on a regular basis:

Medication	Condition it is used for	Frequency	Dose	Before/After Food

Have you been diagnosed with any other chronic illnesses (e.g. cancer, cardiovascular disease, osteoporosis, chronic respiratory disease, chronic renal failure and chronic hepatitis, etc.)? Yes / No

If Yes, please specify:____

Have you been diagnosed by a doctor as having… (Please check that all apply)

- ☐ Heart trouble?
- ☐ Chronic asthma, emphysema, or bronchitis?
- ☐ Osteoporosis?
- ☐ Arthritis?
- ☐ High blood pressure?
- ☐ High cholesterol?
- ☐ Back problems?
- ☐ Foot problems?
- ☐ Allergies (including hay fever and sinus problem)
- ☐ Trouble hearing?

☐ Trouble seeing?
☐ Bladder control difficulties?
☐ Balance problem or frequent falls?
☐ Burning Foot (Neuropathy)?
☐ Poor Appetite/ Increased Appetite?
☐ Kidney problems?
☐ Other health problems? Please explain:____

Are you a… (Please check one)
☐ Current, regular smoker
☐ Occasional smoker
☐ Former smoker
☐ Non-smoker

Circle the appropriate answers

How many of the last SEVEN DAYS have you eaten nutritional snacks that have been recommended as a substitute for your regular snacks?
0 1 2 3 4 5 6 7

How many of the last SEVEN DAYS have you eaten supplements for Diabetes?
0 1 2 3 4 5 6 7

Have you been recommended on any nutrition specific supplements, for example High Protein supplements for your specific diabetes associated status?
Yes No Not aware
If yes, specify the type:____

Apart from the recommended healthy eating plan, have you been prescribed on any nutraceuticals or functional foods?
Yes No Not aware
If yes, specify the type:____

Do you eat foods that are considered as functional foods?
Yes No Not aware

Below is the list of supplements, Please put a check mark in the appropriate boxes. Check all that apply. Specify the Brand name and the purpose for using it e.g. Diabetes, Hypertension, Arthritis…….

Name	Brand name	Purpose
Vitamin A		
Vitamin C		
Vitamin D		

Vitamin E		
Vitamin B6		
Vitamin B complex		
Multivitamins		
Folic acid		
Calcium		
Chromium		
Iron		
Magnesium		
Manganese		
Selenium		
Vanadium		
Zinc		
Alpha lipoic acid		
Co enzyme Q10		
Flavanoids		
Gamma linoleic acid		
Glucosamine		
L- Carnitine		
Omega 3 fatty acid		
Fish oil		
Others(specify)		
Herbal supplements		
Name	Brand name	Purpose
Aloe		
American ginseng		
Asian ginseng		
Cinnamon		
Cayenne		
Caiapo		
Echinacea		
Fenugreek		
Garlic		
Gymnema		
Ginko biloba		
Herbal mixtures		
Kudzu		
Nopal		
Others (specify)		

Appendix F Diabetes self-care activities

SELF-CARE ACTIVITIES AND DIABETES TREATMENT QUESTIONNAIRE

Circle all responses that apply

1. Which of the following has your health care team (doctor, nurse, dietitian, or diabetes educator) advised you to do?

a. Follow Canada's Food Guide
b. Follow a complex carbohydrate diet or a low glycemic index diet
c. Reduce the number of calories you eat to lose weight
d. Eat foods high in dietary fiber
e. Eat lots (at least 7 servings per day) of fruits and vegetables
f. Eat very few sweets (for example: desserts, non-diet sodas, candy bars)
g. Avoid foods high in fat (especially trans-fats from hydrogenated sources and saturated fats)
h. Other (specify):____
i. I have not been given any advice about my diet by my health care team.

2. Which of the following has your health care team (doctor, nurse, dietitian or diabetes educator) advised you to do?

a. Get regular physical activity (such as walking) on a daily basis.
b. Fit physical activity into your daily routine (for example, take stairs instead of elevators, park a block away and walk, etc.)
c. Exercise continuously for a least 30 minutes at least 5 times a week.
d. Engage in a specific amount, type, duration and level of exercise.
e. Other (specify): ____
f. I have not been given any advice about exercise by my health care team.

3. Which of the following has your health care team (doctor, nurse, dietitian, or diabetes educator) advised you to do?

a. Test your blood sugar using a drop of blood from your finger and a color chart.
b. Test your blood sugar using a machine to read the results.
c. Test your urine for sugar.
d. Other (specify): ____
e. I have not been given any advice either about testing my blood or urine sugar level by my health care team

4. Which of the following medications for your diabetes has your doctor prescribed?

a. An insulin shot 1 or 2 times a day.
b. An insulin shot 3 or more times a day.
c. Diabetes pills to control my blood sugar level.
d. Other (specify):____
e. I have not been prescribed either insulin or pills for my diabetes.

Appendix G Physical activity

PHYSICAL ACTIVITY

Considering a 7-Day period (a week), how many times on average do you do the following kinds of exercise for more than 15 minutes.

Times Per Week

A. STRENUOUS PHYSICAL ACTIVITY

(heart beats rapidly, sweating) __________

(e.g., running, jogging, hockey, soccer, squash,

cross country skiing, judo, roller skating,

vigorous swimming, vigorous long distance bicycling,

vigorous aerobic dance classes, heavy weight training)

B. MODERATE PHYSICAL ACTIVITY

(not exhausting, light perspiration) __________

(e.g., fast walking, baseball, tennis, easy bicycling,

volleyball, badminton, easy swimming, alpine skiing,

popular and folk dancing)

C. MILD PHYSICAL ACITIVITY

(minimal effort, no perspiration) __________

(e.g., easy walking, yoga, archery, fishing, bowling,

lawn bowling, shuffleboard, horseshoes, golf, snowmobiling)

Considering a 7-Day period (a week), how often do you engage in any regular activity long enough to work up a sweat (heart beats rapidly)?

1. Often 2. Sometimes 3.Never/rarely

Appendix H Perceived dietary adherence questionnaire

DIETARY ADHERENCE QUESTIONNAIRE

Please circle the best answer.
The questions below ask you about your diabetes diet activities during the past 7 days. If you were sick during the past 7 days, please think back to the last 7 days that you were not sick.

1. How many of the last SEVEN DAYS have you followed a healthful eating plan such as Eating Well with Canada's Food Guide with appropriate serving sizes?

0 1 2 3 4 5 6 7

2. On average, over the past MONTH, how many WEEKS have you followed your eating plan for diabetes?

0 1 2 3 4

3. On how many of the last SEVEN DAYS did you eat the number of fruit and vegetable servings you are supposed to eat based on Canada's Food guide (women aged 19 – 50: 7–8 servings; males aged 19 – 50: 8 – 10 servings; women and men over 50: 7 servings)?

0 1 2 3 4 5 6 7

4. On how many of the last SEVEN DAYS did you eat carbohydrate-containing foods with a low Glycemic Index? (Example: dried beans, lentils, barley, pasta, low fat dairy products)

0 1 2 3 4 5 6 7

5. On how many of the last SEVEN DAYS did you eat foods high in sugar as cakes, cookies, desserts, candies, etc.?

0 1 2 3 4 5 6 7

6. On how many of the last SEVEN DAYS did you eat foods high in fibre such as oatmeal, high fibre cereals, and whole grain breads?

0 1 2 3 4 5 6 7

7. On how many of the last SEVEN DAYS did you space carbohydrates evenly throughout the day?

0 1 2 3 4 5 6 7

8. On how many of the last SEVEN DAYS did you eat fish or other foods high in omega-3 fats?

0 1 2 3 4 5 6 7

9. On how many of the last SEVEN DAYS did you eat food which contained or was prepared with plant oils such as canola, walnut, olive, or flax?

0 1 2 3 4 5 6 7

10. On how many of the last SEVEN DAYS did you eat foods high in fat (such as high fat dairy products, fatty meat, fried foods or deep fried foods)?

0 1 2 3 4 5 6 7

11. On how many of the last SEVEN DAYS did you consume any alcohol?

0 1 2 3 4 5 6 7

12. On how many of the last SEVEN DAYS did you consume red wine?

0 1 2 3 4 5 6 7

Appendix I Weekly record

Eating Healthy with Type 2 Diabetes:

A Smart Menu Plan for Albertans

Weekly Record

Month 1

Name:______________________________

Date: ______________________________

Eating Healthy with Type 2 Diabetes: a Smart Menu Plan for Albertans

Physical Activity and Nutrition for Diabetes in Alberta (PANDA) is an interdisciplinary, multi-sectoral project that aims to improve metabolic control, reduce diabetic complications and improve quality of life for Albertans living with Type 2 Diabetes by designing a nutrition-related program that addresses barriers to diabetes treatment and by developing a usable physical activity “tool box”.

PANDA
Physical Activity
& Nutrition for
Diabetes in Alberta

What is this Menu Plan about?

Diet is one of the key elements of living healthy with Type 2 Diabetes; however, people often face some difficulties when trying to follow a healthy diet. Bearing this in mind we developed this menu plan that features menus, recipes, grocery lists, cooking tips, a list of foods produced in Alberta and other resources to help you achieve a healthy diet.

You don´t have to limit your food choices because of diabetes. This smart menu plan can help you enjoy a well-balanced diet following the nutrition therapy guidelines while still give you the access to a variety of delicious foods. We hope that you find this menu plan useful in the management of Type 2 diabetes.

Something to think about

Let´s begin by thinking about the benefits you can get out of changing your diet

Gains for me	Losses for me
Gains for people around me	**Losses for people around me**

How many gains and losses do you have in your list?

Losses

=

Gains

=

Do the gains outweigh the losses?

Getting the most without giving up too much!

How can this menu plan help you to gain the most?

Who can help you to follow this plan?

How can they help you?

This menu plan includes delicious foods that can be consumed for all individuals while still being appropriate for diabetes management; therefore, all the people around you can enjoy the meals!!

1

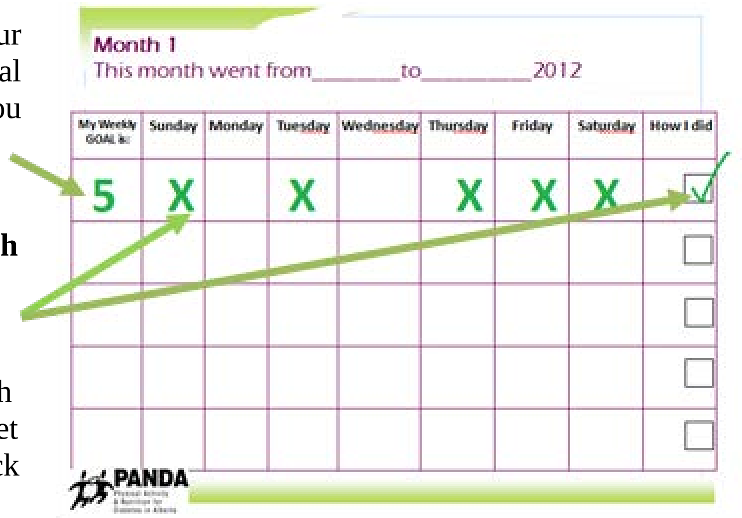
1- Eat Well and Be Active Educational Toolkit, retrieved on November 22, 2011 from www.health.gc.ca/eatwell-beactive

You can gain the most by following this menu plan for 3 months

Each week you will have homework.

1. At the beginning of the week: using your calendar set your own goal on how many days you will use the menu plan.

2. At the end of each week: mark in the calendar how many days you used the menu plan and compare it with your goal; if you meet your weekly goal, check the box for the week.



3. At the end of each week: fill out the questions about your experience using the menu plan.

4. At the end of the month: send us back your weekly record.

The more you try, the better you feel!!

Let's start setting our goal for the 1st week

How many days do you see yourself using the menu plan?

Write it down in your calendar

How would you reach your goal?

____

____

____

____

____

____

____

____

Month 1

This month went from_________to___________2012

My Weekly GOAL is:	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	How I did
								☐
								☐
								☐
								☐
								☐

PANDA Physical Activity & Nutrition for Diabetes in Alberta

Please, at the END of each week answer these questions

We want to keep track of how you use and like Eating Healthy with Type 2 Diabetes: a Smart Menu Plan for Albertans. Please, at the **END** of each week, fill out this record by **circling or writing** the appropriate response. Note that week 4 includes an extra set of questions.

WEEK 1

Date:________________

1. How many days during the past week did you use Eating Healthy with Type 2 Diabetes: a Smart Menu Plan for Albertans?

0 1 2 3 4 5 6 7

2. How often during the past week did you like the meals included in the menu plan?

Never *Almost never* *Occasionally* *Most of the time* *All of the time*

3. How often during the past week did you find the menu plan useful to follow a healthy diet?

Never Almost never Occasionally Most of the time All of the time

4. How often during the past week did you have any difficulty finding or purchasing the ingredients for the recipes?

Never Almost never Occasionally Most of the time All of the time

5. During the past week who helped you to follow your diet? Circle all applicable.

Spouse/Couple Family Friends Other:___________ Not applicable

6. How often during the past week, did the people in your household eat the same food as you?

Never Seldom Often Usually Always

7. If you didn't´ follow "Eating Healthy with Type 2 Diabetes: a Smart Menu Plan for Albertans" this week, what was the main reason for that? Please share with us as much details as possible:

____

____

____

____

WEEK 2

Date:________________

1. How many days during the past week did you use Eating Healthy with Type 2 Diabetes: a Smart Menu Plan for Albertans?

0 1 2 3 4 5 6 7

2. How often during the past week did you like the meals included in the menu plan?

Never Almost never Occasionally Most of the time All of the time

3. How often during the past week did you find the menu plan useful to follow a healthy diet?

Never Almost never Occasionally Most of the time All of the time

4. How often during the past week did you have any difficulty finding or purchasing the ingredients for the recipes?

Never Almost never Occasionally Most of the time All of the time

5. During the past week who helped you to follow your diet? Circle all applicable.

Spouse/Couple Family Friends Other:___________ Not applicable

6. How often during the past week, did the people in your household eat the same food as you?

Never Seldom Often Usually Always

7. If you didn't´ follow "Eating Healthy with Type 2 Diabetes: a Smart Menu Plan for Albertans" this week, what was the main reason for that? Please share with us as much details as possible:

____
____
____
____
____
____
____
____
____
____

WEEK 3

Date:_________________

1. How many days during the past week did you use Eating Healthy with Type 2 Diabetes: a Smart Menu Plan for Albertans?

0 1 2 3 4 5 6 7

2. How often during the past week did you like the meals included in the menu plan?

Never Almost never Occasionally Most of the time All of the time

3. How often during the past week did you find the menu plan useful to follow a healthy diet?

Never Almost never Occasionally Most of the time All of the time

4. How often during the past week did you have any difficulty finding or purchasing the ingredients for the recipes?

Never Almost never Occasionally Most of the time All of the time

5. During the past week who helped you to follow your diet? Circle all applicable.

Spouse/Couple Family Friends Other:____________ Not applicable

6. How often during the past week, did the people in your household eat the same food as you?

Never Seldom Often Usually Always

7. If you didn't´ follow "Eating Healthy with Type 2 Diabetes: a Smart Menu Plan for Albertans" this week, what was the main reason for that? Please share with us as much details as possible:

____

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WEEK 4

Date:_________________

1. How many days during the past week did you use Eating Healthy with Type 2 Diabetes: a Smart Menu Plan for Albertans?

0 1 2 3 4 5 6 7

2. How often during the past week did you like the meals included in the menu plan?

Never Almost never Occasionally Most of the time All of the time

3. How often during the past week did you find the menu plan useful to follow a healthy diet?

Never Almost never Occasionally Most of the time All of the time

4. How often during the past week did you have any difficulty finding or purchasing the ingredients for the recipes?

Never Almost never Occasionally Most of the time All of the time

5. During the past week who helped you to follow your diet? Circle all applicable.

Spouse/Couple Family Friends Other:____________ Not applicable

6. How often during the past week, did the people in your household eat the same food as you?

Never Seldom Often Usually Always

7. If you didn’t´ follow “Eating Healthy with Type 2 Diabetes: a Smart Menu Plan for Albertans” this week, what was the main reason for that? Please share with us as much details as possible:

____
____
____
____
____
____
____
____
____

WEEK 4

DIETARY ADHERENCE QUESTIONNAIRE

Please circle the best answer.

The questions below ask you about your diabetes diet activities during the past 7 days. If you were sick during the past 7 days, please think back to the last 7 days that you were not sick.

1. How many of the last SEVEN DAYS have you followed a healthful eating plan such as Eating Well with Canada's Food Guide with appropriate serving sizes?

   0 1 2 3 4 5 6 7

2. On average, over the past MONTH, how many WEEKS have you followed your eating plan for diabetes?

   0 1 2 3 4

3. On how many of the last SEVEN DAYS did you eat the number of fruit and vegetable servings you are supposed to eat based on Canada's Food guide (women aged 19 – 50: 7–8 servings; males aged 19 – 50: 8 – 10 servings; women and men over 50: 7 servings)?

   0 1 2 3 4 5 6 7

4. On how many of the last SEVEN DAYS did you eat carbohydrate-containing foods with a low Glycemic Index? (Example: dried beans, lentils, barley, pasta, low fat dairy products)

   0 1 2 3 4 5 6 7

5. On how many of the last SEVEN DAYS did you eat foods high in sugar as cakes, cookies, desserts, candies, etc.?

   0 1 2 3 4 5 6 7

6. On how many of the last SEVEN DAYS did you eat foods high in fiber such as oatmeal, high fiber cereals, and whole grain breads?

   0 1 2 3 4 5 6 7

7. On how many of the last SEVEN DAYS did you space carbohydrates evenly throughout the day?

   0 1 2 3 4 5 6 7

8. On how many of the last SEVEN DAYS did you eat fish or other foods high in omega-3 fats?

   0 1 2 3 4 5 6 7

9. On how many of the last SEVEN DAYS did you eat food which contained or was prepared with plant oils such as canola, walnut, olive, or flax?

0 1 2 3 4 5 6 7

10. On how many of the last SEVEN DAYS did you eat foods high in fat (such as high fat dairy products, fatty meat, fried foods or deep fried foods)?

0 1 2 3 4 5 6 7

11. On how many of the last SEVEN DAYS did you consume any alcohol?

0 1 2 3 4 5 6 7

12. On how many of the last SEVEN DAYS did you consume red wine?

0 1 2 3 4 5 6 7

Congratulations! You have completed your first month following "Eating Healthy with Type 2 Diabetes: a Smart Menu Plan for Albertans". Please, send this booklet back to the research team using the pre-paid envelope provided to you.

Diana Soria
6-002 Li Ka Shing Centre for Health Research Innovation
University of Alberta
Edmonton, AB, T6G 2E1

Keep in touch with us.
Dr. Catherine Chan, Principal Investigator
Dr. Rhonda Bell, Co-investigator
Diana Soria, Study coordinator
Albertadiet@gmail.com
780-492-9964-voicemail
780-492-4496- office

The research team acknowledges the contribution of the First Step Program to the development of this material.

Appendix J Exit survey

EXIT SURVEY

We want to know if "Eating Healthy with Type 2 Diabetes: a Smart Menu Plan for Albertans" helped you to improve different aspects of your diet

Please indicate your level of agreement with the following statements

1. Following this menu plan helped to start planning grocery shopping and planning my meals

Strongly disagree Disagree Neutral Agree Strongly agree

2. The menu plan helped me to have more regular meals (e.g. meal schedule, number of meals in a day)

Strongly disagree Disagree Neutral Agree Strongly agree

3. The menu plan helped me to make healthier food choices (e.g. meals and snacks, eating out, etc.)

Strongly disagree Disagree Neutral Agree Strongly agree

4. The menu plan helped me to have healthier foods available at home

Strongly disagree Disagree Neutral Agree Strongly agree

5. The menu plan helped me to eat more servings of fruits and vegetables

Strongly disagree Disagree Neutral Agree Strongly agree

6. The menu plan helped me to estimate portions of food

Strongly disagree Disagree Neutral Agree Strongly agree

7. The menu plan helped me to decrease the amount of food I eat

Strongly disagree Disagree Neutral Agree Strongly agree

Appendix K   Self-rated health questionnaire

SELF-RATED HEALTH

Please put a checkmark in the box

In general, would you say your health is:

☐ Poor
☐ Fair
☐ Good
☐ Very good
☐ Excellent

Appendix L Self-efficacy questionnaire

Diabetes Self-Efficacy Scale

We would like to know *how confident* you are in doing certain activities. For each of the following questions, please choose the number that corresponds to 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	Totally 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	Totally confident

3. How confident do you feel that you can choose 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	Totally 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	Totally 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	Totally confident

6. How confident do you feel that you know what to do when your blood sugar level goes higher or lower than it should be?

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

7. How confident do you feel that you can judge when the changes in your illness mean you should visit the doctor?

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

8. How confident do you feel that you can control your diabetes so that it does not interfere with the things you want to do?

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

Appendix M   Accessibility of foods questionnaire

ACCESSIBILITY TO FOOD AND FOOD RESOURCES

Accessibility refers to "the physical and economic access to foods for all, at all times".

The following questions ask you about convenience, ease of transportation to outlets, availability of foods for your diabetes, the cost of foods compared to non-diabetic diet and time preparing meals.

Food resources include: retail food stores (grocery stores, convenience stores, discount food stores or club stores (e.g. Costco)), farmers' markets, food cooperatives and anywhere that you would regularly shop for foods.

For each question, please circle or write the appropriate answer.

Location and Convenience of Food Resources

1. Are there places where you buy foods that are right for your diabetes close to where you live?
Yes   No

2. Are there places where you buy foods that are right for your diabetes close to where you work?
Yes   No

3. How far do you travel to buy food?
__________________ miles   or   ____________________ km

4. How many different stores do you go to, to buy the foods you need for a week?
a. 1-2
b. 3-4
c. 5-7
d. More than 7

5. Where are groceries usually purchased for you and your family? (Check all that apply)
☐ Chain supermarket (Safeway, Sobey's, Superstore, etc.)
☐ Independent grocery store (Planet Organic, Wild Earth, etc.)
☐ Farmer's Market or similar
☐ Other (please specify) ____

6. Are there food items in your diet plan that are not available at your regular grocery store?
Yes   No   I don't know

7. How long does it take for a typical shopping trip, including commuting time? If you shop at more than one store, include time for each store, and include both shopping and commuting time.

Hours___________ minutes___________

8. If there are items in your diet plan that you don't buy at your regular grocery store, what do you do?

a. .Not buy them at all

b. Go to another store

i. If you go to another store, over SEVEN DAYS, how often do you go to another store?

0 1 2 3 4 5 6 7

c. Other (be specific) ______________________________

9. Do the food resources you use regularly have:

Convenient store hours for you?	Yes	No
Good customer service?	Yes	No
Information that you can use to help you with your diet for diabetes?	Yes	No

10. Aside from grocery stores, convenience stores, discount stores/club stores, farmers' markets, and food co-ops, are there other places that you go to for food <u>on a regular basis?</u> Include food outlets that you go too often (e.g. eating lunch at a work cafeteria or Tim Horton's for breakfast on Saturdays)

Yes No

If yes, describe the situation:

Eating occasion ____________________________________

Place or food outlet _________________________________

Transportation

11. When you go grocery shopping, how do you get there?

Private car Public Transportation Other (be specific) _______________

12. Do any of the stores you shop at for groceries offer delivery service?

Yes No Don't know

Food Costs

13. Please indicate with a check mark whether you spend the **same, less or more** on the following foods compared with a non-diabetic diet

Food Group	Less	Same	More	Not sure
Vegetables				
Fruit				
Meats				
Meat Alternates				
Grain Products				
Dairy Products				

Grocery shopping patterns and time use

14. Who is the MAIN grocery shopper in your home? If shared, circle all applicable
You Spouse Parent Roommate Other Not applicable

15. How often in the past month have you prepared a grocery list?
0 1 2 3 4 5 6 7 8 9 10 More than 10

16. How often in the past month has another family member prepared a grocery list?
0 1 2 3 4 5 6 7 8 9 10 More than 10 Don't know

17. How long (minutes) did it typically take to prepare the grocery list?
Less than 10 10-20 21-30 31-40 41-50 51-60 More than 60 Not applicable

18. Is there a separate shopping list for the foods or ingredients you eat for your diabetes?
Yes No

19. How often in the past month have you or someone in your household gone grocery shopping?
0 1 2 3 4 5 6 7 8 9 10 More than 10 Don't know

Appendix N Acceptability of foods questionnaire

FOOD ACCEPTABILITY QUESTIONNAIRE

Food acceptability refers to foods that are personally and culturally acceptable to you. For example, are the foods recommended in a diet for Type 2 diabetes those that you want to eat?

Please circle or write the appropriate response

1. In thinking about the foods that are part of a diet that you follow for your diabetes, how likely is it that you will regularly eat these foods?

Very unlikely Neutral Very likely

2. When choosing to buy foods that you prepare at home, how often do you choose foods that are part of a diet that you follow for your diabetes?

Never Seldom Usually Often Always

3. When you choose foods that are NOT part of your recommended diet, what are the main 3 reasons for this?

Reason 1____________________________________

Reason 2____________________________________

Reason 3____________________________________

4. Since you were first diagnosed with diabetes, has your enjoyment of foods that are part of your recommended diet:

Decreased Stayed about the same Increased

5. Since you were first diagnosed with diabetes, has the frequency of eating food away from home:

Decreased Stayed about the same Increased

6. How many days out of the week do you enjoy the foods that are part of your recommended diet?

0 1 2 3 4 5 6 7

7. How many days of the week do you find yourself seeking out foods that are NOT part of your recommended diet?

0 1 2 3 4 5 6 7

8. How many days of the week do you eat foods that are part of your ethnic heritage?

0 1 2 3 4 5 6 7 N/A

9. How many days of the week do you eat foods that are NOT part of your ethnic heritage?

0 1 2 3 4 5 6 7 N/A

10. Compared with before you were diagnosed with diabetes, has eating foods that are part of your ethnic heritage:

Decreased Stayed the Same Increased

11. How many days of the week do you eat foods that you would not have chosen to eat if you did not have Type 2 diabetes?

0 1 2 3 4 5 6 7

12. Do you eat foods that are produced locally (i.e. grown or produced in Alberta)?

Yes No Don't know

13. Do you believe those foods produced locally in Alberta are more diabetes friendly than those from elsewhere?

Yes Neutral No Don't know

14. Provide a list of the foods that you eat that are part of your diet for treating your diabetes and that are produced locally. Be as specific as possible.

____

____

____

____

Information about Your Recommended Diet

15. From the information you have received about your diabetes diet, is it clear to you:

What kinds of foods will be most beneficial for you?	Yes	No
What kinds of foods to avoid?	Yes	No
How often you should eat?	Yes	No
Which foods to keep handy for snacks?	Yes	No
Which foods are helpful on a sick day?	Yes	No
The glycemic index of foods that you eat	Yes	No
Foods which fill you up	Yes	No

Appendix O Availability of foods questionnaire

FOOD AVAILABILITY QUESTIONNAIRE

Food availability refers to the variety of food available in retail stores.

Please circle the appropriate response.

Do you find that the foods you would like to eat to follow a diet that is best for your diabetes are readily available in your regular grocery store?

Yes No Don't know

Are these foods easy to find in the stores that you go to?

Yes No Don't know

Do the stores where you buy foods carry a wide variety of foods?

Yes No Don't know

Think about the 1 or 2 stores that you go to most often to buy food. Which of the foods listed below can you buy at these stores?

Fresh Meat	Yes	No	Don't know
Processed Meat	Yes	No	Don't know
Fresh Poultry	Yes	No	Don't know
Fresh seafood	Yes	No	Don't know
Packaged meat	Yes	No	Don't know
Fresh fruits and vegetables	Yes	No	Don't know
Dairy products	Yes	No	Don't know
Eggs	Yes	No	Don't know
Cereals	Yes	No	Don't know
Bakery products	Yes	No	Don't know
Ready to eat foods	Yes	No	Don't know
Other foods	Yes	No	Don't know

How did you find out about where to find the foods that you like to eat to follow a diet that is best for Diabetes? Please be as specific as possible.

____
____
____
____
____
____

Appendix P Three-day dietary intake record

THREE-DAY DIETARY INTAKE RECORD

Name/ID:_______________________________

Record Dates: ___/_____ (Day/month)
___/_____ (Day/month)
___/_____ (Day/month)

UNIVERSITY OF ALBERTA

PANDA
Physical Activity
& Nutrition for
Diabetes in Alberta

Dietary intake record

- Please, record everything you eat and drink during a three-day period (including snacks, water, etc.).
- It is a good idea to carry your Dietary Intake Record book with you and record your entries as soon after eating as possible.
- Please include the following information on your food record:

1. **Day** you are recording (circle the day)
2. **Time** and **name of eating occasion,** for example: 9:00 am-BREAKFAST; 11:00 am-SNACK.
3. In the **food and drink name** column enter all foods and beverages consumed at the eating occasion, e.g. BREAKFAST CEREAL WITH MILK.
4. In the **description** column, provide a detailed description of the food, snack or drink consumed. Specify if homemade or bought. Include recipe detailing ingredients, amounts (using cups, grams, ounces, pieces, teaspoons or tablespoons) and brand name if applicable. e.g. 1 CUP OF ALL BRAN, BREAKFAST CEREAL & 1 CUP OF 1% MILK.
5. In the **cooking method** column, if applicable write the cooking method (e.g. in the example of breakfast cereal with milk, it does not apply).

- In the **additional information** column, if you ate more than one portion of the described food, snack or drink provide the information. Include all other relevant information (e.g. brand name, flavour or label information).
- If you have any questions please phone: **780-492-4496** or email **albertadiet@gmail.com**
- Bring your dietary intake record on: ______________________

SAMPLE MEAL - DAY 1				
Day Sun Mon Tues Wed Thurs Fri Sat				
Time and name of eating occasion	**Food/drink name** Enter all foods/beverages	**Description** Specify if homemade or bought. Detail ingredients, amounts and brand name if applicable Use cups, grams, ounces, pieces, teaspoons or tablespoons, to describe amounts	**Cooking method**	**Additional information**
09:00 am Breakfast	Scrambled eggs and toast	Homemade with: 2 pieces of egg 1 slice of Turkey ham 1 teaspoon of canola oil Pinch of salt and pepper 2 pieces of Wonder, whole wheat bread	Pan fried Toasted	
	Earl grey tea	1 cup of Water 1 teaspoon of Sugar 1 bag of earl grey tea		
11:00 am Snack	Granola bar	1 piece of Natural valley Oats ´N´ honey, granola bar		
12:00 pm Lunch	Ham sandwich	Homemade with: 2 slices of Wonder , whole wheat bread 1 slice of Turkey ham ½ cup Lettuce 3 slices of Tomato 1 slice of Onion 1 tablespoon of Hellmann´s , reduced fat mayonnaise	Grilled	
	Coffee with milk	2 cups of Coffee 1 cup of 1% milk 2 teaspoon of Sugar		

*Vitamin/mineral supplements use (name and brad, dose and label information if possible)

DAY 1- DAY 3				
Day Sun Mon Tues Wed Thurs Fri Sat				
Time and name of eating occasion	**Food/drink name**	**Description**	**Cooking method**	**Additional information**

*Vitamin/mineral supplements use (name and brad, dose and label information if possible)