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Does a Group Lifestyle Behaviour Change Program (PREPARE) Have an Impact on the Nutritional and Health Characteristics in Adults with Prediabetes?

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A thesis submitted in partial fulfillment of the requirements for the Master of Science degree in Foods and Nutrition

DOES A GROUP LIFESTYLE BEHAVIOUR CHANGE PROGRAM (PREPARE) HAVE AN IMPACT ON THE NUTRITIONAL AND HEALTH CHARACTERISTICS IN ADULTS WITH PREDIABETES?

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ABSTRACT AND KEYWORDS

Objective: Lifestyle interventions that target diet and physical activity have been shown to reduce the development of Type 2 diabetes (T2DM) in individuals at risk; however, accessible and effective community-based prevention programs remain lacking. The purpose of this study was to assess the impact of PREPARE, a group lifestyle behaviour change program in adults with prediabetes.

Methods: Adults diagnosed with prediabetes could self-select PREPARE (n=48, intervention arm), consisting of six monthly group nutrition and physical activity education sessions, or, a one-time group education session (n=15, controls), both aimed to prevent Type 2 Diabetes Mellitus (T2DM). Primary outcome measures included dietary, anthropometric, and hemodynamic parameters associated with T2DM. Program impact was evaluated with a one-way ANOVA, while paired t-tests assessed within-group pre-/post- changes.

Results: The PREPARE program did not have a significant impact on the dietary factors examined; however, intervention participants did increase their intake of vegetables and fruit (V&F) by +0.3 servings/day, achieving a mean daily intake of 6.3 V&F servings/day post-program. Additionally, participants that attended ≥50% of the education sessions (n=25) significantly reduced their sodium ($p<0.004$), saturated fat ($p=0.01$), weight ($p=0.01$), waist circumference ($p=0.01$), and diastolic ($p=0.03$) and systolic ($p=0.048$) blood pressure from baseline.

Conclusions: These preliminary results show potential for modifying key lifestyle behaviours known to contribute to T2DM development.

Keywords: Type 2 diabetes mellitus, impaired fasting glucose, impaired glucose tolerance, nutrition, diet, group education, prevention, weight loss, community-based lifestyle program

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List of Abbreviations

Abbreviation	Meaning
#	number
%	percent
2hPG	2-hour plasma glucose
3d-FIR	3-day food intake record and medication log
A1c	glycosylated hemoglobin
AMDR	acceptable macronutrient distribution range
BMI	body mass index
CAD	coronary artery disease
CFG	Canada's Food Guide
CHO	carbohydrate
CI	confidence interval
CKD	chronic kidney disease
cm	centimeter
CPG	clinical practice guidelines
CRIC	Clinical Research Impact Committee
CVD	cardiovascular disease
d	day
DEC	Diabetes Education Centre
DPP	Diabetes Prevention Program
EtOH	alcohol
FFQ	food frequency questionnaire
FPG	fasting plasma glucose
g	grams
GDM	gestational diabetes mellitus
HA	high attendees
HDL-C	serum high density lipoprotein cholesterol concentration
HTN	hypertension
IFG	impaired fasting glucose

IGT	impaired glucose tolerance
in.	inches
IOM	Institute of Medicine of the National Academy
kcal	kilocalories
kg/m^2	kilograms per meter squared
kJ	kilojoules
LA	low attendees
LDL-C	serum low density lipoprotein cholesterol concentration
m	meter
mm Hg	millimeters of mercury
mmol/L	milimoles per litre
n	number
n/a	not applicable
NHANES	National Health and Nutrition Examination Survey
ns	not significant
OGTT	oral glucose tolerance test
ON	Ontario
PG	plasma glucose
PreDM	prediabetes
PREPARE	Prediabetes Research & Education Promoting Activity & Responsible Eating
RCT	randomized control trial
SD	standard deviation
SE	standard error
SES	socioeconomic status
SFA	saturated fatty acids
SJHC	St. Joseph's Health Care London
T2DM	Type 2 diabetes mellitus
V&F	vegetables and fruit
WC	waist circumference

Chapter 1: Introduction

Prediabetes (PreDM), defined as the presence of impaired fasting glucose (IFG) and/or impaired glucose tolerance (IGT), identifies individuals at high risk for developing Type 2 diabetes mellitus (T2DM), the metabolic syndrome, and cardiovascular disease (CVD) (Canadian Diabetes Association, 2008a). The healthcare costs to deal with the epidemic of T2DM are already staggering, and are projected to rise to $8.14 billion in Canada by 2016 (Ohinmaa, Jacobs, Simpson, & Johnson, 2004). It is recommended that healthy individuals over the age of 40 be screened for diabetes every three years, while those diagnosed with PreDM must be evaluated annually (Canadian Diabetes Association, 2008b).

Studies have shown that lifestyle interventions that target physical activity and diet reduce the risk for developing T2DM by about 58% (Knowler et al., 2002; Pan et al., 1997; Tuomilehto et al., 2001). Although these results have been available for the past decade, there is still a lack of accessible community-based interventions in Canada designed to delay or prevent the development of T2DM in those identified as high risk.

In London, Ontario, Canada, over 600 individuals with PreDM were referred to the Diabetes Education Centre (DEC) of St. Joseph's Health Care (SJHC) London between 2006 and 2008. To deal with the growing patient load, in 2007 the diabetes educators of the SJHC London DEC (led by Irene Hramiak, MD) aligned forces with Brescia University College (led by Isabelle Giroux, PhD, RD) to create the Prediabetes Initiative and Partnership, which began as a single education session intended to increase diabetes risk awareness and to offer guidance in lifestyle modification to a larger number of individuals with PreDM in the community. In the program's first year, ten individual 2-hour group education sessions were delivered to 270 people with PreDM. This first education session then became the standard of care for the DEC in 2008 for people diagnosed with PreDM. The program delivery was overseen by Registered Dietitians/Certified Diabetes Educators from the DEC, who were supported by volunteer undergraduate students from the Foods & Nutrition program at Brescia University College.

Next, the PreDM education program expanded to two 2-hour sessions, and from 2007 to 2009, 27 education sessions were delivered to a total of 535 clients at Brescia University College. Based on the feedback from individuals with PreDM and recent funding from The Lawson Foundation in 2010, the current PreDM education program was expanded and piloted in May 2011 as a six session group education series over six months to better meet the needs of this population. The new program had an increased focus on behaviour change related to nutrition and physical activity, with a greater emphasis on increased self-efficacy via hands-on activities, goal setting, and social support to help translate the program into sustainable lifestyle behaviour change to decrease risk factors associated with T2DM development. To better identify the new PreDM education program, it was named PREPARE, which is an acronym for "Prediabetes Research and Education Promoting Activity & Responsible Eating".

The overarching purpose of the entire PREPARE study is to assess whether or not a 6-month, community-based PreDM lifestyle program focused on nutrition and physical activity will result in positive lifestyle behaviour change in a sample of middle and older adults with PreDM from London, ON. This current thesis will look at the impact of the PREPARE program on the dietary intake of the first group of participants recruited to the program in comparison to a control group (cohorts 1 and 2). The results of this research may offer insights for improvements to the program to better deliver healthcare in this patient population.

Chapter 2: Literature Review

2.1 Defining Prediabetes

PreDM is a condition where blood glucose (BG) concentrations are elevated, but remain below the threshold for a formal diagnosis of diabetes (Canadian Diabetes Association, 2008a). Similar to the procedures for diabetes diagnosis, PreDM is measured using two blood tests, fasting plasma glucose (FPG) and oral glucose tolerance test (OGTT), except with lower cut-off points (Public Health Agency of Canada, 2009a). Individuals with PreDM can have impaired fasting glucose (IFG) and/or impaired glucose tolerance (IGT), placing them at higher risk for the development of T2DM and CVD (Canadian Diabetes Association, 2008a). Although there is no worldwide consensus on the definition of IFG (Shaw et al., 2000; Forouhi et al., 2006), the Canadian Diabetes Association defines IFG as a FPG value of 6.1 to 6.9 mmol/L (Canadian Diabetes Association, 2008b). See Table 1 for a summary of the BG concentrations used to diagnose IFG, IGT, and T2DM.

Table 1

Plasma Glucose (PG) Concentrations for Diagnosis of Impaired Fasting Glucose (IFG), Impaired Glucose Tolerance (IGT), and Diabetes

	FPG (mmol/L)		**2hPG in the 75 g OGTT (mmol/L)**	**Diagnosis**
IFG	6.1-6.9		n/a	Prediabetes
IFG (isolated)	6.1-6.9	and	<7.8	
IGT (isolated)	<6.1	and	7.8-11.0	
IFG and IGT	6.1-6.9	and	7.8-11.0	
Diabetes	≥7.0	or	≥11.1	Diabetes

Note. PG = plasma glucose, IFG = impaired fasting glucose, IGT = impaired glucose tolerance, FPG = fasting plasma glucose, mmol/L = millimoles per litre, 2hPG = 2-hour plasma glucose, OGTT = oral glucose tolerance test, n/a = not applicable (Canadian Diabetes Association, 2008a).

2.2 Prevalence and Incidence of Prediabetes and Diabetes

Precise data on the prevalence and incidence of PreDM in Canada is currently lacking, as the key OGTT was excluded from the latest Canadian Health Measures Survey (Public Health Agency of Canada, 2009a). In 2004, the Public Health Agency of Canada

estimated that the number of Canadians over age 20 with PreDM was about 5 million, which is projected to increase to more than 6.3 million by 2016 (Public Health Agency of Canada, 2009a). In 2008, a press release from the Canadian Diabetes Association estimated that approximately 6 million Canadians had developed PreDM (Canadian Diabetes Association, 2008c).

According to the *Report from the National Diabetes Surveillance System: Diabetes in Canada*, in 2006-2007 approximately two million Canadians aged one and older, or 6.2% (roughly 1 in 16 people), were living with diagnosed diabetes (prevalence) (Public Health Agency of Canada, 2009b). The most recent Canadian statistics from 2006-2007 indicate that 211,168 individuals were newly diagnosed with diabetes that year (incidence), which translates to 6.7 individuals per 1,000 people aged one and older (Public Health Agency of Canada, 2009b).

Globally, diabetes mellitus affects a large number of people from diverse ethic and socioeconomic backgrounds (Zimmet, Cameron, & Shaw, 2005), and the most recent statistics about diabetes prevalence from the International Diabetes Federation Atlas suggest that in 2010, approximately 285 million individuals (or 6.6% of the world's population) were living with diabetes and an additional 344 million (7.9%) have PreDM (International Diabetes Federation, 2009). By 2030, this figure is projected to reach 438 million (7.8%) for diabetes prevalence and 472 million (8.4%) for PreDM prevalence (International Diabetes Federation, 2009).

2.3 Economic Burden of Prediabetes and Diabetes

Diabetes is currently one of the most costly chronic diseases (Sherwin, Robert S, Anderson, Robert M, Buse, John B, & Chin, Marshall H, 2002), creating a significant economic burden for the Canadian healthcare system. This is largely due to the associated costs of treating diabetes-related complications (Goeree et al., 2009). Data examining the economic expense of PreDM by itself is lacking; therefore, the following information

comprises the economic cost of diabetes for Canada at large. On a conservative note, one study estimated that the total healthcare costs associated with diabetes in Canada was $4.66 billion in the year 2000, and this number was projected to increase to $8.14 billion in 2016 (Ohinmaa et al., 2004). The Canadian Diabetes Association reports that diabetes will cost the Canadian healthcare system $15.6 billion per year, and will rise to $19.2 billion by 2020 (Canadian Diabetes Association, 2008d). These figures demonstrate that the development of diabetes does impose a significant economic burden on the healthcare system in Canada, and some of these associated costs may be reduced by the prevention or even delay of the development of T2DM.

2.4 Health Consequences of Prediabetes and Diabetes

Chronic health conditions, such as T2DM, impart not only a major economic burden to the Canadian healthcare system and the individual, but also has many associated clinical outcomes. This is largely due to the macrovascular and microvascular complications of the disease, which include: coronary artery disease (CAD), CVD, dyslipidemia, hypertension (HTN), acute coronary syndrome (ACS), heart failure, chronic kidney disease (CKD), retinopathy, neuropathy, and erectile dysfunction (Canadian Diabetes Association, 2008e).

The personal costs of getting T2DM may include a reduced quality of life and the increased likelihood of medical complications such as heart disease, stroke, kidney disease, blindness, amputation, and erectile dysfunction (Canadian Diabetes Association, 2008d). Psychological well-being can also be negatively affected in individuals with diabetes, and depressive symptoms are more common in people living with diabetes compared to the general population (Canadian Diabetes Association, 2008i). Specifically, depressive disorders alongside diabetes are associated with poorer self-care behaviour, poorer glycemic control, health complications, and decreased quality of life (Canadian Diabetes Association, 2008i).

According to one patient fact sheet distributed by the Canadian Diabetes Association, approximately 80% of people with diabetes will die as a result of heart disease or stroke, and Canadian adults with diabetes are twice as likely to die prematurely, compared to people without diabetes (Canadian Diabetes Association, 2008d). These serious health consequences are important to communicate to those at risk, because if left untreated, approximately 25% of people with PreDM will progress to T2DM within three to five years (Canadian Diabetes Association, 2008c). A meta-analysis of studies predicting risk for progression from PreDM to T2DM concluded that, compared to individuals with normoglycemia, annualized relative risks are: 4.66 for those with IFG, 6.35 for those with IGT, and 12.13 for those with both IFG and IGT (Gerstein et al., 2007). Therefore, prevention of T2DM should remain a top priority for those individuals that already have PreDM to help avoid many of the serious health complications of the disease.

2.5 Risk Factors Contributing to the Development of Type 2 Diabetes Mellitus

Prospective cohort studies have identified historical, physical, and biochemical variables associated with the development of T2DM (see Table 2). The main factors include older age, certain ethnic backgrounds, obesity (especially abdominal obesity), physical inactivity, history of gestational diabetes mellitus, overt coronary artery disease, and high fasting insulin concentrations and IGT (Canadian Diabetes Association, 2008f).

Table 2

Risk Factors for Type 2 Diabetes Mellitus

-Age ≥ 40 years -First-degree relative with T2DM -Member of a high-risk population (e.g. people of Aboriginal, Hispanic, South Asian, Asian, or African descent) -History of IGT or IFG -Presence of complications associated with DM -Vascular disease (coronary, cerebrovascular or peripheral)	-History of gestational diabetes mellitus -Delivery of a macrosomic infant -Hypertension -Dyslipidemia -Overweight -Abdominal obesity -Polycystic ovary syndrome -Acanthosis nigricans -Schizophrenia

Note. T2DM = Type 2 diabetes mellitus, IGT = impaired glucose tolerance, IFG = impaired fasting glucose, DM = diabetes (Canadian Diabetes Association, 2008a).

2.5.1 Modifiable Risk Factors. While there are several non-modifiable risk factors associated with the development of T2DM, many of the risk factors are modifiable, offering individuals with PreDM an opportunity to reduce their risk of developing T2DM if they take steps to change what is in their control. Some of the main modifiable risk factors for T2DM include: dietary habits, body weight, body composition, physical activity, and stress management. As a whole, this pilot study specifically explored the impact that a 6-month lifestyle behaviour change program could potentially have on impacting diet, weight, abdominal obesity, and blood pressure in adults with PreDM. These key dietary and anthropometric factors will be discussed further below.

2.5.1.1 Nutrition. Many dietary factors have been researched to help understand the connection between diet and the development of T2DM, and intake of vegetables and fruit (V&F) has been an important area. A diet high in V&F is associated with a decreased risk for many chronic diseases (World Health Organization, 2000), and additionally, because V&F typically have low energy densities (i.e. lower amount of energy relative to a given weight of a food, stated in kcal/g or kJ/g), an increase in daily consumption could be beneficial for weight management (Rolls, Ello-Martin, & Carlton Tohill, 2004). Given that obesity is the dominant modifiable risk factor for T2DM (which drives many of the physical risk factors listed in Table 2), it is reasonable to postulate that adequate V&F consumption may lower the risk by helping an individual lose weight. Most V&F are low in energy density because of their high water, high fibre, and low fat content. As a strategy to encourage weight loss, adding additional V&F to the diet allows for an increase in the amount of food that can be consumed for a given level of energy intake while promoting satiety (Rolls et al., 2004). This is because individuals tend to eat a similar weight of food each day, thus, when energy density of food is decreased, energy intake is spontaneously reduced with similar levels of satiation reported (Poppitt & Prentice, 1996; Yao & Roberts, 2001).

One of the earliest studies that sought to make a connection between V&F consumption and T2DM incidence looked at 9,665 Americans (45.5% male, 54.5% female) aged 25-74 years who participated in the first National Health and Nutrition Examination Survey (NHANES I), of which 1,018 went on to eventually develop T2DM (Ford & Mokdad, 2001). The NHANES I was conducted from 1971 to 1975, where trained nutritionists interviewed participants to collect dietary intake data with a single 24-hour recall and asked about all foods consumed on the preceding day. From the baseline NHANES I data, it was determined that the mean intake of V&F, as well as the percentage of participants who consumed five or more V&F servings per day was lower among participants who developed T2DM than among participants who remained free of the disease. Specifically, the men with T2DM included in the study had a mean V&F intake of 3.1 (SE, 0.2) servings per day, while the non-diabetic men had a mean intake of 3.3 (SE, 0.1) V&F servings per day ($P = 0.257$). The percentage consuming five or more servings of V&F per day was 19.6% among men with T2DM, and 25.6% among non-diabetic men ($P = 0.055$). Among women, mean intake was 2.9 (SE, 0.1) and 3.6 (SE, 0.1) V&F servings per day for diabetic and non-diabetic women respectively ($P < 0.001$), while the percentage consuming five or more V&F servings per day was 18.9% for women with T2DM and 30.2% for non-diabetic women ($P < 0.001$). After adjusting for age, ethnicity, smoking, systolic blood pressure, use of antihypertensive medication, serum cholesterol concentration, BMI, exercise, and alcohol consumption, the hazard ratio for participants consuming five or more servings of V&F per day was 0.73 (95% CI, 0.54-0.98), demonstrating that the overall incidence rate decreased with increasing consumption of V&F. The reduction in diabetes risk with increased V&F intake tended to be greater for women than for men ($P = 0.071$). Among women, those consuming five or more servings of V&F per day had a hazard ratio of 0.61 (95% CI, 0.42-0.88) and a dose response appeared to be present.

In a more recent systematic review and meta-analysis published in 2010, a team of researchers examined six prospective cohort studies that included an individual measure of

intake of V&F and an assessment of the development of T2DM (Carter, Gray, Troughton, Khunti, & Davies, 2010). The combined population of the six studies resulted in 223,512 male and female study participants that ranged in age between 30 to 74 years. Specifically, the meta-analysis looked at the lowest V&F intake values (ranging between 0 to 2.57 servings/day) versus highest intake values (ranging from 5.0 to 10.16 servings/day), and overall, found that there were no significant reductions in the risk of T2DM incidence for consumption of fruit, vegetables, or V&F combined, though their data did suggest a trend toward a benefit of consuming greater quantities (Carter et al., 2010). What was interesting however, was that in those studies that examined intake of green leafy vegetables, Carter et al. (2010) found that consuming 1.35 servings per day of green leafy vegetables (highest intake) compared with 0.2 servings (lowest intake) resulted in a 14% reduction in risk ($P = 0.01$) of T2DM (hazard ratio 0.86, 95% CI, 0.77-0.96).

Of those six studies included in the meta-analysis, Villegas et al. (2008) found that vegetable intake examined on its own in 74,942 Chinese women was associated with a decreased risk of developing T2DM, and inverse associations were especially prevalent for increased intake of specific sub-categories of vegetables, including: green leafy vegetables (i.e. spinach), cruciferous vegetables (i.e. green cabbage, cauliflower), yellow vegetables (i.e. sweet potatoes, carrots), allium vegetables (i.e. garlic, onions), and other vegetables (i.e. asparagus, cucumbers, mushrooms, peppers, tomatoes). Conversely, this study did not find an association between fruit intake and risk of T2DM (Villegas et al., 2008).

Results from the Nurses' Health Study (Bazzano, Li, Joshipura, & Hu, 2008), which included 98,462 female registered nurses between the ages of 30 and 55 years enrolled in the diet cohort found that the median intake of fruit in this population was 1.08 servings/day, whereas that for vegetables was 3.09 servings/day. Interestingly, the intake of fruit juices was positively associated with T2DM incidence, with a hazard ratio of 1.33 (95% CI, 1.19-1.48) for those in the highest quintile of fruit juice intake (0.7 servings/day) compared with those in the lowest (0.2 servings/day). Intake of whole fruits and green leafy vegetables was

found to be inversely associated. Previous findings have demonstrated that whole fruit provides greater satiety compared to fruit juice due to the fibre content and effects on glucose homeostasis, as well as the fact that beverages may affect the regulation of energy intake differently than solid foods, for instance, they offer no displacement of energy later in the day (Rolls et al., 2004).

Also included as part of the meta-analysis, Montonen and colleagues (2005) found that consumption of vegetables (especially green vegetables) and fruit/berries was associated with a reduced risk of T2DM, while conversely, intake of potatoes (a starchy vegetable) was associated with an increased risk (relative risk = 1.42, 95% CI, 1.02-1.98, P = 0.03). These findings were gathered from diet history interviews conducted by trained interviewers on Finnish citizens (n = 10,054) that did not have a history of diabetes who were included in the Finnish Mobile Clinic Health Examination Survey (Montonen, Jarvinen, Heliovaara, Reunanen, & Knekt, 2005).

Results from the Women's Health Study (Liu et al., 2004) reported similar findings in 39,876 female health professionals aged ≥ 45 years at baseline who completed a semi-quantitative FFQ. In models adjusted for age, total energy intake, and smoking, significant inverse relationships with T2DM risk were seen for total V&F intake, fruits, citrus fruits, green leafy vegetables, dark yellow vegetables, and legumes, while a significant positive association was found with intake of potatoes (Liu et al., 2004). In both of these studies, abundant potato intake was linked to the development of T2DM though increased post-prandial BG concentrations due to the high starch content and glycemic index of potatoes relative to other vegetables (Montonen et al., 2005).

Although these studies yield mixed results, continuing to promote increased V&F intake as a strategy for weight management and potential protective factor against developing T2DM remains appealing. For few calories, most V&F offer a host of beneficial components including water, fibre, phytochemicals and antioxidants, as well as numerous vitamins and minerals (i.e. vitamin C, folate, potassium, beta-carotene, magnesium, calcium, iron), while

at the same time acting as a marker for a healthy lifestyle (Villegas et al., 2008). Furthermore, the overall nutrition message remains positive emphasizing the increased consumption of particular foods rather than restriction (Rolls et al., 2004).

2.5.1.2 Obesity. Obesity is often defined as a condition of excessive fat (adipose tissue) accumulation, to the extent that health may be impaired (World Health Organization, 2000). Body mass index (BMI) has frequently been used as a measure of obesity and a predicting factor for the development of chronic disease. BMI is defined by the following formula: weight (kg) / height $(m)^2$ (World Health Organization, 2000). The BMI formula provides a useful, easy to administer, albeit crude measure of obesity and the health risks associated with it, by placing individuals into categories of risk based on BMI scores. Canada uses the following BMI categories to assess disease risk based on an individual's height and weight:

Table 3

Health Risk Classification According to Body Mass Index (BMI)

Classification	BMI category (kg/m^2)	Risk of developing health problems	Notes
Underweight	< 18.5	Increased	For persons 65 years and older the 'normal' range may begin slightly above BMI 18.5 and extend into the 'overweight' range.
Normal weight	18.5 – 24.9	Least	
Overweight	25.0 – 29.9	Increased	
Obese class I	30.0 – 34.9	High	
Obese class II	35.0 – 39.0	Very high	
Obese class III	≥ 40.0	Extremely high	

Note. BMI = body mass index, kg/m^2 = kilograms per meter squared (Health Canada, 2003a).

The graded classification of BMI is useful for several reasons: (a) it allows for meaningful comparisons of weight status within and between populations; (b) permits the identification of individuals and groups at increased risk of morbidity and mortality; (c) helps prioritize interventions aimed at the individual and community level; and (d) provides an objective basis for the evaluation of interventions (World Health Organization, 2000). The use of BMI as a measure of obesity has become common practice, and it is well recognized as a predictor of the morbidity and mortality associated with numerous chronic diseases,

including T2DM, CVD, and stroke (World Health Organization, 2000; National Institutes of Health: National Heart, Lung, and Blood Institute, 2000). Despite BMI's widespread adoption by health authorities, its major limitation is that BMI cannot distinguish between weight associated with muscle as compared to weight associated with fat.

Within the data emerging from the Botnia diabetes study by Lyssenko et al. (2005), in reviewing the risk of developing T2DM in 1,715 relatives of patients with T2DM and 400 control subjects without a family history of diabetes, it was found that subjects with BMIs or waist circumferences (WC) above the median had approximately a twofold ($P = 0.0002$) increase in the risk of developing T2DM compared to those with values below the median. Interestingly, this effect was stronger in those subjects with IFG-IGT (Lyssenko et al., 2005).

Achieving moderate weight loss (defined as 5-7% of initial body weight) in overweight or obese persons with T2DM and/or those at risk of developing T2DM can improve insulin action, decrease fasting blood glucose concentrations, reduce the need for diabetes medications, and improve risk factors for CVD, such as reducing high blood pressure and improving serum lipid profile (Klein et al., 2004; Diabetes Prevention Program Research Group, 2002; Tuomilehto et al., 2001).

2.5.1.3 Abdominal Obesity. Abdominal obesity has specifically been demonstrated to be an independent risk factor for the development of T2DM, often indicating early signs of insulin resistance (Canadian Diabetes Association, 2008b) and other potential chronic diseases (World Health Organization, 2000). It has been established that abdominal obesity, assessed by WC, is a good predictor of obesity-related health risk (World Health Organization, 2000; National Institutes of Health: National Heart, Lung, and Blood Institute, 2000; Zhu et al., 2002), and further evidence indicates that WC coupled with BMI predicts health risk better than does BMI alone (Ardern, Katzmarzyk, Janssen, & Ross, 2003; Janssen, Katzmarzyk, & Ross, 2002). A careful analysis of the relationship between increasing abdominal obesity and the risk of developing T2DM in adults confirms that abdominal obesity is an important

risk factor, even after controlling for age, smoking, and family history (World Health Organization, 2008).

The sex-specific WC cutoff points were originally developed to compare WC and BMI in a large, heterogeneous sample of white men and women (n = 2,206) (Lean, Han, & Morrison, 1995). In that sample, researchers found that a WC of 102 cm in men and 88 cm in women corresponded to a BMI of ≥ 30.0 kg/m^2, with only about 2% of the sample being misclassified. In Canada, the following WC categories are used to assess risk of health problems based on an individual's WC:

Table 4

Health Risk Classification According to Waist Circumference (WC)

WC cut-off points	Risk of developing health problems*	Notes
Men ≥ 102 cm (40 in.)	Increased	*Risk for type 2 diabetes, coronary heart disease, hypertension
Women ≥ 88 cm (35 in.)	Increased	

Note. WC = waist circumference, cm = centimeter, in. = inches (Health Canada, 2003b).

Janssen, Katzmarzyk, and Ross (2002) specifically examined whether the prevalence of HTN, T2DM, dyslipidemia, and the metabolic syndrome was greater in individuals with high compared to normal WC values within the same BMI category (Janssen et al., 2002). Using data collected by the National Centre for Health Statistics for the NHANES III study, Janssen et al. (2002) looked at a sample of 14,924 subjects aged 17 and older in whom measures of WC, height, weight, and metabolic variables were obtained and who fit the BMI categories examined. With few exceptions, Janssen et al. (2002) found that within the three BMI categories studied (normal weight: 18.5-24.9 kg/m^2; overweight: 25.0-29.9 kg/m^2; and obese class I: 30.0-34.9 kg/m^2), those with high WC values were more likely to have HTN, T2DM, dyslipidemia, and the metabolic syndrome compared to those with normal WC values. Furthermore, the authors found that a high WC independent of BMI predicted obesity-related disease. Other researchers have validated these findings indicating that WC

is a stronger marker of health risk than is BMI (Zhu et al., 2002; Janssen, Katzmarzyk, & Ross, 2004).

2.5.1.4 Hypertension. According to the Canadian Diabetes Association, most people with diabetes will develop HTN (Canadian Diabetes Association, 2008g). The Canadian Hypertension Education Program has confirmed that up to 75% of specific diabetic complications are attributable to high blood pressure (BP) (Canadian Hypertension Education Program Task Force, 2010). In the United Kingdom Prospective Diabetes Study consisting of 3,642 British patients with T2DM, it was found that for each 10 millimeters of mercury (mm Hg) decrease in mean systolic BP, the risk of microvascular complications declined by 13% ($P < 0.0001$), the risk for myocardial infarction decreased by 11% ($P < 0.0001$), the risk for death related to diabetes decreased by 15% ($P < 0.0001$), and individuals with T2DM saw an overall 12% reduction in risk for any complication related to diabetes ($P < 0.0001$) (Adler et al., 2000). Current Canadian clinical practice guidelines suggest that persons with diabetes and HTN should be treated to attain systolic BP <130 mm Hg and diastolic BP <80 mm Hg (Canadian Diabetes Association, 2008h; Canadian Hypertension Education Program Task Force, 2010), and that lifestyle interventions including achieving and maintaining a healthy weight and limiting sodium and alcohol intake should be initiated concurrently with pharmacological intervention to reduce BP (Canadian Diabetes Association, 2008g).

2.6 Successful Lifestyle Interventions Aimed at the Prevention or Delay of T2DM

2.6.1 Da Qing Diabetes Prevention Outcome Study. One of the first studies that looked at lifestyle intervention in those with IGT was the Da Qing Diabetes Prevention Outcome study (Pan et al., 1997; Gong et al., 2011). In 1986, 577 adults with IGT from 33 clinics in Da Qing, China were randomly assigned into a control group or one of three intervention groups (diet only, exercise only, or diet-plus-exercise). The diet group was prescribed a diet containing 55-65% carbohydrate, 10-15% protein, and 25-30% fat and was encouraged to consume more vegetables, control intake of alcohol, and reduce intake of simple sugars.

Those subjects with BMI ≥ 25 kg/m^2 were encouraged to reduce their caloric intake so as to gradually lose weight at a rate of 0.5-1.0 kg per month until they achieved a BMI of 23 kg/m^2. The exercise group was taught and encouraged to increase the amount of leisure physical exercise, and the rate of increase and type of exercise recommended was individualized based on age, exercise patterns, and the existence of health problems other than IGT. The diet-plus-exercise group received counselling for both diet and exercise similar to those for the diet-only and the exercise-only intervention groups. The control group was exposed to general information about diabetes and IGT but did not receive any individualized instruction. At the 6-year mark of intervention the cumulative incidence of diabetes was 67.7% (95% CI, 59.8-75.2) in the control group compared with 43.8% (95% CI, 35.5-52.3) in the diet group, 41.1% (95% CI 33.4-49.4) in the exercise group, and 46.0% (95% CI, 37.3-54.7) in the diet plus exercise group ($P < 0.05$) (Pan et al., 1997). In 2006, a 20 year follow-up study of the original participants (n = 542, 94% of the 577 original participants) was completed to compare the incidence of microvascular complications in the combined intervention groups versus the control group. The cumulative incidence of severe retinopathy was 9.2% in the combined intervention group and 16.2% in the control group ($p = 0.03$). After adjusting for clinic location and age, the incidence of severe retinopathy was 47% lower in the intervention group than the control group (hazard rate ratio 0.53, 95% CI 0.29-0.99, $p = 0.048$). No significant differences were found in the incidence of severe nephropathy (hazard rate ratio 1.05, 95% CI 0.16-7.05, intervention versus control, $p = 0.96$) or in the prevalence of neuropathy (8.6% versus 9.1%, $p = 0.89$) among the 20 year survivors (Gong et al., 2011).

2.6.2 Finish Diabetes Prevention Study. The Finish Diabetes Prevention Study was conducted to determine the feasibility and effects of a program aimed at modifying lifestyle factors that could prevent or delay the onset of T2DM in 522 subjects with IGT (172 men and 350 women). Middle-aged (mean age 55 years), obese subjects (mean BMI 31 kg/m^2)

with IGT were randomly assigned to either the intervention group or the control group (Tuomilehto et al., 2001). Each subject in the intervention group received individualized counselling aimed at reducing weight (≥ 5% of initial body weight), total fat intake (< 30% of energy consumed), and saturated fat intake (< 10% of energy consumed), while increasing fibre intake (≥ 15 g per 1000 kcal) and physical activity (moderate exercise for at least 30 minutes per day) (Tuomilehto et al., 2001). Dietary recommendations included frequent consumption of whole grains, vegetables, fruits, low-fat milk and meat products, soft margarines, and vegetable oils rich in monounsaturated fatty acids. The intervention group received dietary advice provided by a nutritionist over seven sessions within the first year, and one session every three months thereafter, with nutritional feedback tailored to each individual on the basis of his/her three-day food intake record (3d-FIR) completed four times per year. Supervised, progressive, individually tailored, circuit-type resistance-training sessions were also offered during the first year. Subjects randomized to the control group were given general oral and written information about diet and exercise at baseline and at subsequent annual visits, but no specific individualized feedback. Overall, the Finish Diabetes Prevention Study found a mean weight loss of 4.2 ± 5.1 kg in the intervention group and 0.8 ± 3.7 kg in the control group ($P < 0.001$) within the first year (Tuomilehto et al., 2001). After an average follow-up of 3.2 years, there was a 58% relative reduction in the incidence of diabetes in the intervention group compared with control subjects ($P < 0.001$), which was directly associated with changes in lifestyle (Tuomilehto et al., 2001).

2.6.3 Japan Lifestyle Intervention Trial. In another large lifestyle intervention trial conducted in Japan (Kosaka, Noda, & Kuzuya, 2005), 483 Japanese males with IGT were randomly assigned in a 4:1 ratio to a standard intervention group (control group, n = 356) or an intensive intervention group (n = 102). The control and intervention groups were advised to maintain a BMI of < 24.0 kg/m^2 and < 22.0 kg/m^2, respectively, by diet and exercise. The intervention group also received detailed instructions on lifestyle every 3-4 months during

hospital visits. Body weight decreased by 0.39 kg in the control group and by 2.18 kg in the intervention group ($P < 0.001$). The cumulative 4-year incidence of diabetes was 9.3% in the control group, versus 3.0% in the intervention group, and the reduction in risk of diabetes was 67.4% ($P < 0.001$). (Kosaka et al., 2005).

2.6.4 Diabetes Prevention Program. Last but certainly not least, is the Diabetes Prevention Program (DPP) (Diabetes Prevention Program Research Group, 1999; Diabetes Prevention Program Research Group, 2000; Diabetes Prevention Program Research Group, 2002). The DPP involved 3,234 non-diabetic subjects with IFG and IGT who were randomly assigned to placebo, metformin (850 mg twice daily), or a lifestyle-modification program with intensive nutrition and exercise counselling with the goals of at least a 7% weight loss and at least 150 minutes of physical activity per week. The mean age of participants was 51 years with a mean BMI of 34.0 kg/m^2; 68% were women, 45% were members of minority groups (e.g. African American, Hispanic), and 20% were ≥ 60 years of age (Diabetes Prevention Program Research Group, 2000). After an average follow-up of 2.8 years, a 58% reduction in the progression to T2DM was observed in the lifestyle-modification group (absolute incidence 4.8%), and a 31% relative reduction in the progression of T2DM was observed in the metformin group (absolute incidence 7.8%) compared with control subjects (absolute incidence 11.0%). On average, 50% of the lifestyle group achieved the goal of ≥ 7% weight reduction, and 74% maintained at least 150 minutes/week of moderately intense physical activity (Diabetes Prevention Program Research Group, 2002).

2.7 Translation of Successful Diabetes Lifestyle Intervention Programs at the Community Level

Without question, programs like the DPP have demonstrated that intensive lifestyle interventions with individualized nutrition counselling and physical activity sessions can reduce the development of T2DM by more than half in adults with PreDM; however, less is

known about the feasibility of offering such interventions in the community with fewer financial and human resources. Listed below are a number of key studies that have attempted to answer this question by delivering group education and lifestyle behaviour change strategies in a community-based setting.

2.7.1 GOAL Implementation Trial. The GOAL implementation trial, designed for delivery in primary health care settings, was piloted on 353 middle-aged Finnish participants at risk for T2DM (Absetz et al., 2007). The program was a group-based, task-oriented counselling model that focused on attainment of five key objectives to prevent T2DM (i.e. <30% kcal from total fat, <10% of kcal from saturated fat, at least 15 g of fibre/1,000 kcal, at least 4 hours/week of moderate physical activity, >5% weight reduction). The program components included information provision, group discussions, self-monitoring of behaviour, goal setting, and planning, and all six program sessions were scheduled for two hours/session. In regards to attrition, 57% of the participants reported attending all six counselling sessions and only thirty-three participants dropped out of the study during follow-up. At baseline 70% of participants were obese (BMI > 30 kg/m^2) and had a mean waist circumference of >100 cm among women and 110 cm among men. After one year follow-up, diastolic BP, weight, and BMI (only men), and waist circumference (both sexes) decreased significantly. This study found that program exposure significantly correlated with weight loss, and favourable nutrition outcomes may partly have been attributed to investment in a program dietitian (Absetz et al., 2007).

2.7.2 Weight Loss through Living Well Study (WILLOW). One 2009 study further discussed the successes and challenges to implementing a group-based version of the DPP lifestyle curriculum in a large medicine practice that included 166 overweight or obese participants referred by their primary healthcare provider, of which 81 enrolled in WILLOW (McTigue, Conroy, Bigi, Murphy, & NcNeil, 2009). The program was delivered by a nurse educator over twelve weekly sessions (versus the original 16 sessions delivered via one-on-

one counselling in the DPP) to help participants meet program goals derived from the DPP: 7% weight loss; 150 minutes/week of moderate physical activity; a total fat intake reduction to 25% of calories; and a calorie restriction of 500- to 1000-kcal/day. Each session included group education, relevant demonstrations (e.g. healthy portion sizes, food labels), and opportunities for participants to share personal experiences, while behavioural techniques focused on goal setting, self-monitoring, and problem solving. The program was made available on a fee-for-service basis, with a charge of $100 for the twelve weekly sessions. Those participants who enrolled in WILLOW had a mean weight change of -5.19 kg (CI, -7.71 to -2.68) versus +0.21 kg (CI, -1.50 to 1.93) among the non-enrollees. Furthermore, 27% of the enrollees versus 6% of the non-enrollees lost ≥ 7% of their initial body weight ($p = 0.001$), which was considered not only statistically but clinically significant (McTigue et al., 2009). The strong counselling skills of the clinical educators were cited as one reason that facilitated patient engagement, and the researchers concluded that WILLOW could fit naturally within the preventive services of primary care medicine while helping patients overcome the daunting challenge of developing and maintaining healthy lifestyles.

2.7.3 DEPLOY Pilot Study. In the DEPLOY pilot study (n = 92), adults who attended a group-based DPP lifestyle intervention program in semi-urban YMCA facilities lost significantly more weight (6% versus 2% weight loss, $p < 0.001$) compared to those who received brief counselling alone (control) (Ackermann, Finch, Brizendine, Zhou, & Marrero, 2008). This study was unique from the others in that it was able to show that partnering with local YMCAs may be another promising channel for wide-scale dissemination of a low-cost approach to lifestyle diabetes prevention, outside of a traditional primary healthcare setting.

From these group-based education programs, some of the key factors that were attributed to their success included the social interaction between participants (via group discussions); the expansion of participants' knowledge, skills, and self-efficacy (via information provision and hands-on learning through activities such as label reading);

encouragement of self-monitoring and planning behaviours (via goal setting, food diaries, etc.); investment in program educators with strong counselling skills; and regular program attendance by participants. Clearly a variety of DPP translation programs appear to be effective in a group setting; however, the key is to find ways to systematically implement them into the existing healthcare system to ensure that they are integrated with care delivery, cost-effectiveness, and are broadly supported by patients, healthcare providers, and funding agencies.

2.8 Clinical Practice Guidelines for the Management of Prediabetes

The 2008 Canadian Diabetes Association Clinical Practice Guidelines (CDA-CPG) emphasizes designing and implementing T2DM prevention programs that: a) target high-risk individuals in the community (i.e. those with PreDM or obesity); b) target high-risk subgroups (i.e. ethnic groups); and c) are aimed at the general population, such as those designed to promote physical activity and healthy eating habits in adults and children (Canadian Diabetes Association, 2008f). Specifically, the 2008 CDA-CPG recommends that healthcare providers and program planners offer "a structured program of lifestyle modification that includes moderate weight loss and regular physical activity… to reduce the risk of T2DM in individuals with IGT [Grade A, Level 1A] and IFG [Grade D, Consensus]" (Canadian Diabetes Association, 2008f).

In a 2004 position paper released by the American Diabetes Association, the North American Association for the Study of Obesity, and the American Society for Clinical Nutrition, the following key recommendations were made based on the evidence that T2DM could be prevented and managed by achieving and maintaining a healthy weight and through lifestyle modification: (a) weight loss is recommended for all overweight or obese adults (BMI $\geq$ 25.0 kg/m^2) who have or are at risk for developing T2DM; (b) the primary approach for achieving weight loss is therapeutic lifestyle change, which includes a reduction in energy intake (moderate decrease of ~500-1,000 kcal/day resulting in weight loss of ~1-2

pounds/week) and an increase in regular, moderate intensity physical activity 3-5 days per week to improve insulin sensitivity (Klein et al., 2004).

2.9 Rationale for the Proposed Intervention

Currently in Canada, lifestyle counselling for PreDM is limited in many practice settings, due to the burden of constrained resources (i.e. time, personnel, financial) within the healthcare system. There is now substantial evidence that T2DM can be prevented or delayed, and community-based group education programs have the potential to alleviate some of the strain on the healthcare system by reaching a larger number of high-risk individuals through a more efficient delivery of resources, as compared to the more individualized, intensive T2DM prevention programs such as the DPP. It is presently unknown if a group education program delivered free of charge in a Canadian community-based setting will be equally effective at achieving sustained lifestyle modifications including weight reduction and increased physical activity in a population of adults with PreDM, as compared to those programs delivered in a traditional, primary healthcare setting.

2.9.1 Objectives. The goal of this research project was to provide an exploratory analysis on the first two cohorts of participants enrolled in a 6-month PreDM lifestyle education program (PREPARE). Only a small subset of the overall study population was included in this early analysis, providing preliminary results while the main study remains ongoing. The primary objective of this research project was to evaluate the impact of PREPARE from a *nutritional standpoint*, examining changes made by PREPARE participants after receiving six months of nutrition education to help prevent or delay the onset of T2DM. Secondary objectives included evaluating changes in anthropometric and hemodynamic risk factors associated with T2DM in PREPARE participants. Specifically, this study sought to investigate the impact of the program on diet by:

(a) Quantifying changes in vegetable and fruit (V&F) consumption from baseline to the end of the study (i.e. intake of whole V&F, V&F juice, dark green vegetables, bright orange V&F, and starchy vegetables).

(b) Quantifying changes in average daily intake of Canada's Food Guide (CFG) servings over the course of the program, and to also assess the percentage of participants who met current minimum CFG V&F recommendations at baseline and at the end of the program.

(c) Quantifying changes PREPARE and control participants made to specific nutrients of interest (i.e. macronutrients, fibre, sodium, saturated fatty acids, alcohol) from baseline to the end of the program.

Secondary outcome objectives were to:

(d) Qualitatively capture changes in PREPARE participants' dietary habits via focus group discussions and questions pertaining to nutrition from the overall program feedback forms post-study.

(e) Quantify changes in key anthropometric and hemodynamic parameters known to increase the risk of developing T2DM from baseline to the end of the study in the PREPARE participants.

2.9.2 Hypotheses. Given the success of other group lifestyle modification programs for the prevention of T2DM, it was hypothesized that this pilot study would:

- Increase participants' average number of daily servings of V&F from baseline, and improve intake of dark green vegetables and bright orange V&F, compared to controls.
- Increase the number of participants who met CFG food group recommendations post-program.
- Offer improvements in intake for selected micro-nutrients, such as sodium and SFA.

- Reduce physical risk factors associated with T2DM, including a reduction a weight, WC, BMI, and BP.

Chapter 3: Methods

3.1 Ethics Approval

Ethics approval for the involvement of human participants was obtained through the University of Western Ontario (Appendix A), the Lawson Health Research Institute Clinical Research Impact Committee (CRIC) of St. Joseph's Health Care in London, ON (Appendix B), and Brescia University College at the University of Western Ontario (Appendix C).

3.2 Study Design

The overall study was a pilot program evaluation utilizing a quasi-experimental design. This single-centre study took place at Brescia University College in London, ON. Individuals diagnosed with PreDM referred to the DEC at SJHC London were offered the opportunity to self-select PREPARE (experimental arm) or the current standard of care (control arm). PREPARE was a newly developed community-based lifestyle and behaviour change program for adults with PreDM that was comprised of six monthly 2-hour group education sessions with hands-on activities related to nutrition and physical activity. The control arm received the current standard of care for PreDM, which was a one-time 2-hour group education session at Brescia University College. Appendix D illustrates a detailed flow chart of the overall study design. This pilot study followed the first 48 research participants that self-selected PREPARE and the first 15 control participants that self-selected the current standard of care. Mixed quantitative and qualitative methods were used to assess the program's impact on dietary behaviour change, specifically focusing in V&F intake from baseline to the end of the study, as well as, examining other key anthropometric and hemodynamic parameters known to increase the risk for developing T2DM.

3.3 Study Participants

A sample of individuals recently diagnosed with PreDM referred to the DEC of SJHC London by their family physician had the opportunity to participate in the study. A sample

Diabetes Education Referral Form used by physicians to refer clients may be found in Appendix E. All referred clients were mailed a Letter of Information and Consent (Appendix F) and were invited to participate in the research study if they met the following criteria:

Inclusion criteria:

- Adults 30 years of age or older
- From London, ON or surrounding area (including Middlesex)
- Prediabetes diagnosis by a healthcare provider (e.g. family physician) who have been referred to the DEC of SJHC London
- Ability to perform low-impact physical activity
- Ability to eat a normal, balanced diet
- Ability to understand English well enough to participate in the educational discussions and activities and to complete required questionnaires

Exclusion criteria:

- Adults less than 30 years of age
- Participation in another lifestyle or behaviour change education or research program
- Poor mobility (i.e. wheelchair-bound), limiting low-impact physical activity
- Unable to chew, digest food, or follow a normal balanced diet (e.g. being on a specialized diet such as a low-fibre diet or enteral nutrition support due to a pre-existing condition, such as Crohn's disease, celiac disease or other digestive disease)
- Pregnant or lactating females
- Diagnosis of Type 1 or Type 2 diabetes mellitus
- Diagnosis of any major health condition (e.g. cancer)
- Diagnosis of any behavioural or psychiatric issues (e.g. major depression, eating disorder, schizophrenia or other mental illness)

Study participants gave informed consent in accordance with the research procedures approved by the Research Ethics Board for Health Sciences Research involving Human Studies at The University of Western Ontario. To confirm participant eligibility, all interested study participants were screened by the research team utilizing a Screening Questionnaire (Appendix G).

The power analysis suggested a sample size of 240 participants for the overall research study. This calculation was based on the primary outcome variable of average number of V&F servings/day. From historical referral records (2007-2010 inclusive) tracking DEC patient referrals for the current standard of care, it was estimated that it would take approximately two years to recruit all 240 participants. This study was a preliminary evaluation of the project's nutritional impact in a sample of individuals from London, ON recently diagnosed with PreDM. As such, all study participants recruited between May 5th to August 26th 2011 who met the eligibility criteria, consented to research involvement, and self-selected to participate in PREPARE or the control arm were included in this exploratory analysis (cohorts 1 and 2).

3.4 Pre-Recruitment of Clients with Prediabetes

Individuals recently diagnosed with PreDM from London, ON and surrounding area were informed of PreDM education programming available to them through their family physicians and the DEC of SJHC London. These referral channels have been previously successful and were used to book clients for the current standard of care (a 2-hour group education session) at Brescia University College since 2007.

A Letter to Family Physicians (Appendix H) was mailed to the majority of practicing family physicians in the London area, so that they could inform their patients with PreDM about the three education options available: (i) PREPARE: 6 monthly 2-hour group education sessions with a research component, (ii) the current standard of care, one 2-hour group education session with a research component and some follow-up, or (iii) the current

standard of care, one 2-hour group education session without a research component or any further follow-up. Included with this letter was a poster (Appendix I) and brochure (Appendix J) that physicians could post in their offices to inform clients about the PreDM program options. The poster and brochure were also posted on the websites of SJHC London and Brescia University College.

Interested individuals were asked to contact the DEC to book an initial visit at Brescia University College (Visit 1: baseline). Personal details such as their name, phone number, and mailing address were collected by the DEC's administrative team to later contact the clients by telephone (Appendix K) and a letter in the mail (Appendix L) to remind them of their scheduled appointment and to ask clients to complete a three-day food intake record and Medication Log (3d-FIR) (Appendix M) on the forms provided.

3.5 Recruitment of Study Participants

At Visit 1 (baseline), the research team presented the three PreDM education options to the clients (Figure 1) to help them make an informed decision about participation in the research study. Individuals interested in PREPARE (experimental arm) or the current standard of care with some research contact (control arm) were asked to review the study's Letter of Information (Appendix F) and provide informed written consent. For those individuals who chose not to participate in the research study or did not meet the eligibility criteria (non-participants), the current standard of care (a one-time 2-hour group education session) was provided in another room on site.

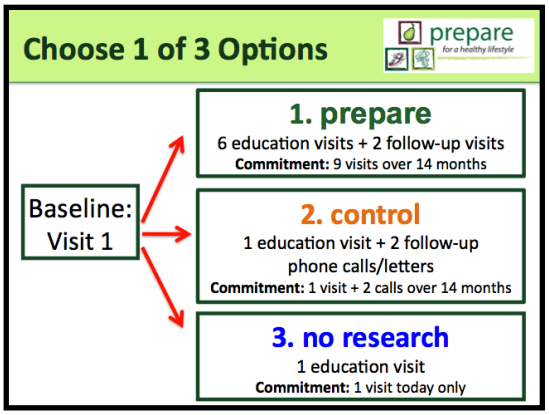

Figure 1. Three options presented to potential research participants at Visit 1 to assist with self-selection.

3.6 Parameters Examined

Study data were collected via a number of self-reported questionnaires, as well as, anthropometric and hemodynamic measurements taken by trained researchers. The self-reported questionnaires incorporated in this study's analysis included: a 3d-FIR (Appendix M), a Demographic Questionnaire (Appendix N), and a Lifestyle Questionnaire (Appendix O). These questionnaires collected a variety of baseline demographic, medical, and current lifestyle information from participants, including: age, gender, ethnicity, socioeconomic status, smoking status, alcohol use, food and beverage intake, cooking ability, medication and supplement use, stress level, weight history, pertinent medical history related to increased risk for developing T2DM, and previous lifestyle change attempts. Additionally, after each of the monthly PreDM education sessions (Visits 2-7) a monthly Session Feedback Form (Appendix P) was administered, and at the post-program follow-up (Visit 8), an Overall Program Feedback Form (Appendix Q) was distributed. A 3d-FIR was completed at home by the study participants to capture two typical week days and one weekend day of all food, beverages, medications, and supplements consumed between the monthly PREPARE visits. Specifically, the following dietary components were evaluated based on the analysis of each participant's 3d-FIR:

Table 5

Dietary Components Evaluated

Energy Intake	Average daily energy intake (in kcal/d and kJ/d)
Macronutrient Intake	**Carbohydrate:** grams of CHO per day, % of energy from CHO **Fibre:** total grams of fibre per day **Protein:** grams of protein per day, % of energy from protein **Fat:** grams of fat per day, % of kcal from fat **Saturated Fat:** grams of SFA per day, % of energy intake from SFA
Micronutrients of Interest	**Sodium:** total milligrams of sodium per day **Alcohol:** grams of alcohol per day, % of energy from alcohol
Intake of Canada's Food Guide Servings	**Number of daily servings:** V&F, grains, milk and alternatives, and meat and alternatives **V&F, sub-divided (number of daily servings):** total vegetables, total fruit, whole fruit, fruit juice, dark green vegetables, orange V&F, starchy vegetables, vegetable juice

Note. kcal = kilocalories, d = day, kJ = kilojoules, CHO = carbohydrate, % = percentage, SFA = saturated fatty acids, V&F = vegetables and fruit

The anthropometric and hemodynamic measurements collected consisted of: height, weight, waist circumference, and blood pressure. Measured height and weight were then used to calculate each participant's body mass index (BMI).

3.7 Data Collection/Analysis Procedures

All data was collected between May 2011 to April 2012.

3.7.1 Three-day Food Intake Record and Medication Log Procedure. The 3d-FIR was mailed to all potential research participants prior to Visit 1 (baseline) to be completed in advance of joining the study. Participants were reminded by letter and a telephone call to record all food and beverages consumed for two week days and one weekend day the week prior to arriving for Visit 1. Instructions were also provided to help individuals fill in their current medication and supplement use on the same form. At each visit, research participants had the opportunity to sit down in a confidential booth with a Registered Dietitian, dietetic intern, or trained upper year undergraduate Foods & Nutrition student to review the contents of their 3d-FIR and clarify any vague or missing details that would impact the dietary analysis. A total of eight 3d-FIRs were completed by each research participant (one per visit, Visits 1-8) to facilitate self-monitoring skills and to assess changes in dietary intake patterns and medication/supplement use over the course of the PREPARE program.

The Visit 1 (baseline) and Visit 8 (post-program) 3d-FIRs were analyzed using ESHA Food Processor SQL (version: 10.8.0.0) that included the Canadian Nutrient File by a Registered Dietitian/Masters candidate, supported by a team of trained undergraduate Foods & Nutrition students (Appendix R). If a participant did not return a post-program (Visit 8) 3d-FIR, intent to treat analysis was applied and the last submitted monthly 3d-FIR was used for dietary analysis. Documents produced by Health Canada, including CFG (Appendix S) and CFG - What is a Food Guide Serving of Vegetables and Fruit (Appendix T) were used by the research assistants to help calculate the number of food guide servings consumed per

day by the study participants, as well as sub-categorize V&F (see Table 6) based on Health Canada's classification. Each record's analysis was reviewed in detail and verified by a Registered Dietitian/Masters candidate for accuracy.

Table 6

Sub-categorization of Vegetables and Fruit

Dark green vegetables	Asparagus, green beans, bok choy/Chinese cabbage (Choi sum), broccoli, Brussels sprouts, chard, dandelion greens, edamame (soy beans), endive, fiddleheads, kale/collards, leeks, Romaine lettuce, mesclun mix, mustard greens, okra, peas, green pepper, seaweed, snow peas, spinach, zucchini
Orange V&F	Orange vegetables: carrots, pumpkin, squash, sweet potato, yam Orange fruit: apricot, cantaloupe, mango, nectarine, papaya, peach
Starchy vegetables	Peas, corn, squash, potato, sweet potato, yam
Vegetable juice	100% vegetable juice (e.g. tomato)
Fruit juice	100% fruit juice (e.g. apple, grape, orange, etc.)

Note. V&F = vegetables and fruit, % = percent

3.7.2 Questionnaire Procedure. At Visit 1, the Demographics Questionnaire (Appendix N) and the Lifestyle Questionnaire (Appendix O) were administered to the participants as part of a larger package of questionnaires for the overall PREPARE study. These questionnaires were provided in a random order to reduce questionnaire order bias and to help combat the fatigue associated with the completion of multiple questionnaires at one time.

3.7.3 Anthropometric and Hemodynamic Procedure. At every visit, all anthropometric and hemodynamic measurements were taken twice for each participant by the research team. Height was measured to the nearest 0.1 cm using a stadiometer (model: Seca 274) with the participant's shoes removed (Visit 1: baseline only). Current body mass (from here on referred to as "weight") was measured at each visit to the nearest 0.1 kg using a digital scale (model: HealthOMeter 130-599KL) with the participant wearing light clothing and his or her shoes removed. At each visit, the scale was calibrated to ensure accuracy. BMI was then calculated according to the formula: weight (kg) / height $(m)^2$. Waist circumference was measured to the nearest 0.1 cm by a trained researcher using the midpoint between the right

iliac crest and bottom right rib to landmark where to place the tape measure against the participant's bare skin in a confidential booth. Any deviations or landmarks used by the trained researcher to measure waist circumference were written down in each participant's file for future reference. Blood pressure was monitored in millimeters of mercury using an automatic blood pressure monitor (model: HEM-907XL) that circulated the room while participants were quiet and relaxed, seated at a desk for at least ten minutes, with their legs uncrossed and palm facing upwards. A detailed Procedure for Physical Measurements (Appendix U) used in training and kept on-site at all times included specific instructions to the research team to repeat any measurement a third time if the initial two measurements did not fall within a close range of one another (i.e. 0.5 cm for height or WC; 0.1 kg for weight; 5 mmHg for BP).

3.7.4 Focus Group Procedure. Focus groups were also used to capture qualitative changes participants made to their health behaviours as a result of the PREPARE program. At each of the post-program follow-up assessments (Visit 8), a focus group was conducted with the participants to provide an opportunity to collect additional information that would be missed from a solely quantitative, deductive approach. Please see Appendix V for an outline of the focus group questions. Questions were designed to afford the opportunity to comment on the different aspects of the program that were most enjoyed by participants or had the greatest impact on changing their health behaviours, and participants were also encouraged to provide constructive criticism and develop solutions to some of the problems and shortcomings that they perceived existed in the PREPARE program.

To avoid potential bias, focus groups were conducted by two trained moderators who were not familiar to the participants. Participants were also assured that their names would not be attached to any data that would personally identify them. Each focus group session lasted between forty-five to sixty minutes and were audio-taped and transcribed verbatim. Focus group transcripts were analyzed by two analysts for recurrent themes.

3.8 Statistical Analysis

The focus of this study's analysis was two-fold: (1) to determine the program's impact by examining between group differences (i.e. intervention (PREPARE) participants versus controls) at the end of the study; and (2) to provide preliminary estimates of the within-group changes for dietary intake and other secondary anthropometric and hemodynamic risk factors for T2DM from baseline to post-program. Mean, standard deviation, and where appropriate, percent were calculated to offer descriptive statistics of the participants' characteristics.

To assess the program's impact on primary outcome measures (i.e. make between group comparisons), a one-way analysis of variance (ANOVA) was conducted using an orthogonal contrast to compare the intervention participants to the control participants. Within the intervention group, PREPARE participants were further divided into two groups, based on their attendance to the program, for exploratory analysis of outcome measures. Participants who attended ≥ 3 of 6 PREPARE education sessions were classified as "high attendees" (HA), while "low attendees" (LA) were defined as those who attended only 1-2 of the 6 PREPARE education sessions offered. To isolate where specific differences existed between the HA, LA, and control participants, an ANOVA with post hoc group comparisons were made by running a Sidak adjustment. To explore data further, paired t-tests were performed to analyze within-group changes in dependent variables from baseline to the end of the study. If post-program (Visit 8) data was unavailable, an intention to treat analysis was performed, where the data gathered at the last point of contact during the program was carried forward.

Statistical significance was considered with a probability < 0.05, using a 2-tailed test. All statistical analyses were performed using the SPSS Statistical Analysis Software (version 14.0 for Windows, SPSS Inc., Chicago, Illinois, 2005) and include all participants who completed data collection and attended one or more of the education sessions offered, regardless of their level of intervention participation.

Chapter 4: Results

4.1 Recruitment

Study recruitment took place between May 2011 and August 2011. During this time, 63 participants agreed to participate in the study after attending a Visit 1 recruitment and data collection session at Brescia University College; 48 of which self-selected PREPARE (intervention arm), while the remaining 15 participants self-selected the current standard of care (control arm). Figure 2 provides a simplified version of the study's methodology (previously outlined in Appendix D) with recruitment and retention results.

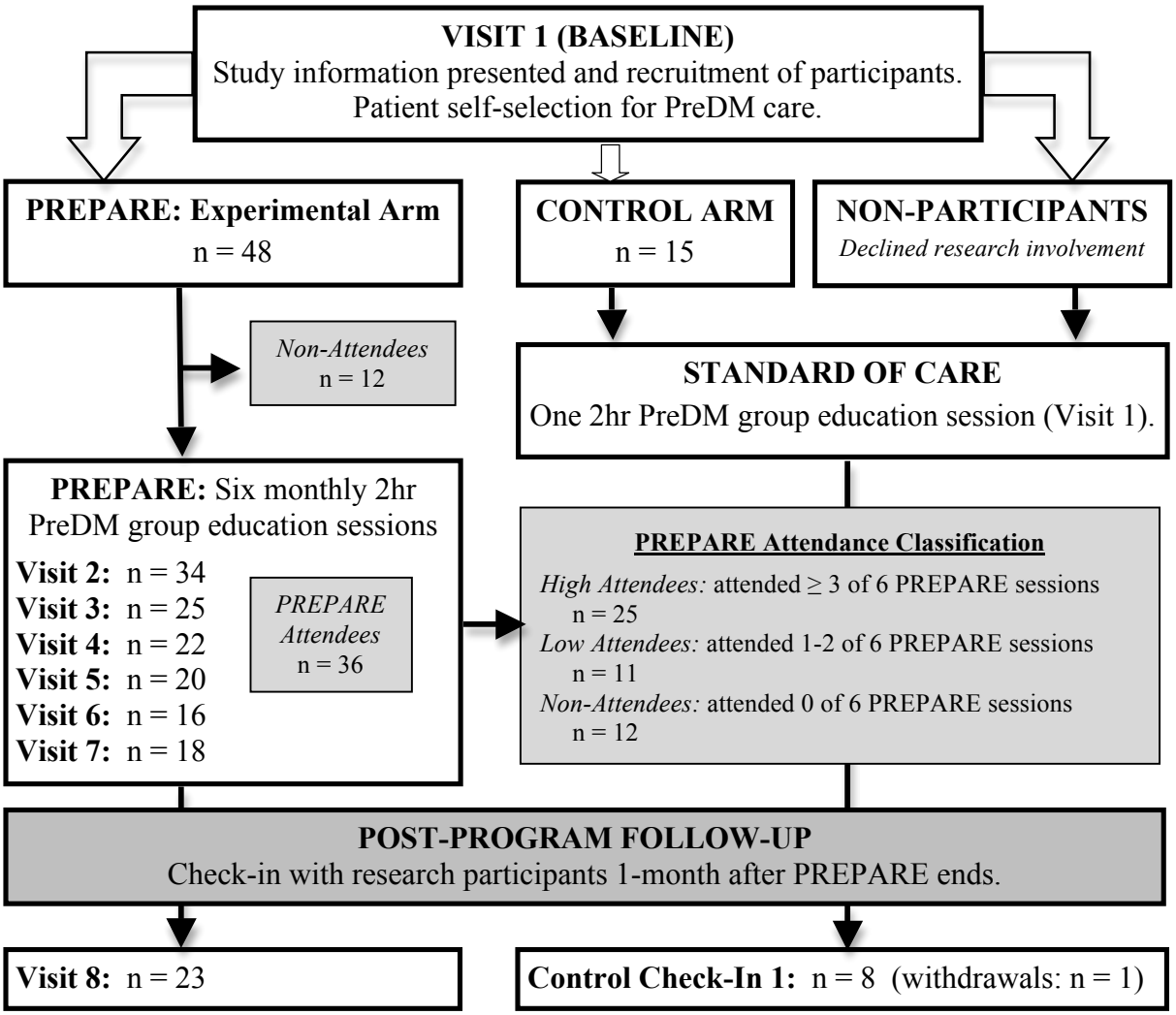

Figure 2. Study recruitment and retention results.

4.2 Retention Rates

At baseline, 48 participants self-selected PREPARE, while 15 participants self-selected the current standard of care as their preferred method for receiving PreDM education. Of those initial 48 PREPARE participants, 36 returned for at least one of six education sessions as part of the PREPARE program. The 12 individuals who chose not to return after Visit 1 were classified as "non-attendees", and their data was excluded from the overall analysis since they did not receive any PreDM education. Of the remaining 36 participants, monthly retention rates were as follows: 94% at Visit 2 (n = 34), 69% at Visit 3 (n = 25), 61% at Visit 4 (n = 22), 56% at Visit 5 (n = 20), 44% at Visit 6 (n = 16), and 50% at Visit 7 (n = 18). Sixty-four percent (n = 23) of PREPARE participants returned for their post-program focus group and data collection session. Mean attendance was 3.6 sessions out of six education sessions offered (Visits 2-7). Raw attendance data for each participant can be found in Appendix W.

The 36 PREPARE participants who returned after Visit 1 were further classified as either "high attendees" (HA), defined as those who attended ≥ 3 of 6 PREPARE education sessions (n = 25, or approximately 69% of the program attendees), or "low attendees" (LA), defined as those who attended only 1-2 of the 6 PREPARE education sessions offered (n = 11, or approximately 31% of the program attendees). Differences between the HA and LA will be examined to determine the impact that the PREPARE program had on key objectives based on rate of attendance.

After receiving the 2-hour PreDM standard of care presentation at Visit 1, the 15 control participants were not in contact with the research team until seven months later, when they received a letter and telephone call to collect data which coincided with the post-program follow-up (Visit 8 for the PREPARE participants). Fifty-three percent (n = 8) of the 15 controls mailed back in their package of questionnaires and 3d-FIR for analysis as requested. Six control participants did not return their package by mail and/or were

unreachable when contacted by telephone, and one control participant requested to be withdrawn from the study due to a diagnosis of cancer.

4.3 Participants Characteristics

Participant characteristics are provided in Table 7. Participants ranged in age between 30 to 82 years old, with the average participant in his or her mid-fifties. There was a fairly equal distribution of male and female participants in each sub-category, with the exception of the PREPARE non-attendees group, which was predominately female (75%, n = 9). Almost all of the participants (>90%) in the HA, LA, and control group were Caucasian, while the PREPARE non-attendees group had greater ethnic diversity, with 41.7% (n = 5) self-identifying as a minority group.

In regards to the baseline anthropometric measurements, the PREPARE and control participants did not differ significantly in mean weight ($p = 0.7$), which averaged 92.7 ± 18.9 kg at baseline. The PREPARE HA, LA, and controls had mean BMIs that fell into the obese class I category (32.1 kg/m^2 ± 4.6; 34.7 kg/m^2 ± 7.0; and 33.2 kg/m^2 ± 8.7 respectively), while the PREPARE non-attendees had a slightly higher mean BMI (35.9 kg/m^2 ± 7.1, obese class II); however, this difference was not significant. Insofar as the sociodemographic characteristics are concerned, the majority (56.0%-83.3%) of participants were married or in a common-law relationship, and most were employed (45.5%-75.0%) or retired (16.7%-42.9%). Mean household income varied considerably, ranging between "under $25,000" to "$150,000 or more", as did the highest level of education achieved. Less than 10% of all participants were smokers.

Table 7

Participant Characteristics

	All PREPARE Participants	Subcategories of PREPARE Participants			Controls
		High Attendees[a]	Low Attendees[b]	Non-Attendees[c]	
Number of participants: n	48	25	11	12	14
Age (years): Mean ± ± SD	57.3 ± 11.6	60.4 ± 11.0	51.0 ± 12.4	56.8 ± 10.7	55.1 ± 12.4
(Range)	(30 to 82)	(47 to 82)	(30 to 75)	(40 to 73)	(40 to 73)
Sex n (%): Male	20 (41.7%)	12 (48.0%)	5 (45.5%)	3 (25.0%)	7 (50.0%)
Female	28 (58.3%)	13 (52.0%)	6 (54.5%)	9 (75.0%)	7 (50.0%)
Height[d] (m): Mean ± SD	1.66 ± 0.1	1.67 ± 0.1	1.68 ± 0.1	1.62 ± 0.1	1.66 ± 0.1
Weight[e] (kg): Mean ± ± SD	92.7 ± 18.9	89.6 ± 17.6	97.9 ± 20.9	94.5 ± 20.1	91.8 ± 28.1
BMI[f] (kg/m^2): Mean ± SD	33.7 ± 6.0	32.1 ± 4.6	34.7 ± 7.0	35.9 ± 7.1	33.2 ± 8.7
Current Smokers: n (%)	4 (8.3%)	2 (8.0%)	1 (9.1%)	1 (8.3%)	1 (7.1%)
Married or Common-Law: n (%)	31 (64.6%)	14 (56.0%)	7 (63.6%)	10 (83.3%)	11 (78.6%)
Employment Status: n (%)					
Employed	27 (56.3%)	13 (52.0%)	5 (45.5%)	9 (75.0%)	7 (50.0%)
Unemployed	4 (8.3%)	2 (8.0%)	2 (18.2%)	0 (0.0%)	1 (7.1%)
Retired	16 (33.3%)	10 (40.0%)	4 (36.4%)	2 (16.7%)	6 (42.9%)
Household Income ($): n (%)					
Under $25,000	9 (18.8%)	4 (16.0%)	2 (18.2%)	3 (25.0%)	2 (14.3%)
$25,000-$49,999	8 (16.7%)	4 (16.0%)	2 (18.2%)	2 (16.7%)	3 (21.4%)
$50,000-$74,999	10 (20.8%)	5 (20.0%)	3 (27.3%)	2 (16.7%)	4 (28.6%)
$75,000-$99,999	5 (10.4%)	2 (8.0%)	2 (18.2%)	1 (8.3%)	1 (7.1%)
$100,000-$124,999	5 (10.4%)	3 (12.0%)	1 (9.1%)	1 (8.3%)	1 (7.1%)
$125,000-$149,000	2 (4.2%)	2 (8.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
$150,000 or more	4 (8.3%)	2 (8.0%)	0 (0.0%)	2 (16.7%)	0 (0.0%)
Would prefer not to say	5 (10.4%)	3 (12.0%)	1 (9.1%)	1 (8.3%)	3 (21.4%)
Ethnicity: n (%)					
Arab	1 (2.1%)	0 (0.0%)	0 (0.0%)	1 (8.3%)	0 (0.0%)
Asian	3 (6.3%)	1 (4.0%)	0 (0.0%)	2 (16.7%)	0 (0.0%)
Black	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)
Caucasian	40 (83.3%)	23 (92.0%)	10 (90.9%)	7 (58.3%)	13 (92.9%)
Other	4 (8.3%)	1 (4.0%)	1 (9.1%)	2 (16.7%)	0 (0.0%)

Note. m = metres, kg = kilograms, BMI = Body Mass Index
[a]High Attendees: attended ≥ 3 of 6 PREPARE sessions; [b]Low Attendees: attended 1-2 of 6 PREPARE sessions; [c]Non-Attendees: attended 0 of 6 PREPARE sessions; [d]Height/[e]Weight: control participants provided a self-reported height and weight on their Lifestyle Questionnaire, while PREPARE participants were measured by the research team; [f]BMI = weight (kg)/ height $(m)^2$

4.4 Risk Factors for the Development of Type 2 Diabetes Mellitus

Table 8 summarizes some of the known risk factors for the development of T2DM that participants self-identified when completing the Lifestyle Questionnaire at baseline. Family history of diabetes was prevalent in 46.8% (n = 29) of the participants, while few

(4.8%, n = 3) had ever delivered a macrosomic infant or had a history of gestational diabetes. Many of the participants had experienced at least one or more of the co-morbidities associated with T2DM, including 14.5% with heart disease (n = 9), 58.1% with HTN (n = 36), 48.4% with dyslipidemia (n = 30), and 4.8% with polycystic ovarian syndrome (n = 3).

Table 8

Participant Risk Factors for Type 2 Diabetes Mellitus

		Subcategories of PREPARE Participants				
	All PREPARE Participants	**High Attendees[a]**	**Low Attendees[b]**	**Non-Attendees[c]**	**Controls**	**Total**
Number of participants: n	48	25	11	12	14	62
T2DM Risk Factors:	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Family History of Diabetes	22 (45.8%)	12 (48.0%)	4 (36.4%)	6 (50.0%)	7 (50.0%)	29 (46.8%)
Macrosomic Infant Delivery	3 (6.3%)	0 (0.0%)	1 (9.1%)	2 (16.7%)	0 (0.0%)	3 (4.8%)
Gestational Diabetes	2 (4.2%)	0 (0.0%)	1 (9.1%)	1 (8.3%)	1 (7.1%)	3 (4.8%)
Heart Disease	5 (10.4%)	3 (12.0%)	0 (0.0%)	2 (16.7%)	4 (28.6%)	9 (14.5%)
Hypertension	28 (58.3%)	18 (72.0%)	4 (36.4)	6 (50.0%)	8 (57.1%)	36 (58.1%)
Dyslipidemia	22 (45.8%)	13 (52.0%)	6 (54.5)	3 (25.0%)	8 (57.1%)	30 (48.4%)
Kidney Disease	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Polycystic Ovarian Syndrome	3 (6.3%)	1 (4.0%)	1 (9.1%)	1 (8.3%)	0 (0.0%)	3 (4.8%)

Note. T2DM = Type 2 Diabetes Mellitus; [a]High Attendees: attended ≥ 3 of 6 PREPARE sessions, [b]Low Attendees: attended 1-2 of 6 PREPARE sessions, [c]Non-Attendees: attended 0 of 6 PREPARE sessions

4.5 Program Impact on Average Number of Vegetable and Fruit Servings and Sub-Categories of Vegetables and Fruit

Based on the items listed in participants' submitted 3d-FIRs at baseline (Visit 1) and post-program follow-up (Visit 8), dietary intake of V&F was translated by a Registered Dietitian into CFG serving sizes. Average daily intake for total servings of V&F consumed as well as sub-categories of V&F was calculated to assess the program's impact on participants' V&F consumption (primary objective).

Table 9 highlights the program's impact on V&F intake by summarizing the mean delta change in daily consumption and ANOVA comparison for total V&F and sub-categories of V&F from baseline to post-program. A change in mean daily intake of total V&F was seen for the intervention group (all PREPARE participants), but not for the control group. The intervention group had a mean increase of +0.3 V&F servings/day (specifically, +0.4 V&F servings/day for the HA, +0.2 V&F servings/day for the LA), while the control participants had no delta change from baseline. Despite these differences, which may have clinical significance from a T2DM prevention standpoint, the results from the 1-way ANOVA failed to show significance (Table 9).

When exploring some of the sub-categories of V&F, likewise, a significant difference was not seen for total vegetables, total fruit, whole fruit, fruit juice, vegetable juice, dark green vegetables, orange V&F, or starchy vegetables (Table 9). Interestingly, although not statistically significant, intake of dark green vegetables, which has previously been shown to reduce the incidence of developing T2DM, was found to increase by +0.3 servings/ day in the intervention group (specifically, +0.4 servings/day for the HA, 0.0 servings/day for the LA) and actually decreased for the controls over time by -0.5 servings/day. Intake of starchy vegetables (e.g. potatoes, corn, etc.) was also something that decreased in the intervention group by -0.1 servings/day (-0.2 servings/day for the HA, +0.3 servings/day for the LA), and increased in the control group by +0.4 servings/day, although this was not significant.

4.5.1 Within-Group Changes for Average Number of Vegetable and Fruit Servings and Sub-Categories of Vegetables and Fruit. Table 10 summarizes the pre- and post-program total V&F and sub-categories of V&F intake, showing within-group differences that occurred over the study. Table 10 does not demonstrate significant changes between groups related to the program's impact (as did Table 9), but does show within-group changes that occurred over the program, which may or may not be related to the education received by participants.

Table 9

Program Impact on Delta Change of Participants' Vegetable and Fruit Average Daily Intake from Baseline to Post-program

	Delta Change of Participants' Intake from Baseline to Post-Program				**1-Way ANOVA**	
Number of servings/day	**All PREPARE[a]** n = 34	**PREPARE HA[b]** n = 25	**PREPARE LA[c]** n = 9	**Controls** n = 8	**Intervention (PREPARE) vs. Control Participants**	**HA[a] vs. LA[b] vs. Controls**
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	p value	p value
Total V&F	**0.3 ± 2.9**	**0.4 ± 2.5**	**0.2 ± 4.1**	**0.0 ± 2.6**	**p = 0.79**	**p = 0.95**
Total vegetables	0.3 ± 2.5	0.2 ± 2.0	0.7 ± 3.5	0.0 ± 2.0	p = 0.66	p = 0.82
Total fruit	-0.1 ± 1.5	0.2 ± 1.0	-0.6 ± 2.7	-0.6 ± 1.5	p = 0.56	p = 0.25
Whole fruit	0.0 ± 1.3	0.2 ± 1.1	-0.4 ± 1.8	-0.5 ± 1.4	p = 0.48	p = 0.32
Fruit juice	-0.1 ± 0.6	0.0 ± 0.6	-0.3 ± 0.8	-0.1 ± 0.7	p = 0.86	p = 0.68
Vegetable juice	0.2 ± 0.8	0.2 ± 0.9	0.0 ± 0.0	0.1 ± 0.2	p = 0.92	p = 0.70
Dark green vegetables	0.3 ± 1.1	0.4 ± 1.1	0.0 ± 1.0	-0.5 ± 1.2	p = 0.27	p = 0.28
Orange V&F	0.0 ± 0.7	0.1 ± 0.8	-0.1 ± 0.3	0.1 ± 0.5	p = 0.63	p = 0.77
Starchy vegetables	-0.1 ± 0.8	-0.2 ± 0.6	0.3 ± 1.2	0.4 ± 0.9	p = 0.31	p = 0.17

Note. n = number of participants, vs. = versus, SD = standard deviation, V&F = vegetables and fruit; [a]All PREPARE = High Attendees + Low Attendees combined; [b]High Attendees: attended ≥ 3 of 6 PREPARE sessions; [c]Low Attendees: attended 1-2 of 6 PREPARE sessions

A primary goal of the PREPARE program was to increase participants' daily intake of V&F, which is exactly what was found in the intervention group. As a group, all PREPARE participants increased their mean daily intake of total V&F from baseline (5.8 servings/day) to post-program (6.3 servings/day), although this change was not significant. The HA's V&F intake increased from 6.5 to 6.9 servings/day over the program, while the LA increased from 4.0 to 4.5 servings/day. The control participants remained at their baseline intake of total V&F post-program, at 5.5 servings/day. No significance was observed for the other within-group comparisons made for all sub-categories of V&F (Table 10).

Table 10

Within-group Comparisons for Changes Made to Sub-categories of Vegetables and Fruit from Baseline to Post-program

Average Number of Daily Servings	All PREPARE[a] n = 34			PREPARE High Attendees[b] n = 25			PREPARE Low Attendees[c] n = 9			Controls n = 8		
	Baseline Mean ± SD	**Post-Study** Mean ± SD	**Paired t-test**	**Baseline** Mean ± SD	**Post-Study** Mean ± SD	**Paired t-test**	**Baseline** Mean ± SD	**Post-Study** Mean ± SD	**Paired t-test**	**Baseline** Mean ± SD	**Post-Study** Mean ± SD	**Paired t-test**
Vegetables & fruit	**5.8 ± 4.1**	**6.3 ± 3.6**	**p=0.50**	**6.5 ± 4.4**	**6.9 ± 3.6**	**p=0.45**	**4.0 ± 2.7**	**4.5 ± 3.2**	**p=0.74**	**5.5 ± 4.1**	**5.5 ± 3.0**	**p=1.00**
Total vegetables	3.7 ± 3.2	4.0 ± 2.9	p=0.42	3.9 ± 3.6	4.1 ± 3.0	p=0.62	3.0 ± 2.1	3.7 ± 2.9	p=0.54	3.0 ± 2.1	3.0 ± 1.4	p=0.96
Total fruit	2.2 ± 2.0	2.2 ± 1.7	p=0.83	2.6 ± 1.9	2.8 ± 1.7	p=0.45	1.1 ± 2.0	0.7 ± 0.8	p=0.57	2.5 ± 2.2	1.8 ± 1.9	p=0.29
Whole fruit	1.9 ± 1.7	2.0 ± 1.7	p=0.89	2.3 ± 1.7	2.5 ± 1.6	p=0.40	0.9 ± 1.2	0.7 ± 0.9	p=0.67	2.0 ± 2.3	1.6 ± 1.5	p=0.35
Fruit juice	0.3 ± 0.9	0.2 ± 0.5	p=0.42	0.3 ± 0.9	0.3 ± 0.6	p=0.81	0.2 ± 0.8	0.0 ± 0.1	p=0.48	0.4 ± 0.7	0.3 ± 0.5	p=0.72
Vegetable juice	0.2 ± 0.9	0.4 ± 1.7	p=0.22	0.3 ± 1.1	0.5 ±1.9	p=0.23	0.0 ± 0.0	0.0 ± 0.0	p=1.00	0.0 ± 0.0	0.1 ± 0.2	p=0.35
Dark green vegetables	1.1 ± 1.1	1.3 ± 1.4	p=0.18	1.1 ± 1.0	1.4 ±1.4	p=0.12	1.2 ± 1.2	1.0 ± 1.1	p=0.69	1.3 ± 1.2	1.0 ± 0.7	p=0.46
Orange V&F	0.5 ± 0.5	0.5 ± 0.6	p=0.94	0.5 ± 0.5	0.6 ± 0.7	p=0.74	0.3 ± 0.5	0.2 ± 0.4	p=0.53	0.2 ± 0.2	0.3 ± 0.5	p=0.56
Starchy vegetables	0.6 ± 0.8	0.6 ± 0.6	p=0.62	0.6 ± 0.7	0.4 ± 0.4	p=0.14	0.5 ± 0.8	0.9 ± 0.8	p=0.32	0.6 ± 0.5	0.9 ± 0.8	p=0.27

Notes: n = number of participants, V&F = vegetables and fruit, [a]All PREPARE = High Attendees + Low Attendees, [b]High Attendees = attended ≥ 3 of 6 PREPARE sessions, [c]Low Attendees = attended 1-2 of 6 PREPARE sessions; * = significant finding ($p < 0.05$)

4.5.2 Participants' Intake of Vegetables and Fruit in Comparison to Canada's Food Guide Recommendations. Figures 3a, 3b, and 3c provide the percentage of participants who met minimum CFG guidelines for daily intake of total V&F (Figure 3a), as well as dark green vegetables (Figure 3b), and bright orange V&F (Figure 3c) at baseline and post-program. In regards to V&F intake (Figure 3a), at baseline, 17% (n = 6/36) of all PREPARE participants met CFG minimum recommendation of seven (for females) to eight (for males) V&F servings per day, while 20% of HA (n = 5/25), 9% (n = 1/11) of LA, and 38% (n = 3/8) of controls achieved this minimum intake. By the end of the program, 29% (n = 10/34) of all PREPARE participants, 32% (n = 8/25) of HA, 22% (n = 2/9) of LA, and 25% (n = 2/8) of controls were eating the minimum daily target of V&F to meet recommendations.

Canada's Food Guide also recommends that Canadians "eat at least one dark green and one orange vegetable each day" (Health Canada, 2007). At baseline (Figure 3b), 47% (n = 17/36) of all PREPARE participants, 44% (n = 11/25) of HA, 55% (n = 6/11) of LA, and 50% (n = 4/8) of controls consumed one or more dark green vegetable servings/day. At the post-program follow-up, 47% (n = 16/34) of all PREPARE participants, 48% (n = 12/25) of HA, 44% (n = 4/9) of LA, and 63% (n = 5/8) of controls were consuming at least one dark green vegetable serving/day.

As for consumption of bright orange V&F (Figure 3c), at baseline 14% (n = 5/35) of all PREPARE participants, 16% (n = 4/25) of HA, 9% (n = 1/11) of LA, and 0% (n = 0/8) of controls consumed at least one orange V&F/day. Post-program, this figure rose to 23% (n = 8/34) for all PREPARE participants, 28% (n = 7/25) for HA, 11% (n = 1/9) for LA, and 13% (n = 1/8) for controls.

See Appendix T for classification of dark green vegetables and bright orange V&F recommended for daily consumption by CFG that were used to calculate these figures. Please also note that eleven LA participants submitted a 3d-FIR at baseline, while only 9 re-submitted a 3d-FIR post-program (or date of last visit), which is why the denominators do not match for the "All PREPARE" and "LA participants" at baseline and post-program.

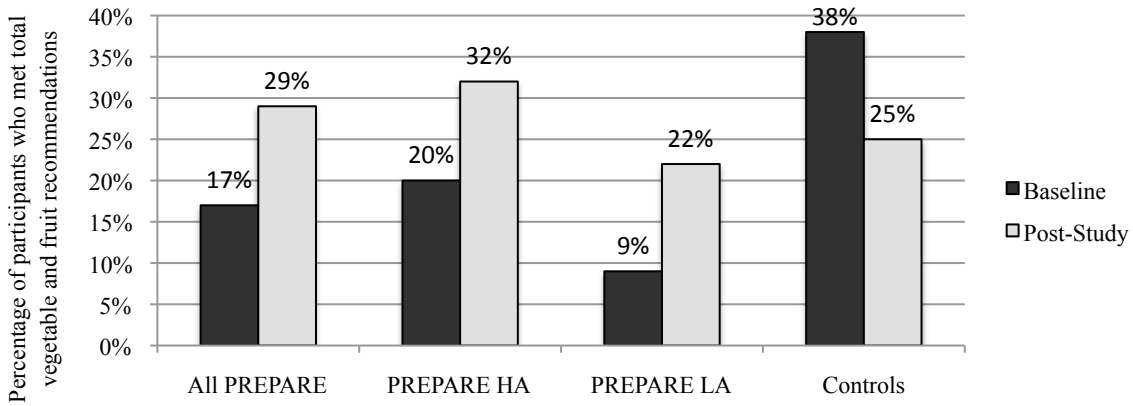

Figure 3a. **Total vegetables and fruit:** percentage of participants who met Canada's Food Guide recommendations for minimum daily intake pre- and post-program.

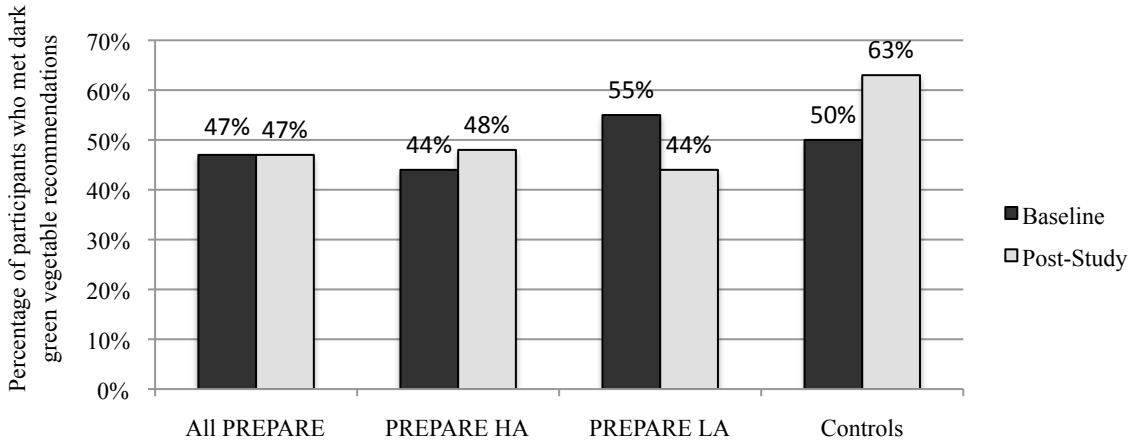

Figure 3b. **Dark green vegetables:** percentage of participants who met Canada's Food Guide recommendations for minimum daily intake pre- and post-program.

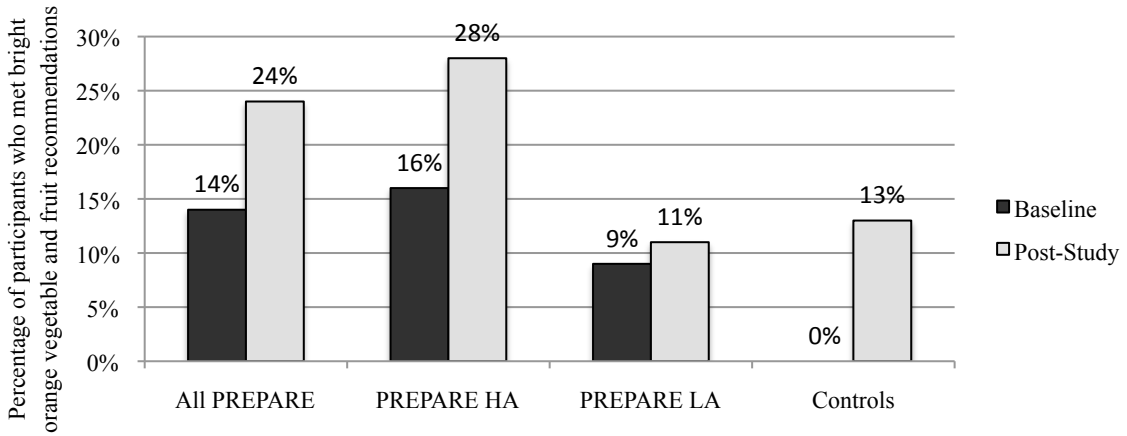

Figure 3c. **Bright orange vegetables and fruit:** percentage of participants who met Canada's Food Guide recommendations for minimum daily intake pre- and post-program.

4.6 Program Impact on Average Number of Canada's Food Guide Daily Servings

Canada's Food Guide (CFG) provides age and gender-specific targets for daily intake of healthy foods from four major food groups: vegetables and fruit, grain products, milk and alternatives, and meat and alternatives (Appendix S). Based on the 3d-FIRs submitted at baseline (Visit 1) and post-program (Visit 8), dietary intake was translated by a Registered Dietitian into CFG serving sizes to calculate average daily intake for each food group to assess the program's impact on CFG dietary choices. Table 11 summarizes the program's impact on intake of CFG food groups by displaying the mean delta change for number of daily servings consumed and ANOVA comparison for all four CFG food groups from baseline to post-program. Table 11 also looks at the post hoc multiple group comparisons of the delta change using a Sidak adjustment, comparing the HA, LA, and control participants to one another.

From the results of the 1-way ANOVA in Table 11, a change in the mean daily intake of grain products and meat and alternatives were found to have significantly changed over the course of the program. Specifically for grain products, although there was no significance when the intervention group was compared to the control group (intervention group decreased intake of grains by -1.4 servings/day, while controls decreased by -0.7 servings/day), a Sidak adjustment used to make post hoc multiple group comparisons revealed that a significant difference did exist between the HA and LA and between the LA and controls (Table 11). HA decreased their mean daily intake of grain products by -1.0 servings/day versus the -3.1 decrease made by the LA ($p = 0.043$), and when the LA were compared to the controls, a trend was found to exist ($p = 0.074$). Program impact on daily intake of V&F (previously discussed) and milk and alternatives was not significant.

For meats and alternatives, no significant difference existed between the intervention and control participants post-program in regards to the change in their average number of daily servings; however, exploring a significant result from the 1-way ANOVA using a Sidak adjustment found that the HA increased their mean daily intake by +0.1 servings/day, while

the LA decreased intake by -1.4 servings/day, which was significant (p = 0.006), while comparisons made between the HA and controls and LA and controls were not significant.

Table 11

Program Impact on Delta Change of Participants' Canada's Food Guide Average Daily Intake from Baseline to Post-program

	Delta Change of Participants' Intake from Baseline to Post-Program				**1-Way ANOVA**	
Number of servings/ day	**All PREPARE[a]** n = 34	**PREPARE HA[b]** n = 25	**PREPARE LA[c]** n = 9	**Controls** n = 8	**Intervention (PREPARE) vs. Control Participants**	**HA[a] vs. LA[b] vs. Controls**
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	p value	p value
V&F	0.3 ± 2.9	0.4 ± 2.5	0.2 ± 4.1	0.0 ± 2.6	p = 0.79	p = 0.95
Grain products	-1.4 ± 2.4	-1.0 ± 2.1	-3.1 ± 2.7	-0.7 ± 1.4	p = 0.13	p = 0.03* ***Sidak adjustment:*** HA vs. LA: p = 0.043 HA vs. C: 0.98 LA vs. C: p = 0.074
Milk & Alternatives	-0.2 ± 1.4	-0.1 ± 1.3	-0.7 ± 1.5	-0.5 ± 1.2	p = 0.63	p = 0.34
Meat & Alternatives	-0.3 ± 1.5	0.1 ± 1.0	-1.4 ± 2.0	-0.1 ± 1.2	p = 0.22	p = 0.008* ***Sidak adjustment:*** HA vs. LA: p = 0.006 HA vs. C: 0.98 LA vs. C: p = 0.071

Note. n = number of participants, vs. = versus, SD = standard deviation, V&F = vegetables and fruit, C = controls; [a]All PREPARE = High Attendees + Low Attendees combined; [b]High Attendees: attended ≥ 3 of 6 PREPARE sessions; [c]Low Attendees: attended 1-2 of 6 PREPARE sessions; * = significant finding (p < 0.05)

4.6.1 Within-Group Changes for Average Number of Canada's Food Guide Daily Servings. Table 12 summarizes the baseline and post-program CFG food group daily intake, showing within-group differences that occurred over the study in the intervention, HA, LA, and control participants. Similar to findings already presented which looked at the program's impact on CFG food group daily intake (Table 11), significant within-group changes were found from pre- to post-study (Table 12).

The one significant within-group change for CFG that occurred during the study was a decrease in intake of grain products for the intervention group, and specifically, the HA. Health Canada recommends a minimum of 6-7 grain product servings/day for females, and 7-8 servings/day for males (Health Canada, 2007). Overall, the intervention group decreased their mean daily intake of grain products from 5.7 to 4.4 servings/day ($p = 0.001$) over the 6-month program, and as a sub-group, the HA decreased their intake 5.4 to 4.4 servings/day ($p = 0.03$) (Table 12). As for the LA and control participants, the LA decreased their mean daily intake of grain products from 6.4 to 4.4 servings/day, while the controls decreased from 6.7 to 6.1 servings/day (Table 12); however, neither of these two results were significant.

In regards to the "milk and alternatives" and "meat and alternatives", the intervention, HA, LA, and control participants were not found to have any significant changes to their mean daily intake for either of these two food groups. Mean daily intake of V&F, the final food group category that also appears on CFG, was discussed previously in results section 4.5.1 (Table 10).

Table 12

Within-group Comparisons for Changes Participants Made to Canada's Food Guide from Baseline to Post-program

Average Number of Daily CFG Servings	All PREPARE[a] n = 34			PREPARE High Attendees[b] n = 25			PREPARE Low Attendees[c] n = 9			Controls n = 8		
	Baseline Mean ± SD	**Post-Study** Mean ± SD	**Paired t-test**	**Baseline** Mean ± SD	**Post-Study** Mean ± SD	**Paired t-test**	**Baseline** Mean ± SD	**Post-Study** Mean ± SD	**Paired t-test**	**Baseline** Mean ± SD	**Post-Study** Mean ± SD	**Paired t-test**
Vegetables & fruit	5.8 ± 4.1	6.3 ± 3.6	**p=0.50**	6.5 ± 4.4	6.9 ± 3.6	**p=0.45**	4.0 ± 2.7	4.5 ± 3.2	**p=0.74**	5.5 ± 4.1	5.5 ± 3.0	**p=1.00**
Grain products	5.7 ± 2.7	4.4 ± 1.7	p=0.001*	5.4 ± 2.1	4.4 ± 1.8	p=0.03*	6.4 ± 3.7	4.4 ± 1.2	p=0.15	6.7 ± 2.3	6.1 ± 2.9	p=0.23
Milk & alternatives	1.7 ± 1.3	1.4 ± 1.0	p=0.32	1.7 ± 1.3	1.6 ± 0.9	p=0.83	1.6 ± 1.4	0.9 ± 1.1	p=0.24	1.6 ± 1.2	1.0 ± 0.3	p=0.27
Meat & alternatives	2.8 ± 1.6	2.5 ± 1.0	p=0.24	2.3 ± 0.9	2.4 ± 0.8	p=0.50	3.8 ± 2.3	2.5 ± 1.4	p=0.17	2.5 ± 1.4	2.4 ± 1.4	p=0.91

Notes: n = number of participants, CFG = Canada's Food Guide, [a]All PREPARE = High Attendees + Low Attendees, [b]High Attendees = attended ≥ 3 of 6 PREPARE sessions, [c]Low Attendees = attended 1-2 of 6 PREPARE sessions; * = significant finding ($p < 0.05$)

4.7 Program Impact on Dietary Intake of Macro- and Micro-Nutrients

Table 13 highlights the program's impact on participants' macro- and micro-nutrient intake by summarizing the mean delta change and ANOVA comparison for all macro- and selected micro-nutrients from baseline to post-program. The only significant difference that emerged when assessing the program's impact was for the macronutrient protein. The intervention participants had a meal delta change in their protein intake of -12.1 g/day from baseline to post-program (specifically, HA participants decreased protein by -7.1 g/day, while LA decreased by -27.3 g/day), and controls increased intake by +1.6 g/day (Table 13). This difference was found to be significant ($p = 0.04$) when the intervention participants' protein delta change was compared to the controls in a 1-way ANOVA (Table 13). When a Sidak adjustment was performed for protein, a significant difference was found when the LA were compared to the controls ($p = 0.03$), and a trend emerged when the HA were compared to the controls ($p = 0.062$) (Table 13).

The program did not appear to have a statistically significant impact on other dietary components considered, including: energy intake, intake of other macronutrients (i.e. CHO, fat) or percentage of energy intake from macronutrients, or intake of other nutrients of interest (i.e. SFA, alcohol, fibre, sodium) (Table 13). Two non-significant findings, but interesting dietary changes to note from a clinical perspective include the changes in SFA and sodium intake between the intervention and control participants. Over the 6-month program, the intervention participants decreased their mean daily intake of SFA by -5.1 g/day, while the controls actually increased their intake by +2.0 g/day. In addition, the intervention participants successfully decreased their mean daily intake of sodium by -575.9 mg/day, while the controls actually increased by +416.3 mg/day, representing almost a 1000 mg difference in sodium intake between the two groups (Table 13). Although not significant, both of these dietary changes may have important clinical implications for the prevention of complications related to CVD.

Table 13

Program Impact on Delta Change of Participants' Macro- and Micro-nutrient Intake from Baseline to Post-program

	Delta Change of Participants' Intake from Baseline to Post-Program				**1-Way ANOVA**	
Number of servings/day	**All PREPARE[a]** n = 34	**PREPARE HA[b]** n = 25	**PREPARE LA[c]** n = 9	**Controls** n = 8	**Intervention (PREPARE) vs. Control Participants**	**HA[a] vs. LA[b] vs. Controls**
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	p value	p value
Energy intake (kcal/d)	-244 ± 432	-180 ± 459	-461 ± 276	-124 ± 336	p = 0.25	p = 0.14
Energy intake (kJ/d)	-1023 ± 1806	-755 ± 1921	-1929 ± 1156	-519 ± 1405	p = 0.25	p = 0.14
Total CHO (g/d)	-24.3 ± 56.6	-16.3 ± 57.7	-51.5 ± 47.6	-31.3 ± 45.1	p = 0.94	p = 0.21
% energy from CHO (%)	0.6 ± 6.7	1.1 ± 6.7	-0.7 ± 7.6	-2.4 ± 4.7	p = 0.33	p = 0.40
Total protein (g/d)	-12.1 ± 24.8	-7.1 ± 24.5	-27.3 ± 21.4	1.6 ± 13.8	p = 0.04*	p = 0.02* ***Sidak Adjustment:*** HA vs. LA: p = 0.062 HA vs. C: p = 0.74 LA vs. C: p = 0.03*
% energy from protein (%)	-0.4 ± 3.7	0.2 ± 3.4	-1.9 ± 4.2	1.6 ± 3.0	p = 0.09	p = 0.12
Total fat (g/d)	-11.0 ± 25.8	-9.6 ± 28.5	-15.6 ± 19.4	-4.7 ± 18.6	p = 0.44	p = 0.66
% energy from fat (%)	-0.9 ± 7.9	-1.4 ± 8.4	0.9 ± 6.9	0.0 ± 5.7	p = 0.91	p = 0.68
Total EtOH (g/d)	0.8 ± 9.1	-0.5 ± 9.9	2.76 ± 5.4	1.5 ± 11.3	p = 0.99	p = 0.77
% energy from EtOH (%)	0.7 ± 3.2	0.1 ± 3.3	1.6 ± 2.6	0.6 ± 4.1	p = 0.79	p = 0.66
SFA (g/d)	-5.1 ± 9.4	-5.1 ± 9.5	-5.1 ± 9.4	2.0 ± 4.4	p = 0.051	p = 0.13
% energy from SFA (%)	-1.4 ± 4.7	-1.4 ± 4.0	-1.4 ± 6.5	1.4 ± 2.0	p = 0.12	p = 0.27
Fibre (g/d)	-1.6 ± 9.8	-1.1 ± 10.0	-3.0 ± 9.5	-2.9 ± 6.8	p = 0.83	p = 0.82
Sodium (mg/d)	-575.9 ± 1273.8	-642.8 ± 996.5	-390.1 ± 1913.4	416.3 ± 2339.0	p = 0.14	p = 0.25

Note. n = number of participants, vs. = versus, kcal = kilocalories, d = day, SD = standard deviation, kJ = kilojoules, CHO = carbohydrate, g = grams, % = percentage, EtOH = alcohol, SFA = saturated fatty acids, mg = milligrams, C = controls; [a]All PREPARE = High Attendees + Low Attendees combined; [b]High Attendees: attended ≥ 3 of 6 PREPARE sessions; [c]Low Attendees: attended 1-2 of 6 PREPARE sessions; * = significant finding ($p < 0.05$)

4.7.1 Within-Group Changes for Dietary Intake of Macro- and Micro-Nutrients.

Looking at within-group changes that occurred for macro- and micro-nutrient intake, several significant findings were observed in the intervention group when their post-study dietary intake was compared to their baseline pattern of eating. Specifically, decreases in mean daily intake of energy intake ($p = 0.002$), total CHO ($p = 0.02$), total protein ($p = 0.01$), total fat (0.01), SFA ($p = 0.003$), and sodium ($p = 0.01$) were found to have significantly decreased from baseline, while a trend was observed for the decrease in percent of energy intake consumed from SFA ($p = 0.08$) (Table 14). No significant changes were observed for percent of energy intake from CHO, protein, fat, or alcohol; total alcohol intake; or total fibre intake throughout the intervention.

Within the sub-group analysis, for the HA participants, notable changes were observed for SFA and sodium, where mean daily intake of SFA was decreased from 24.3 to 19.2 g/day ($p = 0.01$), and for sodium from 2760.3 to 2117.4 mg/day ($p < 0.004$) from baseline to post-program, respectively (Table 14). The LA and control participants did not make any notable within-group statistically significant changes to their dietary macro- or micro-nutrients over the course of the study. Of clinical note, however, was the fact that control participants actually increased their mean daily intake of sodium from 2987.1 to 3403.4 mg/day from pre- to post-program.

Table 14

Within-group Comparisons for Changes Made to Macro- and Micro-nutrient Average Daily Intake from Baseline to Post-program.

Dietary Component	All PREPARE[a] n = 34			PREPARE High Attendees[b] n = 25			PREPARE Low Attendees[c] n = 9			Controls n = 8		
	Baseline Mean ± SD	**Post-Study** Mean ± SD	**Paired t-test**	**Baseline** Mean ± SD	**Post-Study** Mean ± SD	**Paired t-test**	**Baseline** Mean ± SD	**Post-Study** Mean ± SD	**Paired t-test**	**Baseline** Mean ± SD	**Post-Study** Mean ± SD	**Paired t-test**
Energy intake (kcal/d)	1904 ± 466	1659 ± 362	p=0.002*	1873 ± 479	1708 ± 388	p=0.08	1865 ± 488	1529 ± 289	p=0.09	1813 ± 530	1689 ± 575	p=0.33
Energy intake (kJ/d)	7967 ± 1951	6944 ± 1516	p=0.002*	7838 ± 2006	7145 ± 1622	p=0.08	7803 ± 2041	6399 ± 1211	p=0.09	7586 ± 2216	7066 ± 2406	p=0.33
Total CHO (g/d)	228.6 ± 60.0	204.3 ± 59.6	p=0.02*	227.9 ± 61.7	213.1 ± 61.9	p=0.22	214.8 ± 65.8	179.0 ± 51.7	p=0.20	256.6 ± 88.8	225.3 ± 92.2	p=0.09
% energy from CHO (%)	47.1 ± 6.2	47.7 ± 7.7	p=0.60	47.4 ± 6.6	48.4 ± 7.9	p=0.42	46.0 ± 9.3	45.6 ± 7.8	p=0.91	53.9 ± 8.2	51.5 ± 7.2	p=0.19
Total protein (g/d)	86.5 ± 24.0	74.3 ± 18.4	p=0.01*	80.7 ± 22.9	74.0 ± 16.5	p=0.18	95.6 ± 25.9	75.3 ± 24.0	p=0.09	71.4 ± 19.2	73.0 ± 26.4	p=0.75
% energy from protein (%)	17.9 ± 3.6	17.6 ± 3.5	p=0.55	16.8 ± 2.7	17.0 ± 3.9	p=0.81	20.6 ± 4.1	19.1 ± 4.4	p=0.43	16.3 ± 4.4	17.9 ± 3.4	p=0.17
Total fat (g/d)	73.3 ± 22.8	62.3 ± 21.8	p=0.02*	73.2 ± 21.8	63.9 ± 23.7	p=0.11	69.7 ± 27.8	58.0 ± 15.7	p=0.28	58.4 ± 19.9	53.7 ± 19.1	p=0.50
% energy from fat (%)	33.8 ± 6.2	32.9 ± 7.9	p=0.51	34.3 ± 5.9	32.8 ± 8.4	p=0.36	32.7 ± 8.4	33.3 ± 6.8	p=0.86	28.3 ± 4.5	28.3 ± 5.1	p=1.00
Total EtOH (g/d)	3.4 ± 9.6	4.2 ± 7.6	p=0.60	4.3 ± 11.4	4.4 ± 8.1	p=0.95	1.6 ± 3.1	3.8 ± 6.0	p=0.31	5.1 ± 7.7	6.5 ± 9.1	p=0.73
% energy from EtOH (%)	1.2 ± 3.2	1.8 ± 3.2	p=0.23	1.4 ± 3.7	1.8 ± 3.2	p=0.60	0.8 ± 1.5	2.0 ± 3.1	p=0.28	1.8 ± 2.9	2.4 ± 3.3	p=0.70
SFA (g/d)	24.5 ± 10.0	19.4 ± 7.3	p=0.003*	24.3 ± 9.8	19.2 ± 7.8	p = 0.01*	22.8 ± 11.2	19.8 ± 5.9	p=0.48	13.9 ± 4.9	16.0 ± 5.9	p=0.24
% energy from SFA (%)	11.8 ± 4.5	10.4 ± 3.3	p=0.08	11.4 ± 3.6	10.0 ± 3.4	p=0.08	12.1 ± 6.2	11.4 ± 2.7	p=0.78	7.3 ± 3.2	8.6 ± 2.7	p=0.09
Fibre (g/d)	24.4 ± 10.4	22.8 ± 10.0	p=0.34	25.8 ± 9.8	24.6 ± 10.0	p=0.58	20.7 ± 10.7	17.6 ± 8.7	p=0.49	28.7 ± 15.1	25.8 ± 12.4	p=0.27
Sodium (mg/d)	2892.9 ± 1112.3	2316.9 ± 1109.6	p=0.01*	2760.3 ± 1126.0	2117.4 ± 650.3	p<0.004*	2882.4 ± 1259.8	2871.1 ± 1827.5	p=0.99	2987.1 ± 2476.8	3403.4 ± 2500.7	p=0.63

Note. n = number of participants, SD = standard deviation, kcal = kilocalories, d = day, kJ = kilojoules, CHO = carbohydrate, g = grams, % = percentage, EtOH = alcohol, SFA = saturated fatty acids, mg = milligrams, [a]All PREPARE = High Attendees + Low Attendees, [b]High Attendees = attended ≥ 3 of 6 PREPARE sessions, [c]Low Attendees = attended 1-2 of 6 PREPARE sessions; * = significant finding ($p < 0.05$)

4.8 Subjective Assessment of Changes in Dietary Habits via Focus Group Discussions and Overall Program Feedback Form

The three focus groups conducted with participants from the experimental arm of the program yielded a number of interesting insights. During each focus group, PREPARE participants were asked to reflect on the parts of the program that they enjoyed, did not enjoy, areas of their life that have been positively impacted by the program, and to offer feedback regarding the content and logistics of the program delivery to help the research team improve PREPARE for future participants. Overall, the PREPARE program was well-received by participants who attended the focus groups, who predominately consisted of HA participants. For the purposes of this study, program impact on the dietary habits and V&F consumption of participants will be examined from the data generated from the focus group discussions.

Participants discussed the perceived benefits of taking part in the 6-month lifestyle behaviour change program, and what impact this had on their dietary behaviours. As a group, participants stated the PREPARE program had exposed them to new healthy foods they would not have considered trying in the past; had helped them to incorporate more V&F into their diet; had taught them many practical skills via the education sessions and cooking workshops; and overall, was an experience they were grateful to have taken part in. The main impressions that participants shared regarding the impact PREPARE had on their dietary behaviours are demonstrated in the following quotes:

New Foods/Dietary Changes:

> *"You know, before it was ah no vegetables and ah…you know, it was an orange and once in a while, but now I eat lots and lots of vegetables and fruit."*

> *"Well more conscience of the colours because each colour has something different in nutrition, but no, I cook up a 3 or 4 sweet potatoes, and then I mash them, and put them in half cup things, and put them in a bag, then freeze them, so I always got my stuff, so I have things in the freezer that I can make different meals and I have vegetables that I have cooked, frozen bags of vegetables."*

> *"Now I'm eating a lot more salads."*

"That's when I found out for the first time in my life that yogurt is eatable!" [referring to the healthy snacks offered at break time]

Cooking Workshops:

"We really, we enjoyed the cooking part. I think I would recommend that to anybody."

"Well just the fact that we got to prepare recipes that we wouldn't normally, like I would never of normally picked to make squash lasagna. [laughter] I'm sorry but that's just not on a list of things that I would even try and so doing that at the cooking class and trying it and realizing that is was really good [laughter] and making it for other people and having that become part of my diet which it never would of."

"I think it was really a great idea that you allowed us to bring a friend or spouse or whatever with us to the sessions, or to the cooking classes because then my husband got more involved. And if he hadn't been a part of it then he might of fought me on some of the grocery issues because he does the grocery shopping and so he's been really good you know if I ask for certain things that maybe are more expensive or whatever he's gone ahead and bought them, but I think it was because he was a part of it, and able to go to those cooking classes too."

"I took our spinach and goat cheese salad to a party and everyone really enjoyed it. And it included, mandarin oranges, never thought of putting that in a salad, and cranberries, dried cranberries."

Canada's Food Guide:

"I found I referred to [Canada's Food Guide] a few times when I was trying to see if I was balancing my meals. That's something I never thought of before. Like I, if I was…in the past if I was dieting I'd just eat like less meat or less bread, and not realising that you know I still should have meat and grains with my meal. Just you know decrease the size or the quantity, but still have something from each of the food groups."

"I have [Canada's Food Guide] on my dining room table all the time."

"I most enjoyed learning how much I should be eating everyday. Like, I had no idea 8 servings of fruits and vegetables: that's a lot of fruits and vegetables. You know, and that it's ok to have like bread and nuts and crackers and stuff that I would have always avoided before, thinking it was just fat. So, it more um, teaches you how to balance your diet better."

Nutrition Education:

"I think just the fact of learning what to look for on the food labels and what to avoid."

"I liked the diagram of the plate, half vegetables then your potato or your rice or whatever on a quarter of a plate, and then a quarter of the plate was meat. So I've got that sitting in front of me all the time."

"I liked the food tips."

"I think tracking is huge. If you eat it, write it down. If you write it down then it becomes a bit clearer."

Overall Feedback:

"I just want to say on the whole I think it's a fantastic program."

"And I am very appreciative that this was offered and that I was able to come."

"I've recommended it to everyone I talk to."

Participant feedback on the nutrition component from the Overall Program Feedback Form (Appendix Q) echoed similar thoughts about how PREPARE had positively impacted their lives and nutritional habits. Nineteen of the twenty-two participants (86%) who completed the form at the post-program follow-up agreed or strongly agreed that they would recommend the PREPARE program to a friend or family member. What participants liked most and least about the program is summarized in Table 15.

Table 15

What Participants Liked Most and Least about the PREPARE Program

What I liked most about my experience with the PREPARE program was:	**What I liked least about my experience with the PREPARE program was:**
• Student interaction. • Information on healthy foods, what fatty foods are, and sodium. • All of the information given, and the way the girls explained. All girls were very friendly and helpful. • Questions were answered. • The nice people who put on the program - lots of good information. • The exercise ideas & snack ideas. • How important it is to eat well and exercise. • How friendly and helpful everyone was. • The information that we were given, so that we may be able to stop diabetes or delay it. • Learning about the nutritional side - what can be in certain food types that you aren't aware of. • Positive atmosphere. • Learning about healthy choices & how to balance my diet. Also learning how to read & understand nutrition labels. • It was interesting and very informative. • Education. • Informative. • Hands on cooking classes. • Information on diet and food values. • Cooking classes & recipes. • Education portion - tips on foods.	• Paperwork. Not enough feedback from all that paperwork. • Loose pieces given out with no order in folder. (Give info out to put in binders, in sections per week.) • None of it. Loved all my visits. Learned a lot. Thank you so much! • Handouts at start - there were a lot. • It took too much time, was not self-paced (info came in a slow trickle), and there was limited personal feedback on a week-to-week basis. It was not personalized. The food log was tedious (in its current form). • Goal setting. • The long questionnaires and food logs. • Time filling out forms. • There wasn't anything I found I liked least. • Too basic. • Gym exercises. • Individual attention. • Filling out forms. • Weather prevented me from coming to cooking class. • Group physical activity. • Nothing. (x 2 participants)

When asked to reflect specifically on the nutrition component of the PREPARE program, 96% of participants (n = 21) agreed or strongly agreed that they benefited from the nutrition sessions, and the same percent found the educational information provided during the nutrition sessions to be useful or very useful. Likewise, 96% (n = 21) agreed or strongly agreed that the nutrition sessions were easy to understand, as well as practical (96%, n = 21). Seventy-three percent (n = 16) agreed or strongly agreed that the nutrition sessions were interactive, while the remaining 23% (n = 5) neither agreed nor disagreed with the statement.

Fifty-five percent (n =12) agreed or strongly agreed that they enjoyed the interactive optional monthly cooking workshops, while 36% (n = 8) admitted that this did not apply to them, as they did not attend one of the optional monthly cooking workshop sessions offered throughout the program. Likewise, 55% (n = 12) agreed or strongly agreed that they took away some practical ideas from the cooking workshops.

In regards to the monthly nutrition goal setting that was promoted throughout the PREPARE program, 73% (n = 16) agreed or strongly agreed that this component of the study helped to keep them on track with their healthy eating goals. Encouragingly, 91% (n = 20) of participants agreed or strongly agreed with the statement that they will continue to set healthy eating goals to stay on track in the future. When asked specifically about the utility of the monthly food record (3d-FIR) that was a requirement of the PREPARE program, 82% (n =18) agreed or strongly agreed that the tool was useful for keeping them on track with their healthy eating goals, while 9% (n = 2) strongly disagreed, expressing their displeasure that more individualized feedback would have been appreciated, given the amount of work that went into completing the monthly three-day food records.

As an overall summary, 91% (n = 20) of participants agreed or strongly agreed that they had been able to make positive changes to their diet during the program, 82% (n = 18) agreed or strongly agreed that the nutrition component of PREPARE had enhanced their skills, and 87% (n = 19) agreed or strongly agreed that at the end of the program, they felt confident that they could continue to implement many of the healthy eating strategies that they had learned as part of the PREPARE program. For further details, the complete set of responses for the Overall Program Feedback Form can be found in Appendix X.

4.9 Anthropometric & Hemodynamic Data

Table 16 summarizes the baseline and post-program anthropometric and hemodynamic data for all intervention, HA, and LA participants, while Table 17 illustrates the delta change for the PREPARE HA and LA from baseline to the end of the program.

This data was unavailable for the controls, as they only submitted a nutrition package by mail at the post-program follow-up to collect the study's primary outcome measures, and did not return in-person to have physical measurements collected by the research team.

In looking at the changes the PREPARE program had on intervention participants' anthropometric and hemodynamic measurements (Table 16), significant changes were found in weight ($p = 0.01$), BMI ($p = 0.01$), WC ($p = 0.003$), and systolic BP ($p = 0.04$) from baseline to the end of the program. Within-group changes were also significant for the HA participants post-program: weight ($p = 0.01$), BMI ($p = 0.01$), WC ($p = 0.01$), systolic BP ($p = 0.03$), and diastolic BP ($p = 0.05$). No significant changes were seen in any of the same factors for the LA participants over the same time period.

When comparing how the two groups did against one another by examining the delta change for the same anthropometric and hemodynamic factors, it was apparent that the HA participants achieved significant changes compared to the LA (Table 17). The HA lost an average of -2.1 kg over the course of the study, which was statistically significant ($p = 0.04$) to the LA, who only lost an average of -0.2 kg. Furthermore, a significant difference emerged for the percentage of body weight lost, where the HA lost an average of -2.6% of their initial body weight, whereas the LA lost only -0.2% ($p = 0.02$). When looking at clinically significant weight loss in the context of managing PreDM (defined as losing 5-7% of initial body weight), 28% ($n = 7$) of the HA participants lost 5% or more of their initial body weight, while none of the LA participants achieved this degree of weight loss during the study. In connection with weight loss, it was found that the HA were able to decrease their BMI by -0.8 kg/m^2 over the 6-month program, while the LA did not (0.0 kg/m^2) ($p = 0.03$). The HA participants were also more successful at decreasing their mean WC and systolic BP as compared to the LA, but this difference was not found to be statistically significant. Lastly, a significant difference also emerged when comparing the difference in diastolic BP ($p = 0.05$), where the HA decreased by -4.7 mmHg on average from baseline, whereas the LA increased by +2.1 mmHg during the study.

Table 16

Within-group Comparisons for Changes made to Anthropometric and Hemodynamic Data from Baseline to Post-program

	All PREPARE[a] n = 36			**PREPARE High Attendees[b] n = 25**			**PREPARE Low Attendees[c] n = 11**		
	Baseline Mean ± SD	**Post-Study** Mean ± SD	**Paired t-test**	**Baseline** Mean ± SD	**Post-Study** Mean ± SD	**Paired t-test**	**Baseline** Mean ± SD	**Post-Study** Mean ± SD	**Paired t-test**
Weight (kg)	92.1 ± 18.8	90.6 ± 19.9	p=0.01*	89.6 ± 17.6	87.5 ± 18.9	p=0.01*	97.9 ± 20.9	97.7 ± 21.0	p=0.76
BMI[d] (kg/m^2)	32.9 ± 5.4	32.3 ± 5.8	p=0.01*	32.1 ± 4.6	31.3 ± 4.9	p=0.01*	34.7 ± 7.0	34.7 ± 7.1	p=0.84
WC (cm)	108.5 ± 13.0	105.9 ± 14.2	p= 0.003*	106.0 ± 10.7	103.0 ± 12.3	p=0.01*	114.4 ± 16.2	112.4 ± 16.4	p=0.14
Systolic BP (mm Hg)	126.5 ± 15.8	121.4 ± 11.6	p=0.04*	128.6 ± 16.1	121.4 ± 12.2	p=0.03*	121.8 ± 14.7	121.4 ± 10.7	p=0.90
Diastolic BP (mm Hg)	72.6 ± 13.1	70.0 ± 10.6	p=0.15	72.5 ± 14.0	67.8 ± 11.0	p=0.05*	72.9 ± 11.3	75.0 ± 8.2	p=0.40

Notes: n = number of participants, kg = kilograms, BMI = body mass index, m^2 = meters squared, cm = centimeters, WC = waist circumference, BP = blood pressure, mm Hg = millimeters of mercury; [a]All PREPARE = High Attendees + Low Attendees, [b]High Attendees = attended ≥ 3 of 6 PREPARE sessions, [c]Low Attendees = attended 1-2 of 6 PREPARE sessions, [d]BMI = weight (kg)/ height $(m)^2$; * = significant finding ($p < 0.05$)

Table 17

Delta Change of PREPARE High Attendees' versus Low Attendees' Anthropometric and Hemodynamic Data from Baseline to Post-program

	PREPARE High Attendees[a] Delta Change n = 25	**PREPARE Low Attendees[b] Delta Change** n = 11	**Unpaired t-test**
	Mean ± SD	Mean ± SD	
Weight (kg)	-2.1 ± 3.7	-0.2 ± 1.8	p = 0.04*
Percent body weight lost (%)	-2.6 ± 0.0	-0.2 ± 0.0	p = 0.02*
Participants that lost ≥5% of initial body weight[c] (n, %)	7 (28.0%)	0 (0.0%)	n/a
BMI[d] (kg/m^2)	-0.8 ± 1.3	0.0 ± 0.6	p = 0.03*
Waist circumference (cm)	-3.0 ± 5.3	-2.0 ± 4.1	p = 0.54
Systolic blood pressure (mm Hg)	-7.1 ± 15.1	-0.4 ± 10.8	p = 0.14
Diastolic blood pressure (mm Hg)	-4.7 ± 11.3	2.1 ± 7.9	p = 0.048*

Note. n = number of participants, kg = kilograms, % = percent, ≥ = greater than or equal to, BMI = body mass index, m^2 = meters squared, cm = centimeters, mm Hg = millimeters of mercury, n/a = not applicable; [a]High Attendees: attended ≥ 3 of 6 PREPARE sessions; [b]Low Attendees: attended 1-2 of 6 PREPARE sessions; [c]Participants that lost ≥5% of initial body weight = [(1-month post-program body weight - baseline body weight) x 100%/ baseline body weight]; [d]BMI = weight (kg)/height $(m)^2$; * = significant finding ($p < 0.05$)

Chapter 5: Discussion

The purpose of the study was to explore the nutritional impact of a group lifestyle behaviour change program in adults with PreDM from London, ON. Both objective (e.g. anthropometric) and subjective (e.g. self-report) measures were utilized to gain a better understanding of the program's impact on participants' overall health within the context of T2DM prevention. A total of 63 participants (28 males and 35 females) enrolled in the first two cohorts of the study, with only one control participant withdrawing due to illness. The participants ranged in age from 30 to 82 years old, and the majority (85.5%) were Caucasian. Results centered around two major outcomes: (a) nutritional intake and (b) anthropometric and hemodynamic parameters of participants before and after the PREPARE program, as well as compared to controls. Where relevant, each of these outcomes will be discussed within the contexts of: (1) current Canadian guidelines and (2) current clinical practice guidelines for the prevention and management of T2DM.

5.1 Insight to the Nutritional Findings

With regard to nutritional intake and dietary habits, several findings warrant discussion.

5.1.1 Total Vegetables and Fruit. At baseline, it was apparent that the majority of participants were not meeting the minimum recommended number of daily servings for one or more CFG food groups based on age and gender. Put fourth by Health Canada, CFG exists to help guide Canadians in making healthy dietary choices to maintain a healthy body weight, meet macro- and micro-nutrient requirements, and reduce the risk of chronic disease (Health Canada, 2002).

Specifically for V&F, which was a predominant focus of this study and major component of the nutrition curriculum for the group education sessions, at baseline, none of the sub-groups of participants (HA, LA, or controls) had a mean daily intake that met the minimum recommendation of seven V&F servings/day. Upon closer examination of the

data, the HA participants did have a significantly higher mean daily V&F intake, as compared to the LA participants. It is unknown if this influenced their choice to enter PREPARE; however, it has been suggested that positive health behaviours may be a reflection of an individual's self-efficacy, or the belief that one can be successful in achieving a desired goal (Lawson et al., 2001). It is plausible that this difference in baseline V&F intake that emerged between the HA and LA participants may attribute to an underlying difference in self-efficacy, which in turn, may also be related to the higher attendance seen in the HA group.

Regardless, at the end of the 6-month education program, HA participants were closer to meeting CFG recommendations for mean daily V&F intake, falling on average just 0.1 servings short of the minimum recommendation of seven V&F servings/day. Control and LA participants lagged appreciably behind, falling short by 1.5 and 2.5 servings/day, respectively. When these figures are compared to how other Canadian adults are doing, the most recent Canadian Community Health Survey from 2004 found that mean V&F intake for adults was 5.2 servings/day (Statistics Canada, 2006). What is promising about the present program is that although a statistically significant difference did not emerge in the change in V&F intake between any of the sub-groups of participants, at the end of the study, the HA subgroup's mean V&F intake increased by +0.4 servings/day and actually exceeded the rest of Canada by 1.7 V&F servings/day. It is important to note that at baseline, the HA started the program with a mean V&F intake that was higher than the Canadian average.

Furthermore, post-program, 29% of intervention participants, 32% of HA, 22% of LA, and 25% of control participants had adequate intake to meet the minimum CFG recommendation for V&F intake based on age and gender, which for PREPARE participants, was an improvement from baseline (+12% improvement for intervention participants, +12% for HA, +13% for LA, and -13% for controls). As previously discussed, V&F are thought to play a protective role in the development of T2DM (Ford & Mokdad, 2001; Rolls et al., 2004; Villegas et al., 2008). Thus, if a lifestyle behaviour change program such as

PREPARE can help those at high risk for T2DM get closer to achieving Canadian nutrition guidelines, as seen in the HA's V&F intake, hopefully the additional fibre, phytochemicals, vitamins, minerals, and other protective factors found in V&F can help these individuals control their energy intake, achieve a healthy weight, and delay or prevent the progression from PreDM to T2DM.

5.1.2 Dark Green Vegetables. In regards to the sub-categories of V&F examined, although program impact on intake of dark green vegetables was not significant, it was of interest to see that the intervention participants had a mean increase of +0.3 servings/day from baseline (specifically +0.4 servings/day for HA, no change for LA), while control participants actually decreased intake by -0.5 servings/day. It has previously been reported that consuming 1.35 servings/day of green leafy vegetables can result in a 14% reduction in risk of T2DM (Carter et al., 2010). At the end of the PREPARE program, only the HA participants achieved this clinically significant intake of dark green vegetables (1.4 servings/day), versus 1.0 servings/day for both LA and controls. It remains to be seen if the HA can maintain this increased intake, and potentially reduce their risk of developing T2DM.

5.1.3 Starchy Vegetables. A second V&F sub-category of interest was the change in intake from baseline to post-program of starchy vegetables (e.g. potatoes). Although significance was not shown in the preliminary analysis, it is of clinical importance to note that the intervention participants decreased their mean intake of starchy vegetables by -0.1 servings/ day (HA decreased by -0.2 while LA increased by +0.3 servings/day), versus an increase of +0.4 servings/day for control participants. Previous research has found a significant positive risk of developing T2DM with increasing intake of starchy vegetables (Liu et al., 2004; Montonen et al., 2005), so potentially, this change in dietary behaviour for HA participants, if maintained long-term, may offer some protection against developing T2DM.

5.1.4 Qualitative Feedback on Vegetable and Fruit Intake. Qualitative data collected from the overall program feedback forms and focus group discussions further demonstrated the positive impact the PREPARE program had on V&F consumption in the study participants. The focus group discussions largely consisted of HA participants, who attended three or more of the six education sessions offered. The PREPARE program was designed to increase nutrition and physical activity knowledge, skills, and self-efficacy, so that participants not only learned more about the health behaviours known to reduce the risk of T2DM, but also translated this education into meaningful lifestyle behaviour change. Literature on diabetes self-management education programs have consistently shown that educational sessions that were interactive and actively involved patients were more effective in generating positive self-management outcomes than those where education was didactic (Eakin, Bull, Glasgow, & Mason, 2002). In the focus group discussions, clients were enthusiastic not only about the new knowledge they gained about eating colourful V&F, CFG, and hidden sources of sodium, but also the hands-on learning and skill building that was incorporated into the monthly curriculum and optional cooking workshops. Participants felt they benefited through learning how to prepare unfamiliar healthy foods in novel ways, how to read nutrition labels, and what to look for when grocery shopping and eating out so that the healthy eating guidelines being taught as part of the PREPARE program could be incorporated into their daily lives. Recent literature has also concluded that interventions that combine educational and behavioural strategies produce better outcomes than either alone, and that group programs with smaller numbers of participants produce better results than those with more members (Eakin et al., 2002), both of which were features of the PREPARE program. The data collected from the focus group discussions highlights some of the lifestyle behaviour changes participants felt they learned from the education sessions and optional cooking workshops that they had begun to adopt into their lives. Despite not seeing as many statistically significant results from the analysis of the 3d-FIR as was hypothesized for V&F intake, the qualitative data collected illustrates that the PREPARAE program did

increase participants' awareness about the importance of eating a wide variety (i.e. different colours) and increased quantity of V&F as a strategy to potentially delay or prevent T2DM.

5.1.5 Saturated Fatty Acids. Delving into some of the other significant findings related to changes participants made to their overall diets, it was interesting to see that the PREPARE curriculum had a potential influence on participants' eating habits in regards to SFA and sodium – two dietary factors connected with CVD (Institute of Medicine, 2005). The nutrition curriculum for PREPARE was modeled after successful large-scale lifestyle behaviour change trials such as the Finnish Diabetes Prevention Study (Tuomilehto et al., 2001) and the Diabetes Prevention Program (Diabetes Prevention Program Research Group, 2002), which promoted a moderate fat diet (<30% of energy from fat) and SFA intake (<10% of energy consumed), coming from a diet rich in V&F, whole grains, low-fat milk and meat products, and vegetable oils.

In this study, the intervention group and HA participants specifically were found to have a significant reduction in their SFA intake from baseline to the end of the program, whereas the LA and control participants did not make a significant change when looking at their within-group changes. Again, it is important to point out that caution should be used when interpreting these results, as no significant difference was observed between the intervention and the control participants when program impact was examined for the change in mean daily SFA intake.

Looking to current clinical practice guidelines, the American Diabetes Association's position paper discussing weight management through lifestyle modification for the prevention and management of T2DM suggests that SFA intake should be reduced to <7% of total calories, especially in the case of adults with high blood cholesterol (Klein et al., 2004). Intervention participants were able to reduce their percentage of energy intake from SFA by -1.4% (from 11.8% at baseline to 10.4% post-program). HA participants similarly reduced their percentage of energy intake from SFA by -1.4% (from 11.4% at baseline to 10.0% post-

program), which moved HA participants as a collective whole closer to targets recommended by clinicians. For T2DM prevention, SFA intake is recommended to fall within the range of 7-10% of total energy consumed to help with weight management and dyslipidemia (Canadian Diabetes Association, 2008h; Canadian Hypertension Education Program Task Force, 2010; Klein et al., 2004; National Institutes of Health: National Heart, Lung, and Blood Institute, 2000). LA participants did decrease their SFA intake over the course of the study, but this reduction was not statistically significant, nor did it reach clinical significance falling outside of the range of 7-10% of total energy consumed coming from SFA (12.1% at baseline, 11.4% post-program).

5.1.6 Sodium. Sodium education was another important aspect of the PREPARE curriculum, as high dietary sodium intake is a well-known determinant for HTN and HTN-related complications such as CVD (Canadian Hypertension Education Program Task Force, 2010; World Health Organization, 2000). The average sodium intake of Canadians is about 3500 mg/day, which is well above the recommended level for good health (Hypertension Canada, 2012). In conjunction with the Institute of Medicine, Health Canada recommends a dietary sodium intake of 1500 mg/day for adults age 50 years or less, 1300 mg/day for adults 51-70 years old, and 1200 mg/day for those older than 70 (Institute of Medicine, 2004), which is also appropriate for the prevention and treatment of HTN (Hypertension Canada, 2012).

HA did experience a significant reduction in their mean daily sodium intake from baseline to post-program ($p < 0.004$), dropping from 2760.3 to 2117.4 mg/day, with an average change of -642.8 mg/day per participant. This decrease in sodium intake is of clinical importance, as sodium intake has been associated with stroke and CVD (Canadian Hypertension Education Program Task Force, 2010). According to one meta-analysis, it has been estimated that a salt reduction of 100 mmol/day (equivalent to a sodium decrease of -2400 mg/day) is associated with a fall in BP of -7.11 (systolic)/-3.88 (diastolic) mmHg in

hypertensive and -3.57/-1.66 mmHg in normotensive individuals (He & MacGregor, 2000). In this study, the HA participants did experience a significant decrease in mean BP, falling from 128.6/72.5 mmHg at baseline to 121.4/67.8 mmHg post-study, which was an average decrease of -7.2/-4.7 mmHg over the 6-month program. Outside of the HA's reduction in dietary sodium intake, this fall in BP may also be attributed to their achievement of significant weight loss (discussed in section 5.2) and potential increase in physical activity levels (not explored in this preliminary analysis but monitored as part of the larger PREPARE study). As for the LA and control participants, post-program, both groups had sodium intakes below the Canadian average of 3500mg/day (2871.1 mg/day for LA, a decrease of -11.3 mg/day from baseline; 3403.4 mg/day for controls, an increase in sodium intake of +416.3 mg/day) as both groups did receive some sodium reduction education; however, these results were not significant compared to what was found for the HA.

Despite not seeing the majority of participants falling within the 1200-1500 mg/day sodium recommendation put fourth by Health Canada, as a sub-goal of trying to increase participants' V&F intake and consumption of minimally processed foods was the hope that sodium intake would decrease concurrently. Given the linear association between sodium intake and blood pressure and the proven benefits of sodium-reduced diets (Sacks et al., 2001), seeing a significant reduction in HA's intake of dietary sodium was a welcome finding. Again, this within-group change for the HA's sodium reduction should be interpreted with caution, since results from the 1-way ANOVA analyzing the program's impact in relation to the delta change for all PREPARE participants versus control participants did not yield a statistically significant result for the nutrient sodium.

Qualitatively, participants expressed appreciation during the focus group discussions for learning more about the hidden sources of sodium in commercially prepared foods. These types of comments demonstrated an increase in nutrition knowledge and sodium awareness that came out of attending the group education classes. The optional cooking workshops were another important element of the PREPARE program to help address

sodium intake, where low-sodium recipes were deliberately selected so that participants could learn new ways to season home-cooked dishes without the use of added salt. Almost all of the low-sodium recipes and healthy snacks offered were well received, and from the data gathered from the focus groups and overall program feedback forms, it was apparent that participants were trying to incorporate many of the new foods and recipe ideas into their lives.

Multiple strategies adopted from research findings can be attributed to the success seen in sodium reduction by PREPARE participants. Firstly, participants were exposed to trying new foods (especially a wide range of V&F) during the healthy snack breaks and optional cooking workshops, and were given the opportunity to gain hands-on experience with food preparation under the guidance of Registered Dietitians, a chef, and Foods & Nutrition student volunteers. Secondly, participants received an abundance of sodium-reduction strategies during the group education sessions to increase awareness and help them translate knowledge into action. Thirdly, individualized dietary feedback was provided to participants at the mid-point and post-program follow-up based on the analysis of their 3d-FIRs to help make them aware of their own sodium intake patterns. This three-tiered approach may have allowed for an increase in knowledge, self-efficacy, and self-monitoring and awareness skills to enable participants to make a positive lifestyle behaviour change that is hopefully sustainable in the long run (Eakin et al., 2002).

5.1.7 Unexpected Dietary Findings

5.1.7.1 Grain Products. A few unanticipated dietary findings emerged at the end of the study that warrant discussion. To begin, a significant difference surfaced when the change in average intake of grain products was examined in closer detail at the end of the program. Specifically, the intervention participants were found to have significantly decreased their mean intake of grain products from baseline (5.7 servings/day) to post-program (4.4 servings/ day), and both sub-categories of PREPARE participants (HA & LA) did not meet CFG

minimum recommendation of 6 grain servings/day at the end of the study. Meanwhile, control participants maintained a fairly consistent intake of grain products, decreasing from 6.7 (baseline) to 6.1 (post-program) servings/day; a change that was not significant. Despite the regular use of CFG in the PREPARE education sessions to inform participants about their own minimum food group recommendations and how to use it to make healthy eating choices to prevent T2DM, it is apparent that many participants partially reduced their energy intake to promote weight loss by cutting back on their consumption of grain products. This is not an uncommon practice among dieters, as many low-carbohydrate, high-protein diets have become increasingly popular and many best-selling diet books have promoted this approach (e.g. Atkins, South Beach, Paleolithic diets). In one randomized clinical trial that involved 63 obese men and women who were randomly assigned to either a low-carbohydrate, high-protein, high-fat diet or a low-calorie, high-carbohydrate, low-fat (conventional) diet, researchers found that at three months, subjects on the low-carbohydrate diet had lost more weight than subjects on the conventional diet, but the difference at twelve months was not significant (Foster et al., 2003). They also found that adherence to the assigned diets was poor and attrition was high in both groups. The present diet mentality that the consumption of grain products hinders weight loss is strong in current North American culture, and may have played a role in the decrease seen in this study.

5.1.7.2 Meat and Alternatives. Another unanticipated finding was the LA's decrease in meat and alternatives intake, which decreased by -1.4 servings/day over the study, in comparison to a +0.1 serving/day increase for the HA and -0.1 serving/day decrease for the control participants. From a program impact standpoint, this different was not significant when the intervention participants were compared to the controls; however, the post hoc analysis did indicate significance when the HA were compared to the LA. From an adequacy standpoint, all sub-groups were still meeting the CFG minimum recommendation of 2 meat and alternative servings/day post-study. This finding should be explored further during the

analysis of the on-going PREPARE study, since presently, there is only speculation that LA participants may have decreased their portion size of meat more so than the other sub-groups, as this group had the largest decrease in total energy intake (-461 kcal/day), compared to the HA (-180 kcal/day) and control participants (-124 kcal/day).

5.1.7.3 Protein. A third unexpected finding that emerged from the analysis of participants' 3d-FIR was the significant difference in the delta change for total grams of protein consumed by the PREPARE participants compared to controls, and likewise, between the HA and LA participants and between the LA and controls over the course of the study. This preliminary analysis revealed that from baseline to the end of the program, HA decreased their protein intake by -7.1 g/day, LA decreased by -27.3 g/day, while the controls increased by +1.6 g/day. As with CFG, the PREPARE nutrition curriculum and the current standard of care presentation did not focus specifically on protein intake directly other than promoting healthy protein options and appropriate portion sizes that appear on CFG. This result is likely connected with the significant decrease LA participants made to their meat and alternatives intake, which is an excellent source of dietary protein, and likely the reason for the significant decrease in total protein intake seen for this group.

From the latest Canadian Community Health Survey conducted in 2004, it was found that nearly all Canadians in every age and gender group fell within the acceptable range for protein intake and Canadians were easily meeting their protein requirements from foods such as meat, poultry, fish, eggs, dairy products, and beans (Statistics Canada, 2006). The relation between processed meat consumption and the development of diabetes has been addressed in the literature, with alleged mediators that include saturated fat, cholesterol, nitrites, and its contribution to a higher fat intake which may promote obesity and thus, increase risk for the development of T2DM (Montonen et al., 2005). One consistent message throughout the PREPARE program was to use CFG to select leaner cuts of meat (e.g. have poultry with the skin removed, limit fatty cuts of processed meat) and to be more conscientious of portion

sizes, since early in the PREPARE program participants were educated about their risk for developing CVD and T2DM as a result of having PreDM. The preliminary results from this study suggest that the PREPARE program had an impact on participants' intake of protein as compared to controls, and that the message to consume adequate protein, yet avoid excessive intake and protein sources that contained lots of additional SFA, may have potentially translated into lifestyle behaviour change for these individuals. What remains unknown is the long-term effect of this preliminary dietary change in protein intake, and what impact this may have on participants' risk of developing T2DM or CVD complications in the future.

5.2 Insight to the Anthropometric and Hemodynamic Findings

Beyond dietary intake, it was also important to assess what influence the program had on other health parameters related to the potential development of T2DM. In adults, the risk of developing T2DM increases continuously with increasing obesity, and decreases with weight loss (World Health Organization, 2008). As such, weight and percentage of weight lost, BMI, and WC were all key parameters examined in the study. At baseline, participants in this study were very similar to other studies that worked with individuals with PreDM (Absetz et al., 2007; Diabetes Prevention Program Research Group, 2000; McTigue et al., 2009) in the fact that most fell into the obese class I category (BMI 30.0 to 34.9 kg/m^2). Achieving a moderate weight loss of 5-7% of one's initial body weight in overweight or obese persons with PreDM or T2DM has been shown to improve insulin action, decrease fasting blood glucose, reduce the need for diabetes medications, and improve risk factors for CVD (Diabetes Prevention Program Research Group, 2002; Klein et al., 2004; Tuomilehto et al., 2001). In this study, the HA participants lost a significant amount of weight as compared to the LA, losing an average of -2.1 kg per person over the 6-month study, versus only -0.2 kg for the LA participants. Since weight and BMI are connected mathematically, this also affected mean BMI, where HA participants significantly reduced their mean BMI by -0.8 kg/m^2, versus no change for the LA participants.

The Finish Diabetes Prevention Study found that the mean amount of weight lost one year from baseline was -4.2 kg in the intervention group, and only -0.8 kg in the control group ($p < 0.001$), which was similar to this study, but encompassed a longer time-frame (i.e. one year versus six months) (Tuomilehto et al., 2001). In the Diabetes Prevention Program, participants assigned to the lifestyle intervention lost -5.6 kg on average, compared to a -0.1 kg and -2.1 kg weight loss for the placebo and metformin group, respectively (Diabetes Prevention Program Research Group, 2002). The DPP findings were based on a mean follow-up of 2.8 years, and dietary counselling took place in a more clinical, one-on-one setting. In the Japan Lifestyle Intervention Trial, participants that received the intervention (diet and physical activity education every 3-4 months during hospital visits) lost a mean of -2.5 kg at the one year mark, and at the four-year follow-up, on average maintained a significantly lower weight loss (-2.18 kg) than baseline, and also lost significantly ($p < 0.001$) more weight than the controls whose body weight only decreased by -0.39 kg (Kosaka et al., 2005). Even though this population consisted of 483 Japanese males with PreDM that received education on a slightly less frequent schedule that what PREPARE offered its participants, overall weight loss was found to be very similar.

In community-based group education settings, weight loss results have been more inconsistent. Absetz and colleagues (2007) did not find significant weight loss in men and women with PreDM at the one-year follow-up time point taking part in the GOAL Implementation Trial. In their study, participants only lost an average of -1.0 kg at the one-year mark, after receiving six group education sessions that took place over eight months (Absetz et al., 2007). The study's methodology and timeframe were very similar to PREPARE, and one of the reasons cited by authors to explain the non-significant weight loss was the speculation that many of the individuals had likely received previous lifestyle counselling prior to joining the trial, since participants were recruited among healthcare patients and many were found to already be following key lifestyle recommendations at baseline. This made it difficult for researchers to see further health improvements in

participants during the study. In the Weight Loss through Living Well Study (WILLOW), which was a self-select fee-for-service group program offered to overweight or obese participants, program enrollees had a mean weight change of -5.19 kg after attending twelve weekly sessions delivered by a nurse educator, as compared to a +0.21 kg weight gain in the non-enrollees (McTigue et al., 2009). Not only did the enrollees receive more education and support which helps to explain the difference in weight change, it can be speculated that the enrollees also had fewer barriers to program entry (i.e. financial, self-efficacy, social support, time) as compared to the non-enrollees. This group-based program was more prescriptive with its dietary instructions provided to participants (i.e. reduce fat to < 25% of total energy, reduce energy intake by 500-1000 kcal/day) than PREPARE which focused on teaching healthy eating principles based on CFG and did not set specific caloric or fat targets, which may explain the greater degree of weight loss see in the WILLOW study. It is also noteworthy that WILLOW participants received double the number of education sessions compared to PREPARE (twelve versus six).

Regardless, the PREPARE program, which included six group education sessions on the topic of nutrition and physical activity in a Canadian, community-based setting, did see significant weight loss results at the post-program follow-up between the HA and LA. Another factor considered beyond the mean amount of weight lost was the percentage of initial body weight lost. On average, HA lost around -2.6% of their initial body weight over the course of the 6-month study, while the LA only lost -0.2%, which was significantly different. Based on clinically meaningful parameters within the context of managing PreDM, losing ≥5% of initial body weight over the 6-month time frame was an important element that was considered in this study. Twenty-eight percent (n = 7) of the HA participants achieved clinically significant weight loss (≥5% of initial body weight lost) by the end of the program, while none of the LA lost a meaningful amount of weight. In the WILLOW community-based study previously mentioned, 27% of the enrollees versus 6% of the non-enrollees lost ≥7% of their initial body weight (McTigue et al., 2009), and in the DEPLOY

group-based lifestyle intervention program that was hosted in semi-urban YMCA facilities, the intervention arm lost a mean body weight percentage of -3.7% compared to only -2.6% for the control arm after approximately 20 months of follow-up (Ackermann et al., 2008).

As a result of losing weight over the duration of the PREPARE program, many of the anthropometric and hemodynamic factors were positively impacted in the HA participants. Compared to baseline, HA participants experienced significant reductions in their mean weight, BMI, waist circumference, systolic BP, and diastolic BP at the post-program follow-up, whereas the LA participants did not see any significant changes in any of these health parameters. Reducing obesity through achievement of moderate weight loss in overweight or obese persons with T2DM and/or those at risk of developing T2DM is known to improve insulin action, decrease FBG, and improve risk factors for CVD, including HTN (Klein et al., 2004), so it is not a surprise, in combination with the reduction in dietary SFA and sodium intake seen in the HA participants, that there was also a favourable response in key anthropometric and hemodynamic risk factors associated with T2DM. Given that the LA participants received less than 50% of the PREPARE education sessions offered and had less interaction with the healthcare team due to low attendance, it is not surprising that the HA participants made significant progress in altering key health parameters associated with T2DM, while the LA did not from baseline to the end of the program.

5.3 Insight to the Program's Retention Rates

Although PREPARE experienced declining attendance rates from baseline (n = 48 PREPARE participants, 15 control participants) to post-program follow-up (n = 23 PREPARE participants, 8 control participants, 1 control withdrawal), retention rates were within the range of similar community-based programs reported in the literature. In this study, monthly attendance rates to the education sessions ranged between a high of 94% at Visit 2 to a low of 44% at Visit 6, with 64% of participants returning for the Visit 8 post-program follow-up. As previously mentioned, mean attendance was 3.6 sessions of 6

education visits offered (60%). These figures were slightly higher than the DEPLOY pilot study offered at local YMCAs, which had a mean attendance rate of 6.4 sessions per intervention participant (out of 12 sessions offered), and for their controls, mean attendance was 6.3 sessions (Ackermann et al., 2008). The GOAL Implementation Trial, another group-based PreDM lifestyle modification program conducted in Finland, had better success in its retention rates. This study indicated that 57% of the participants attended all six counselling sessions (out of six), and that attendance to the first five sessions remained steadily over 90% but dropped to 81% in the last session (Absetz et al., 2007). This study credited it low attrition to its investment in a strong dietitian for the program, as well as allowing its session facilitators at 16 different sites to add to or omit the program curriculum as they best saw fit to meet the needs of their participants. In continued trials of the PREPARE program, granting program facilitators this type of flexibility to mold educational material to best meet the needs of the group may help to improve retention rates. Additionally, as funding allows, continuing to invest in a program dietitian is another useful strategy to reduce attrition, as indicated in other comparison studies. For PREPARE, there was always an excellent dietitian/student volunteer to participant ratio. At any given visit, one to three Registered Dietitians were present accompanied by one to two dietetic intern/graduate students as well as six to twelve trained university-educated student volunteers to assist a small group of clients and provide individualized feedback, especially on the 3d-FIR and physical activity logs. Even though PREPARE was not able to offer one-on-one, individualized nutrition counselling that was attributed to the success of the Diabetes Prevention Program, similar to the GOAL Implementation Trial (Absetz et al., 2007) and WILLOW study (McTigue et al., 2009), with group nutrition education, investment in a program dietitian and strong counselling skills of the clinical educators was another thing that strengthened the PREPARE program and contributed to participant engagement. Furthermore, as funding allows, continuing to invest into the optional cooking workshops and healthy snacks offered at the education sessions is recommended, as this was an important strategy to increase

participants' awareness and acceptance of healthy, V&F-inspired foods and encouraged regular attendance to the program.

5.4 Limitations

The preliminary analysis of PREPARE has shown some promising results. The program was well-received by participants, and resulted in some positive lifestyle behaviour changes (e.g. openness to trying new healthy foods; moderate, non-significant increase in intake of V&F; reduced consumption of sodium and SFA), especially in those with high attendance to the PREPARE education sessions, which lead to some changes in health status, including weight loss in many of the participants. The success of the PREPARE program, however, warrants further investigation. The challenges and limitations associated with the program's implementation must be adequately addressed to help improve the program for future participants.

As mentioned, this was an exploratory study with some notable limitations. Firstly, this study utilized a quasi-experimental design that allowed adults with PreDM to self-select between the 6-month PREPARE program (intervention group) or a one-time, 2-hour group education session (current standard of care, control group) at baseline. This introduced a self-selection bias, and it is highly probable that underlying differences in motivation, self-efficacy, and resources (i.e. time, financial, social support) existed between the PREPARE and control group, and even within the PREPARE HA, LA, and non-attendee participants. For example, there was a clear distinction between the ethnicity of the HA, LA, and control participants (primarily of Caucasian descent) and the non-attendee PREPARE participants, who had a greater degree of ethnic diversity. One of the eligibility criteria was the capability to participate in an English-based group education program that required reading, writing, and English-speaking ability, and this limitation may have created a barrier for some of the non-attendee participants who enrolled in PREPARE but never returned for education. This limits the generalizablity of the results to primarily English-speaking adults of Caucasian

descent. Additionally, with a self-selection bias, further research is also needed within the larger PREPARE study to connect discrepancies in self-efficacy and other self-care capacity indicators with the nutritional and anthropometric variables considered in this subset. Self-efficacy data has been collected by collaborating researchers involved with the study, but not yet analyzed or included in this preliminary investigation. Furthermore, even though a quasi-experimental design was used for this study, results from a recent Cochrane review comparing outcomes for patients who participated in randomized control trials (RCTs) to those who received similar clinical interventions but did not take part in a RCT found that, on average, the clinical outcomes of both groups were similar (Vist, Bryant, Somerville, Birminghem, & Oxman, 2009). This Cochrane review examined a total of 86,640 patients treated in RCTs to 57,205 patients treated outside RCTs and concluded that participation in RCTs was associated to similar outcomes to receiving the same treatment outside of RCTs, and that both study designs offer comparable results. In addition, the World Health Organization acknowledges that although RCTs offer a way to rigorously evaluate public health interventions, they are often impracticable to adopt, due to difficulty obtaining individual and community buy-in, selecting an appropriate and ethical control group, and sustaining an intervention in the community after a RCT ends (Osrin et al., 2008). For many of these reasons, the current study was designed as a non-RCT to achieve program objectives while best serving the prediabetic community of London, ON.

Secondly, this study did not collect anthropometric and hemodynamic parameters in the control group that self-selected to attend the current PreDM standard of care at baseline. The study's methodology was intentionally set up in this way, due to the time constraints at baseline which included presenting the study options to all potential participants and screening for eligibility, obtaining informed written consent, administering numerous baseline questionnaires, and getting the control participants through the 2-hour current standard of care presentation. For this reason, it was decided that only nutrition, physical activity, and knowledge/self-efficacy data would be collected from the controls at baseline

(the overall study's primary outcome objectives), which excluded the collection of physical measures. Unfortunately, at the post-program follow-up, this did not allow for a comparison of any anthropometric and hemodynamic factors, especially considering that the control participants had no further in-person contact with the research team beyond baseline. In the future, it would be helpful to redesign the baseline data collection procedures to potentially administer some of the questionnaires by mail in advance of the first visit, which would cut down on the amount of time completing paperwork at baseline and could create an opening to collect physical measurements data. Later, at the post-program follow-up point, control participants could be invited back for a physical re-assessment, instead of the current procedure that involves re-administering the baseline questionnaires by mail to the controls. Thirdly, like many community-based group education programs, participant retention decreased over time, despite numerous attempts to contact participants by telephone and mail to remind them of upcoming visits and accommodate barriers to attendance, such as illness. To assist with participant retention, it may be worth revisiting the education sessions themselves to see if they can be made even more personalized and interactive with the Registered Dietitians and other participants present, which was feedback provided by participants. Furthermore, many PREPARE participants expressed feeling overwhelmed and frustrated with the amount of paperwork associated with data collection. For improved program delivery, it is worth reviewing key study objectives to create a more focused approach for data collection to ease participant burden and promote continued interest in attending the education sessions. For instance, the 3d-FIR can potentially be replaced by a 24-hour recall conducted by a Registered Dietitian and/or trained assistant. Although this will reduce the robustness and accuracy of the dietary data collected, it will alleviate some participant burden and assist those with visual impairment and/or limited literacy skills.

5.5 Strengths

Despite the limitations of this study, the program had a number of strengths that are worth mentioning. To begin, the delivery of the PreDM education sessions was supported by a strong inter-professional and dedicated research team that included Registered Dietitians, Certified Diabetes Educators, dietetic interns, graduate students, and more than 60 undergraduate university students from various health sciences disciplines. This allowed for increased interaction between participants and the research team, helping to increase participant engagement, as well as offer greater opportunities for individualized attention within a group education setting. Furthermore, by having a committed team of volunteers assist with data collection, food preparation, education delivery, and so on, the cost-effectiveness of the program was enhanced by reducing the amount of money required to be spent on study personnel.

Secondly, offering the program free of charge to participants in a community-based setting with additional cost-cutting incentives such as free parking, free healthy snacks, and free hands-on cooking workshops was another strength that helped to attract and retain motivated individuals. By reducing some of the financial barriers to participation, this facilitated greater program involvement, especially for those participants of lower socio-economic status.

Lastly, a strong referral relationship between the local DEC and Brescia University College was another huge asset to help recruit and enroll participants with PreDM in a timely manner. As previously mentioned, the Prediabetes Initiative and Partnership was formed between these two organizations in 2006, and had been steadily growing and serving an increasing number of individuals with PreDM from London, ON. Having this partnership established in advance of PREPARE's launch ensured that individuals with PreDM could receive the healthcare and education they required without delay.

Chapter 6: Conclusions

6.1 Relevance to Practice

Without question the incidence of T2DM is on the rise, both in Canada and around the world. PreDM explicitly places individuals at risk for developing T2DM, the metabolic syndrome, and CVD, placing a huge burden upon the afflicted individuals, their families, and our healthcare system. At present, patients with PreDM are an under-served population at high risk for developing T2DM. Anecdotal feedback from more than five hundred clients who have attended the current PreDM standard of care at Brescia University College in London, ON between 2007-2009 have verified that clients want more nutrition and physical activity education and skill-building over a longer period of time to assist them in changing their lifestyle behaviours. From that feedback, PREPARE was developed to deliver six monthly education sessions to enable middle and older adults with PreDM to progressively implement positive lifestyle changes in a supportive, community-based learning environment. The overall research study is currently ongoing, and seeks to evaluate the general program effectiveness in regards to practicability, feasibility, and acceptability in adults with PreDM in the hopes that a sustainable and efficacious program can be developed and shared with other clinical and community-based settings across Canada.

Assessing the nutritional impact of the 6-month group education program was identified as an important research objective. As a first step, it was imperative to see what components of the educational curriculum were well received by participants and could be successfully adopted to create meaningful behaviour change over time. This in turn, could have an effect on some of the secondary research objectives, such as changes to anthropometric parameters associated with the development of T2DM. Based on the objective data and subjective feedback collected from participants, program educators can continue to tailor future education sessions to best meet the needs of individuals with PreDM from London, ON. Furthermore, other healthcare professionals delivering both clinical and

population-based education and care to patients with PreDM can utilize these findings to adopt effective, lower-cost strategies to best serve their target populations.

6.2 Areas for Future Research

This study provided a preliminary analysis and aimed to explore the impact of a 6-month lifestyle behaviour change program (PREPARE) primarily from a nutritional and anthropometric standpoint in a convenience sample of adults with PreDM from London, ON. The larger PREPARE study remains ongoing, which allows for further investigation within this patient population to consider other important factors not explored in this preliminary analysis, including a larger sample size, a longer period of follow-up, and other lifestyle factors included in the larger research study design but not yet analyzed, including physical activity levels, biochemical results, and participant knowledge and self-efficacy data. Re-examining the data utilizing a larger sample size will help to identify and potentially confirm statistically significant results that emerged from this preliminary analysis.

Future research may also include the possibly to expand from a single centre study and branch out to other community venues, such as London's Inter-Community Health Centre that services lower income individuals, or to other communities outside of London, ON. Drawing conclusions from a larger and more ethnically diverse population will help to identify aspects of the PREPARE program that have successfully helped participants reach their dietary, physical activity, and lifestyle behaviour change goals within the context of reducing their risk of T2DM, improving the generalizability of the results.

Ongoing comparisons made between the HA, LA, and control participants is another important area of continued exploration for the research team. Follow-up of the intervention and control participants is scheduled six months after PREPARE ends (around one year after the baseline assessment), which offers insight into whether the dietary, anthropometric, and hemodynamic changes observed during the PREPARE program are upheld over time. It also offers the opportunity to further explore differences in self-selection of healthcare between

participants. Lastly, gathering additional data at this final time point will allow researchers to compare the findings from this study to other lifestyle behaviour change programs in the literature and evaluate components such as weight loss maintained over time.

Finally, participant feedback suggested that a more individualized approach to nutrition and weight loss would have benefited them further. Future delivery of the PREPARE program can take this feedback into consideration, and the overall study design can potentially be adjusted to offer participants more one-on-one time with the program's Registered Dietitians, dietetic interns, and physical activity specialists, while still maintaining key aspects of the group education setting. This blended design, adopting some one-on-one components from other successful lifestyle behaviour change programs such as the Diabetes Prevention Program, while still maintaining the group dynamic which offers increased social support and wise use of limited financial resources, respects the wishes and feedback from the first group of participants enrolled in the PREPARE program and offers the opportunity to further research program impact with this change in delivery design.

6.3 Closing Remarks

In summary, this study was a community-based, PreDM lifestyle behaviour change program in adults from London, ON to assess the impact of a 6-month nutrition and physical activity education series designed to help prevent or delay the development of T2DM. The educational curriculum, based on current Canadian nutrition and physical activity guidelines, was delivered by a dedicated team of Registered Dietitians and graduate and undergraduate Foods and Nutrition students. All education sessions were held at Brescia University College, which served to act as an accessible location for program participants and attracted many devoted student volunteers to help run the program free of charge to participants. Although the overall PreDM study is on-going, this preliminary analysis of PREPARE has shown some early signs of progress towards modifying risk factors associated with T2DM,

and offers researchers some insight into the more successful and well-received aspects of the program.

Although the program's impact on V&F intake based on CFG recommended number of daily servings and guidelines for sub-categories of V&F was not shown to be statistically significant, the intervention participants did increase their V&F intake by +0.3 servings/day from baseline, and as a group, consumed more V&F daily servings compared to the current Canadian average intake. This V&F increase is of clinical significance, and may potentially play a protective role in preventing the development from PreDM to T2DM. Likewise, by the end of the program, a larger percentage of participants were meeting CFG recommendations for V&F intake and consumption of dark green vegetables and bright orange V&F, which is an important factor for the prevention of T2DM and other chronic diseases. Offering hands-on cooking classes and healthy snacks to taste-test during the education sessions were two important components of the PREPARE program that played a key role in encouraging increased V&F intake. Additionally, an improvement in certain micro-nutrients of interest was observed during the study, such as a reduction in dietary sodium and SFA intake in the HA participants, although it cannot be said at this time that this is directly related to the impact of the 6-month PREPARE program. Furthermore, positive feedback obtained from the majority of participants who completed the overall program feedback form and focus group discussions indicated that the nutrition components of the PREPARE program were well-received and were starting to be incorporated into their daily lives. Finally, PREPARE has begun to show a trend in reducing physical risk factors associated with the development of T2DM, including weight loss, decreased WC, and reduced BP in many of the intervention participants. When put together, all of these small changes towards improved health may have a powerful, synergistic effect in the long-run helping to prevent T2DM in those individuals who were committed to making the lifestyle behaviour changes suggested throughout the program.

In light of the growing number of individuals diagnosed with PreDM each year, developing and evaluating accessible and sustainable intervention programs designed to prevent or delay T2DM should remain a top priority for research conducted within, and in partnership with, the Canadian healthcare system.

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Appendix A: UWO Certificate of Approval of Human Research

Office of Research Ethics

The University of Western Ontario
Room 5150 Support Services Building, London, ON, Canada N6A 3K7
Telephone: (519) 661-3036 Fax: (519) 850-2466 Email: ethics@uwo.ca
Website: www.uwo.ca/research/ethics

Use of Human Subjects - Ethics Approval Notice

Principal Investigator: Dr. I. Giroux
Review Number: 17755 **Review Level:** Full Board
Review Date: January 11, 2011 **Approved Local # of Participants:** 240
Protocol Title: Prepare: "Prediabetes Research and Education Promoting Activity & Responsible Eating", a 6-month Prediabetes Lifestyle and Behaviour Change Intervention Program.
Department and Institution: Nutrition and Food Sciences, University of Western Ontario
Sponsor: LAWSON FOUNDATION
Ethics Approval Date: February 03, 2011 **Expiry Date:** January 31, 2015
Documents Reviewed and Approved: UWO Protocol (including instruments noted in section 8.1), Letter of information & consent form & Advertisement
Documents Received for Information:

This is to notify you that The University of Western Ontario Research Ethics Board for Health Sciences Research Involving Human Subjects (HSREB) which is organized and operates according to the Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans and the Health Canada/ICH Good Clinical Practice Practices: Consolidated Guidelines; and the applicable laws and regulations of Ontario has reviewed and granted approval to the above referenced study on the approval date noted above. The membership of this REB also complies with the membership requirements for REB's as defined in Division 5 of the Food and Drug Regulations.

The ethics approval for this study shall remain valid until the expiry date noted above assuming timely and acceptable responses to the HSREB's periodic requests for surveillance and monitoring information. If you require an updated approval notice prior to that time you must request it using the UWO Updated Approval Request Form.

During the course of the research, no deviations from, or changes to, the protocol or consent form may be initiated without prior written approval from the HSREB except when necessary to eliminate immediate hazards to the subject or when the change(s) involve only logistical or administrative aspects of the study (e.g. change of monitor, telephone number). Expedited review of minor change(s) in ongoing studies will be considered. Subjects must receive a copy of the signed information/consent documentation.

Investigators must promptly also report to the HSREB:

a) changes increasing the risk to the participant(s) and/or affecting significantly the conduct of the study;
b) all adverse and unexpected experiences or events that are both serious and unexpected;
c) new information that may adversely affect the safety of the subjects or the conduct of the study.

If these changes/adverse events require a change to the information/consent documentation, and/or recruitment advertisement, the newly revised information/consent documentation, and/or advertisement, must be submitted to this office for approval.

Members of the HSREB who are named as investigators in research studies, or declare a conflict of interest, do not participate in discussion related to, nor vote on, such studies when they are presented to the HSREB.

[redacted]

Chair of HSREB: Dr. Joseph Gilbert
FDA Ref. #: IRB 00000940

Ethics Officer to Contact for Further Information			
☒ Janice Sutherland (jsuther@uwo.ca)	☐ Elizabeth Wambolt (ewambolt@uwo.ca)	☐ Grace Kelly (grace.kelly@uwo.ca)	

This is an official document. Please retain the original in your files.

cc: ORE File

Appendix B: Lawson Health Research Institute Approval

LAWSON HEALTH RESEARCH INSTITUTE

FINAL APPROVAL NOTICE

RESEARCH OFFICE REVIEW NO.: R-11-124

PROJECT TITLE: PREPARE: "Prediabetes Research and Education Promoting Activity & Responsible Eating", a 6-month Prediabetes Lifestyle and Behaviour Change Intervention Program.

PRINCIPAL INVESTIGATOR: Dr. Isabelle Giroux

DATE OF REVIEW BY CRIC: April 5, 2011

Health Sciences REB#: 17755

Please be advised that the above project was reviewed by the Clinical Research Impact Committee and the project:

Was Approved

PLEASE INFORM THE APPROPRIATE NURSING UNITS, LABORATORIES, ETC. BEFORE STARTING THIS PROTOCOL. THE RESEARCH OFFICE NUMBER MUST BE USED WHEN COMMUNICATING WITH THESE AREAS.

Dr. David Hill
V.P. Research
Lawson Health Research Institute

All future correspondence concerning this study should include the Research Office Review Number and should be directed to Sherry Paiva, CRIC Liaison, LHSC, Rm. C210, Nurses Residence, South Street Hospital.

cc: Administration

Appendix C: Brescia Research Ethics Board Approval

Brescia
Choose to Lead.

May 31, 2011

Dear Dr. Giroux,

This letter is to confirm Brescia Research Ethics Board (REB) approval of the protocol, *Prepare: "Prediabetes Research and Education Promoting Activity & Responsible Eating", a 6-month Prediabetes Lifestyle and Behaviour Change Intervention Program,* as approved by the Office of Research Ethics at the University of Western Ontario on February 3, 2011 review number **17755**. The expiry date of the Western approval is January 31, 2015. Please provide a copy of all future correspondence with the Western REB including any revisions or extensions an update to the Brescia REB if applicable.

On behalf of the Brescia REB, we wish you success in your research.

Regards,

[redacted]

Paula DN Dworatzek, PhD RD
Chair, Brescia REB

cc. John B Mitchell, Academic Dean

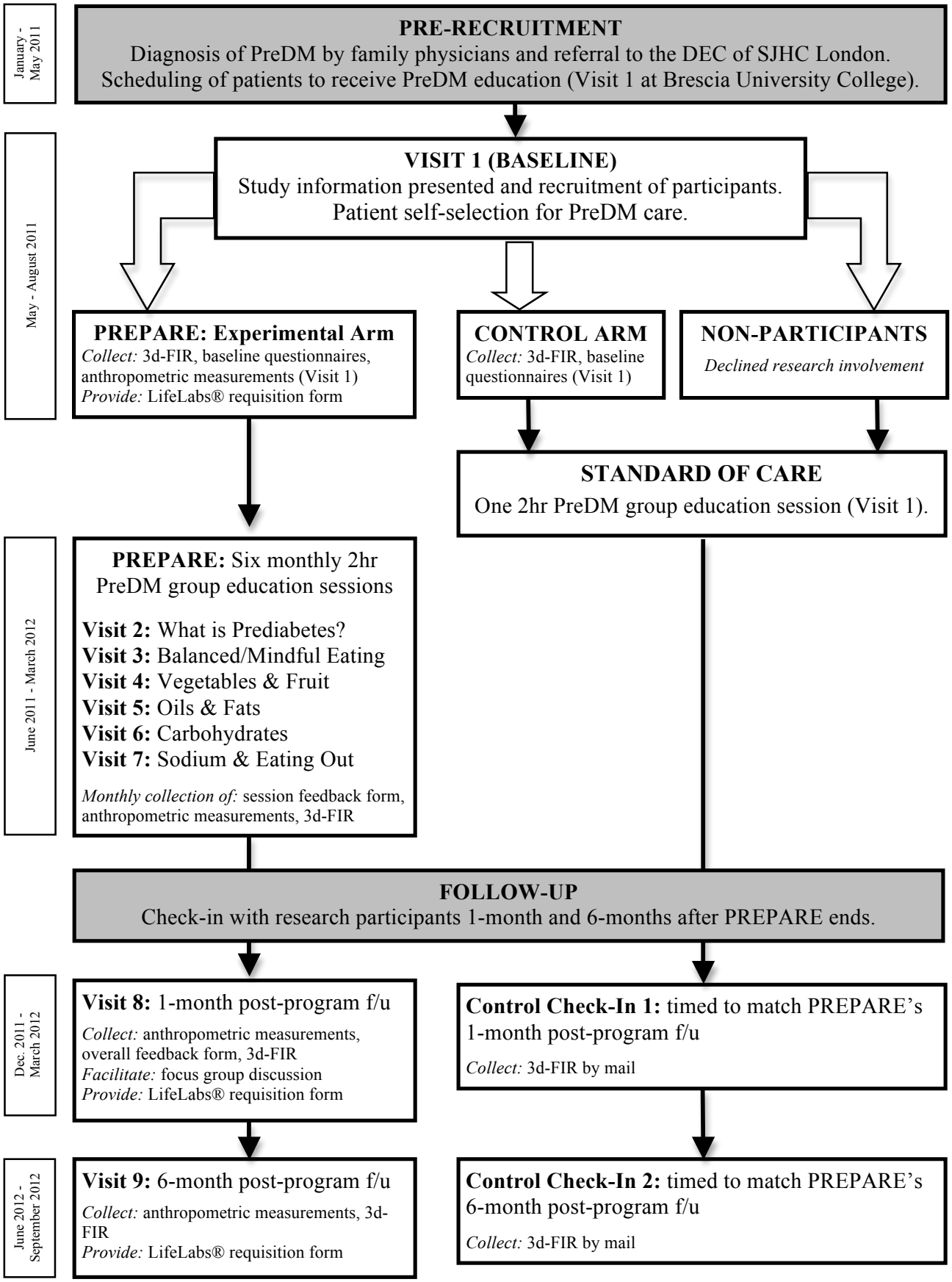
Brescia University College
1285 Western Road
London, Ontario Canada N6G 1H2

Tel: 519.432.8353
Fax: 519.858.5137

www.brescia.uwo.ca

Affiliated with The University of Western Ontario

Appendix D: Flow Chart of the Research Methodology



Appendix E: Diabetes Education Referral Form

Diabetes Education Referral Form

St JOSEPH'S HEALTH CARE LONDON

Phone [redacted] **Diabetes Education Centre** [redacted]

DATE:

Ms/Miss/Mrs/Mr/Dr _____ **D.O.B** Y_____M_____D_____

Address_____Postal Code:_____ **J#**_____

Phone # Home: _____Cell: _____Work: _____**OHC#**_____

Prediabetes ☐ **(FBS** 6.1-6.9 or 2 hr 7.8-11.0) **(All Prediabetic Patients Will Be Seen in Groups)** **PCOS** ☐

***** FBG:** _____ **1 hr.:** _____ **2 hr. :**_____ **HbA1C (if available):**_____ **Date:**_____

Diabetes

New Diagnosis ☐ **Type 1**☐ **Type 2**☐ **Other** ☐

(New Diagnosis: Two Lab tests showing FBS ≥ 7.0 &/or Random BG ≥11.1 or 1 result + acute symptoms, please specify:_____**)**

Established Diabetes ☐ **No. of years:**_____ **or Date:**_____

***** FBG:** _____ **1 hr.:** _____ **2 hr. :**_____ **HbA1C (if available):**_____ **Date:**_____

Creatinine_____ eGFR_____ Alb/Cr Ratio_____ Renal Impairment ☐ Date:_____

Hyperlipidemia: Cholesterol_____ HDL_____ LDL_____ Triglycerides_____ Date:_____

Current Diabetes Medications:

€ **Script: Physician has given patient script for insulin, needles and testing supplies. (Generic prescriptions can be written for insulin e.g. 12 units 'N' insulin at bedtime)**

€ **Insulin Orders:**

____ units of _____insulin at breakfast
____ units of _____insulin at lunch
____ units of _____insulin at supper
____ units of _____insulin at bedtime (before hs snack)
____ units of _____insulin at _____(other)

€ **Adjustment of insulin: (choose one)**

___ Patient to call Referring physician for all insulin adjustment
___ Patient to follow-up with Referring physician AND may be instructed to adjust insulin by 2 units OR 10% for high blood sugars pattern. (Patient will be instructed to adjust based on 3 days pattern of consistent high blood sugars if the patient demonstrates understanding of insulin action and the recognition and treatment of low blood sugar).

€ **Oral Diabetes Medications**

Choose one:
__ No changes to orals once insulin started OR __ Once insulin started, change oral medications as follows:
_____

€ **Blood Sugar Goals (choose one)**

___ Standard Goals: 4-7 mmol/L before meals, 5-10mmol/L 2hr after OR
___ Individualized Goals: ___mmol/L before meals, __ mmol/L 2 hours after

Special Considerations/Blood Sugar Targets: _____

☐ **Please note most patients will be seen in groups unless a barrier is identified. Please circle:**

Vision Hearing Low Literacy Developmentally Delayed Emotionally Challenged
Additional medical/social considerations (e.g. Dialysis) Language Barrier (speaks_____)

Physician Referring:
Name: Address:
Phone #: **FAX #:**
Signature of Referring Physician:

Other Physician Provider

For Office Use Only:
Appointment with **RN**_____ **RD**_____ **Group** _____

(Form Revised 2011/03/15)

Appendix F: Letter of Information and Consent

RESEARCH TITLE

prepare*: "Prediabetes Research and Education Promoting Activity & Responsible Eating"*, a 6-month Prediabetes Lifestyle and Behaviour Change Intervention Program.

MEMBERS OF THE RESEARCH TEAM

- **Dr. Isabelle Giroux**, PhD, RD, **Dr. Paula Dworatzek**, PhD, RD, and **Dr. Danielle Battram**, PhD, Division of Food & Nutritional Sciences, Brescia University College (Brescia), at The University of Western Ontario (UWO)
- **Dr. Irene Hramiak**, MD, FRCP(C), **Pam Colby**, BSc, RD, CDE, and **Janine Mathyssen**, BSc, RD, CDE, Diabetes Education Centre, St. Joseph's Health Care London
- **Jennifer Broxterman,** RD, **Laura Francis** and **Lisa Cianfrini,** MScFN candidates, Brescia
- **Gillian Mandich,** BhSc, Prediabetes Research Project Coordinator, Brescia
- **Other Partners:** The Canadian Diabetes Association – Southwest Ontario Regional Leadership Centre and the Canadian Centre for Activity and Aging at UWO.

BACKGROUND

You are being invited to participate in a research study that assesses the impact of a prediabetes education program on your food choices, physical activity level and blood glucose (sugar) levels.

Please read the following information carefully, feeling free to ask questions to clarify any points or phrases. Please initial each page to confirm that you have read and understand the information. If after reading the below information you wish to participate in this study, please sign the consent form provided.

WHAT ARE MY OPTIONS?

There are three options available to you.

OPTION 1: The first option is to participate in a research intervention called prepare, which stands for Prediabetes Research and Education Promoting Activity and Responsible Eating. This is a 6-month program that consists of monthly nutrition and physical activity education sessions (2 hours per session) and includes interactive hands-on activities to help you gain knowledge and skills to make positive lifestyle choices. It is a pilot study to test the effectiveness of this type of health-care program in individuals with prediabetes. Your consent is required to participate in option 1.

OPTION 2: The second option is to receive the current standard of care for prediabetes, which is a one-time 2-hour group education session. In addition, you will be asked to provide some information at the beginning of the session and 6 months and 1 year later. The information collected will include a short record of your dietary and physical activity habits

and whether or not you have developed Type 2 diabetes. This is also part of the research study and your consent is required to participate in option 2.

OPTION 3: The final option is to receive the current standard of care for prediabetes, which is a one-time 2-hour group education session. You will not receive any further follow-up care or contact after this session. This is not part of the research study and you do not need to fill out the consent form.

Whatever you decide, the choice is up to you. No matter what you decide, it will not affect your ability to receive the current standard of care. You should feel free to discuss your options with your doctor, family members, and friends. The research investigators involved with this study will also be available to answer any questions you have about participating in the program.

WHY IS THIS STUDY BEING DONE?

Type 2 diabetes is a serious and complex disease affecting many Canadians. People with prediabetes are especially at risk of developing Type 2 diabetes. While many factors affect the risk of developing Type 2 diabetes, physical activity and dietary habits are important modifiable factors you can influence to help reduce your risk. We know that education programs aimed at changing eating and physical activity habits and building healthy lifestyle skills can be effective to help reduce the risk for developing Type 2 diabetes.

The purpose of this research study is to gain a better understanding of the effect of a 6-month education program in adults with prediabetes from London (Ontario) to see if it successfully helps individuals make better lifestyle choices, including food choices and physical activity habits. The goal of this research is to determine if this program helps prevent or delay the onset of Type 2 diabetes by improving your food choices and increasing your physical activity, as well as to gather your feedback about the program. It is hypothesized that the education program will better assist individuals to make healthy food choices, increase their physical activity, and may help to prevent the development of Type 2 diabetes. The number of participants in this study is estimated to be 240 individuals with prediabetes.

WHO IS ELIGIBLE FOR THIS STUDY?

Adults 30 years of age and older from the London or surrounding area, who currently have prediabetes diagnosed by a physician, and who have been referred to the Diabetes Education Centre of St. Joseph's Health Care London by a physician are eligible. You must be able to understand English enough to participate in the educational discussions and activities and to fill in required questionnaires. You must not be currently participating in another lifestyle or behaviour change education or research program.

To be eligible, you must be able to perform low impact physical activity. You also must be able to eat a balanced diet based on healthy eating principles. Pregnant or lactating women and patients with Type 1 or Type 2 diabetes, and those who are chair-bound or with low mobility will not be eligible for the current study. Individuals diagnosed with behavioural or psychiatric issues and those with digestive disease are not eligible.

WHAT IS BEING ASKED OF YOU AS A PARTICIPANT?

OPTION 1: Baseline Appointment (Visit 1)
Your baseline appointment at Brescia will require about 2 hours of your time. You will interact with members of the research team in order to complete the following assessments and questionnaires:

- **Screening Questionnaire:** You will be asked to complete a Screening Questionnaire to determine if there are any underlining health conditions that would prevent you from participating in the study. It will take you about 2 minutes to fill this questionnaire. If no underlying conditions exist, you will be invited to continue in the study.
- **Consent Form:** You must sign a Consent Form to participate in this research study. The Consent Form will allow us to reach you by phone or email to remind you to come to scheduled education sessions. We will also send you information by mail, such as a reminder to complete a food intake record to bring at your next visit. Signing the Consent Form will serve as a medical information release through which you allow the Diabetes Education Centre of St. Joseph's Health Care London to contact your doctor in order to share such information as your height, weight, body mass index, blood pressure, blood glucose and blood fat tests to better assist in your care.
- **Demographic Questionnaire:** You will be asked to provide basic information about your age, sex, education level, employment status, etc. This will take about 3 minutes to complete.
- **Lifestyle Questionnaire:** You will be asked to provide basic information about your current lifestyle habits and weight history. This will take about 7 minutes to complete.
- **PAR-Q Questionnaire:** If you have not already completed this short physical activity readiness questionnaire with your doctor, you will be asked to complete it. It will take about 5 minutes to complete. If you answered "yes" to any of the questions on this questionnaire, you will be required to visit your doctor and obtain his/her consent to participate in this study.
- **Physical Activity Questionnaire**: You will be asked to complete a short questionnaire to determine your current physical activity level, which will take about 10 minutes.
- **Lifestyle Beliefs Questionnaire**: You will be asked to complete a survey about your intentions and beliefs towards physical activity, eating, and making changes to your lifestyle habits. This questionnaire will take about 20 minutes to complete.
- **Physical Measurements:** You will have your height, weight, waist circumference and blood pressure measured by trained staff. This will take about 12 minutes to complete.
- **3-Day Food Intake Record and Medication Log:** After you contacted the Diabetes Education Centre and booked the visit for today, you received a 3-Day Food Intake Record and Medication Log by mail to complete at home. This form asks you to record all beverages, foods, and supplements consumed and all medications taken on 2 week days and 1 weekend day, and it takes about 12 minutes to complete per day. We will ask you to give us that form and we will go over it with you. This will take 1 to 5 minutes.

During your baseline visit, we will give you the following forms to complete and bring back at your second visit a month later. We will also give you information about doing blood tests.

- **3-Day Food Intake Record and Medication Log**: You will be asked to complete this log for the week prior to your next visit.
- **7-Day Physical Activity and Step Log:** You will be asked to complete a physical activity log for 1 week following the baseline assessment. This log will require you to record all physical activity for the one week prior to each session and includes you recording all your steps taken with a pedometer. This will take about 1 minute to complete each day and can be filled out at home.
- **Laboratory Blood Tests:** You will be asked to visit a London location of LifeLabs® Medical Laboratories Services for your baseline blood tests within the two weeks following your baseline assessment. In order to make sure that each test we do is similar throughout the study, we will need you to: 1) refrain from consuming alcohol and caffeine 48 hours prior to the test, 2) avoid physical activity 24 hours prior to the test and 3) be fasted (no eating, but water is allowed) 12 hours prior to reporting to the laboratory. At the laboratory, the following three tests will be performed at the same visit and the cost will be covered by the researchers:
    - **Blood Sugar Testing:** This test, called the Oral Glucose Tolerance Test (OGTT), lasts about 2.5 hours in length. Blood samples will be collected from a very small needle placed into a vein in your arm 2 times during the procedure (at the beginning and two hours later). The total amount of blood collected will be 13 milliliters or a little less than a tablespoon, which is far less than what would be taken if you donated blood. This test allows researchers to see how your blood sugar levels are affected in the 2 hours following the consumption of a sugary drink.
    - **Blood Lipid Profile:** This test will use some of the blood taken during the OGTT to measure the different levels of healthy and unhealthy fats, including cholesterol, in your blood.
    - **Hemoglobin test (HbA1c):** This test will also use some of the blood taken during the OGTT to measure your average plasma blood sugar level within the past 3 months.

OPTION 1: Visits 2-7 at Months 2 to 7 (Six Monthly Nutrition & Physical Activity Education Sessions)

For six months, you will be asked to attend a monthly 2-hour education session at Brescia, lead by a team of specialists. They will present education material in a variety of ways, including Powerpoint presentations and hands on activities designed to help you make informed decisions about your lifestyle. These group education sessions are meant to be interactive with food demonstrations and physical activity components. A Registered Dietitian will be present at each session to answer any questions you may have about dietary and lifestyle changes. Some graduate and undergraduate student trainees will be there to assist with the sessions. At the education sessions, the research team will collect the following from you:

- **Physical Measurements:** weight, waist circumference, and blood pressure
- **7-Day Physical Activity and Step Log**
- **3-Day Food Intake Record and Medication Log**

- **Type 2 Diabetes Status:** You will be asked if you have been diagnosed with Type 2 diabetes by your doctor (yes or no). This will take less than 1 minute to complete.
- **Lifestyle Goal Setting Log:** You will be asked to formulate a monthly goal to help improve your health. It will take about 5 minutes to formulate a new goal each month and to review your previously set goals.
- **Session Feedback Form:** You will be asked to complete a short questionnaire providing feedback on the education program you receive each month. This will take about 4 minutes to complete and will be collected at every visit.
- **Lifestyle Beliefs Questionnaire** and **Physical Activity Questionnaire:** at Visit 5 only

In addition to the education sessions, you will be invited to attend optional monthly cooking workshops (on some Thursday evenings from 6 to 8 PM) and a weekly walking program (Mondays or Wednesdays from 6:15 to 7:15 PM or Saturdays from 9:30 to 10:30 AM).

OPTION 1: Visit 8 (Post-Intervention Follow-Up)
Following the completion of the six months of educational sessions, you will be asked to return for a follow-up visit lasting 2 hours in length at Brescia to reevaluate a number of items that were collected at your baseline appointment. These include the **3-Day Food Intake Record and Medication Log**, **Physical Measurements**, **Type 2 Diabetes Status**, **7-Day Physical Activity and Step Log**, **Lifestyle Goal Setting Sheet**, **Lifestyle Beliefs Questionnaire**, **Physical Activity Questionnaire** and **Laboratory Blood Tests**.

In addition, you will be asked to complete a **Program Feedback Form**. This form will ask your feedback on the whole program and your suggestions for the future. This form will take you about 15 minutes to complete. Finally, you will be asked to partake in **Focus Groups**. These focus groups will take about 1 hour of your time and be scheduled with a small group of individuals who were also part of the program. A moderator will ask you to respond to open-ended questions concerning the prediabetes education program and to share your feedback and suggestions. The focus groups will take place at Brescia and will be audio-recorded to allow our researchers to transcribe and compile all feedback. Although complete confidentiality cannot be guaranteed, we will ask all participants to keep the discussions of the focus group private and not to discuss its contents beyond the session.

OPTION 1: Visit 9 (6-month Follow-Up)
Six months after you complete the program, you will be asked to return to Brescia for your final follow-up visit lasting 2 hours in length to reassess the items that were collected at your post-intervention visit. These include the **3-Day Food Intake Record and Medication Log**, **Physical Measurements**, **Type 2 Diabetes Status**, **7-Day Physical Activity and Step Log**, **Lifestyle Goal Setting Sheet**, **Lifestyle Beliefs Questionnaire**, **Physical Activity Questionnaire** and **Laboratory Blood Tests**.

OPTION 2: Baseline Appointment (Visit 1)
If you decide not to participate in Option 1 (the 6-month program of nutrition and physical activity education explained above), you may choose to be involved with the research study by selecting Option 2. If you consent to Option 2, you would not be required to complete the blood tests or attend the 6 months of educational sessions. You will only be asked to provide

the following at your baseline appointment prior to attending the 2-hour standard of care education session for prediabetes.

- **Screening Questionnaire** (about 2 minutes) and **Consent Form**
- **3-Day Food Intake Record and Medication Log** (12 minutes/day x 3 days)
- **Demographic Questionnaire** (about 3 minutes)
- **Lifestyle Questionnaire** (about 7 minutes)
- **Physical Activity Questionnaire** (about 10 minutes)
- **Lifestyle Beliefs Questionnaire** (about 20 minutes)

OPTION 2: Follow-Up Six and Twelve Months Later

Approximately 6 months and 12 months after your baseline assessment and 2-hour standard of care education session, you will receive a 2-minute phone call to ask you one question, if you have been diagnosed with Type 2 diabetes by your doctor (yes or no). You will also receive a package in the mail containing all the questionnaires you completed at baseline (with the exception of the screening and demographic questionnaires) listed above. If all questionnaires are completed and returned to us each time, you will receive a $10 grocery store gift certificate ask a token of our appreciation.

WHEN DO THE VISITS TAKE PLACE?

All sessions will be held at Brescia on Thursday evenings (6-8 pm) or Friday afternoons (2-4 pm). Each month you have the option to choose which session works best for you.

We will contact you by phone or email, as you prefer, two days before each visit to remind you of your upcoming visit. This will take only 1 minute.

ARE THERE ANY RISKS TO YOU BY PARTICIPATING IN THE RESEARCH?

There may be some risk for your participation in this study.

- **Laboratory Blood Tests:** Blood testing will require a very small needle to be placed in an arm vein, which is a very common medical procedure that involves few risks. There is a slight risk of infection at the puncture site. There may be some initial discomfort. There may be some minor bruising at the puncture site. On very rare occasions, there is a slight risk of a small blood clot forming, which normally dissolves within 12 hours. To minimize these risks, only experienced personnel from LifeLabs®, a reputable company with experienced and certified staff, will perform the procedure using clean technique (e.g. wearing gloves, using alcohol swabs).
- **Dietary Recommendations:** There is no known risk to consuming healthy foods (such as vegetables and fruit) in individuals with prediabetes who do not have other significant medical issues (e.g. kidney disease). Please speak with the research team if your doctor or any other healthcare provider has discussed any special dietary considerations with you related to a health condition. All dietary recommendations will be reviewed and monitored by Registered Dietitians and Certified Diabetes Educators who are involved with this study.
- **Physical Activity:** While our physical activity sessions are of low intensity, there are risks to beginning any physical activity program. To minimize this, we ask that if you answer "yes" to any question on the PAR-Q, that you consult your physician and

get his/her approval before partaking in the program. Also, we are using experienced and qualified exercise physiologists to lead the physical activity sessions and they will guide you in modifications during the physical activity sessions if needed. Finally, all weekly walking program staff will be CPR certified.

- **Physical Measurements:** There are no known risks to collecting your height, weight, waist circumference, and blood pressure. The measurements will be taken in a way to respect your privacy with only yourself and the researcher present. Furthermore, measurements will be taken with your clothes on. If at any time you are uncomfortable during the measurements, let the study investigators know.
- **Questionnaires:** There are no known risks to filling out the questionnaires for this study.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

You will not be paid for taking part in this study. There will be no direct cost to you for being involved with this study. Parking will be provided free of charge when you attend the educational sessions at Brescia. The cost of all requested blood tests is provided by the researchers.

YOUR RIGHTS

Participation in this study is voluntary. You may refuse to participate, refuse to answer any questions or withdraw from the study at any time with no effect on your future care.

You do not waive any legal rights by signing the consent form.

WHAT ABOUT CONFIDENTIALITY?

Maintaining your confidentiality and privacy is our utmost priority. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. The following measures have been taken to keep your identity and information, as well as all questionnaires, confidential and secure. To protect the confidentiality of the data we collect from you, your name will be coded with a participant identification number at all points throughout the study. This number will appear on all documents pertaining to you. Records of your study participation will be locked and kept in a confidential file at Brescia. The master list linking participants to unique identification codes will be stored separately from the questionnaires and other research data in a locked filing cabinet in a locked office at Brescia and will be accessible only by the Principal Investigator and the Research Project Coordinator. The confidentiality of any computer records will also be carefully guarded by security measures (e.g. password protected files and encryption when necessary). Your research records will include your medical history, medications, results from your blood work, physical measurements collected during the study (i.e. weight, blood pressure, etc.), food intake records, physical activity records, and answers you provide to other questionnaires administered during the study.

Research data will be retained for 5 years after the study results have been published and will be destroyed at the end of that time. All computer data will be erased and all paper data will be shredded. When the results of the study are published, your name and personal information will not appear within any of the reports.

Tapes with information audio-recorded during the focus group will not include names and will be kept in the locked filing cabinet in the locked office of our research coordinator. The transcribed text from the focus group discussions will not include the name of participants.

You have the right to withdraw from the study at any time. In addition, if you chose to leave the study, you may choose to have the data we have collected from you excluded from the study. However, if you complete the study and the results are published in a scientific journal, we cannot allow your data to be withdrawn at a later date. If the research study results are published, none of your personal information will be identified. This is to ensure that no one will be able to tell that you took part in the research study. If you wish, you will be able to take a look at the main research study results posted on the following internet page when the study is completed:

Please be aware that Representatives of The University of Western Ontario Health Sciences Research Ethics Board may contact you or require access to your study-related records to monitor the conduct of the research. However, no information by which you may be identified will be released or published.

ARE THERE ANY BENEFITS TO YOU BY PARTICIPATING IN THIS RESEARCH?

There may or may not be direct medical benefit to you for participating in this study. Your participation in this study will allow you to have access to six months of free education sessions offered by a team of specialists in nutrition and physical activity. It is possible that you may find that you are better able to make informed decisions about your lifestyle, including healthy food choices and physical activity. Throughout this study you will receive guidance about how to improve your dietary intake and will be given opportunities to partake in physical activity. You will be provided with resources and opportunities to build skills to help you improve your diet and move toward a healthier lifestyle. The guidance provided to you by study personnel will be personally relevant as the program includes many activities in which you can reflect on your eating patterns and personal life environments. This may lead to positive lifestyle changes that have been shown to reduce the risk of developing Type 2 diabetes.

OTHER INFORMATION

You will receive a one year membership to the Canadian Diabetes Association ($30 value) after Visit 9 follow-up and blood testing. You will also receive a pedometer at Visit 1 ($10 value). Furthermore, they will be offered a small gift at Visits 2 to 7 (about $5 value), such as a water bottle, measuring cups, a healthy recipe calendar, a pass for an exercise class at the Canadian Centre for Activity and Aging at UWO or GoodLife Fitness Clubs, etc. You will also be given the option to attend free monthly cooking workshops at Brescia during months 2 to 7, and/or the option to join our free weekly walking club during those months. Lastly, focus group participants will receive a cookbook to thank them for providing feedback on the program.

WHO CAN ANSWER QUESTIONS ABOUT THE STUDY?

You can speak with the Principle Investigator, Dr. Isabelle Giroux, if you have any questions or concerns about the study. She can be reached at:

Dr. Isabelle Giroux, PhD, RD **Email:** **Tel:** 519-XXX-XXXX ext. XXXXX

If you have any questions about your rights as a research participant or the conduct of the study, you may contact Dr. David Hill, Scientific Director, Lawson Health Research Institute at (519) XXX-XXXX. You can also contact the Office of Research Ethics (University of Western Ontario), at ethics@uwo.ca or (519) XXX-XXXX.

This letter is yours to keep.

Consent Form

prepare*: "Prediabetes Research and Education Promoting Activity & Responsible Eating"*, a 6-month Prediabetes Lifestyle and Behaviour Change Intervention Program.

I have read the letter of information, have had the nature of the study explained to me and agree to participate. All questions have been answered to my satisfaction.

Please check ONE of the following options:

☐ I consent to **OPTION 1** of the research study as outlined in the letter of information (includes 6 months of nutrition and physical activity education) and for my data to be shared with the Diabetes Education Centre of St. Joseph's Health Care London and my family physician.

Initials_____

☐ I consent to **OPTION 2** of the research study as outlined in the letter of information (does not include the 6 months of nutrition and physical activity education) and for my data to be shared with the Diabetes Education Centre of St. Joseph's Health Care London and my family physician.

Initials_____

Name of participant (please print):

Signature:_____ Date:_____

Person obtaining consent (please print):

Signature:_____ Date:_____

Participant Contact Information

Name of participant (please print): _____

Participant's phone number:_____
Area Code *Phone Number*

Participant's e-mail:_____

Participant's address:_____
Street *Postal Code*

Name of doctor:_____

Appendix G: Screening Questionnaire

PREPARE Screening Questionnaire

PART A: Please read the following statements to see if you are eligible to participate in this research study.

Eligibility Criteria	Check One	
1. I am 30 years of age or older.	☐ Yes	☐ No
2. My doctor or other healthcare provider has told me that I have prediabetes.	☐ Yes	☐ No
3. I am able to attend educational presentations at Brescia University College (at The University of Western Ontario) on either Thursday evenings (6-8 pm) or Friday afternoons (2-4 pm) once per month for six months.	☐ Yes	☐ No
4. I am able to stand up without support for at least 30 seconds.	☐ Yes	☐ No
5. I am able to chew and swallow my food with little difficultly and can eat a balanced diet.	☐ Yes	☐ No
6. I am able to safely engage in low impact physical activity, such as walking and stretching.	☐ Yes	☐ No
7. I am able to fill out written questionnaires about my health and behaviours.	☐ Yes	☐ No
8. I am currently taking part in another lifestyle education program or research study.	☐ Yes	☐ No
9. I am currently pregnant or lactating (breastfeeding).	☐ Yes	☐ No
10. I have Type 1 or Type 2 Diabetes.	☐ Yes	☐ No
11. I have a digestive disease (e.g. Crohn's disease, celiac disease, etc).	☐ Yes	☐ No
12. I have a diagnosed mental illness (e.g. major depression, anorexia nervosa, binge eating disorder, schizophrenia, etc).	☐ Yes	☐ No
Administrative Use Only: Any boxes checked that are shaded in grey exclude participant from research study. Deemed ☐ **ELIGIBLE** ☐ **NOT ELIGIBLE** to participate in PREPARE. Initials:_____		

PART B: I acknowledge the information provided is accurate to the best of my ability.

Participant Signature:_____

Date:_____
day/month/year

PART C: Complete only if you are ineligible or are not interested in participating. Check all reasons that apply.

- ☐ Did not meet the study's eligibility criteria (see Part A)
- ☐ Not interested
- ☐ Time constraints / too busy
- ☐ Financial constraints
- ☐ Location was not accessible to me
- ☐ Receiving education & care elsewhere
- ☐ Not available on the days/times program was offered
- ☐ Other (please specify):_____

Appendix H: Letter to Family Physicians

Dear [Family Physician]:

The *Prediabetes Initiative and Partnership* is excited to inform you that we have expanded and renamed our prediabetes education program, now called **prepare***: **P**rediabetes **R**esearch and **E**ducation **P**romoting **A**ctivity and **R**esponsible **E**ating.*

The partnership has also grown to include:

- Brescia University College, Division of Food & Nutritional Sciences
- The Diabetes Education Centre (DEC), St. Joseph's Health Care London
- The Canadian Diabetes Association, Southwest Ontario Regional Leadership Centre
- The Canadian Centre for Activity and Aging, The University of Western Ontario

prepare is a community-based, healthy lifestyle research project targeting middle and older adults with prediabetes. This program emphasizes goal-setting and self-management approaches to engage and support patients in making positive lifestyle changes to prevent or delay the development of Type 2 diabetes. All education will be based on the most recent clinical practice guidelines for prediabetes.

Program Highlights	Eligibility Criteria
• 6 months of free interdisciplinary nutrition and physical activity education and hands-on activities (2 hours per session) • Ongoing monitoring of weight, waist circumference, blood pressure, HbA1c, fasting BG (OGTT), and blood lipid profile • Use of a lifestyle log to help formulate realistic goals and increase self-management • Access to drop-in periods with a Registered Dietitian • Free pedometer to record daily steps • Free 1 yr membership to the Canadian Diabetes Association • Free monthly cooking workshops • Free walking club • Small incentives throughout the program, including: water bottle, healthy recipe calendar, exercise class passes (i.e. Goodlife Fitness Club, Canadian Centre for Activity and Aging at Western), measuring cups, and a cookbook • Participants may bring significant others/family members to each education session free of charge	• 30 years of age or older • Diagnosis of prediabetes • Ability to eat a normal diet • Ability to stand and engage in low-impact physical activity (i.e. walking) • Ability to complete written questionnaires in English • Not pregnant or breastfeeding • No diagnosis of: o Type 1 or Type 2 diabetes o Mental illness (e.g. major depression, binge eating disorder, schizophrenia) o Digestive disorder (e.g. Crohn's disease)

The program flowchart can be found on the back of this letter. Please inform all patients you diagnose with prediabetes about this intervention program and ask them to contact the DEC to book their first session if interested. Those patients who are not eligible or do not wish to participate in research are still invited to the current standard of care (via the DEC). With

your support, we are excited to expand **prepare** to assist a larger number of individuals with prediabetes make healthy lifestyle changes to help prevent or delay Type 2 diabetes. Please do not hesitate to contact the DEC or Dr. Isabelle Giroux (Principal Investigator) if you have any questions.

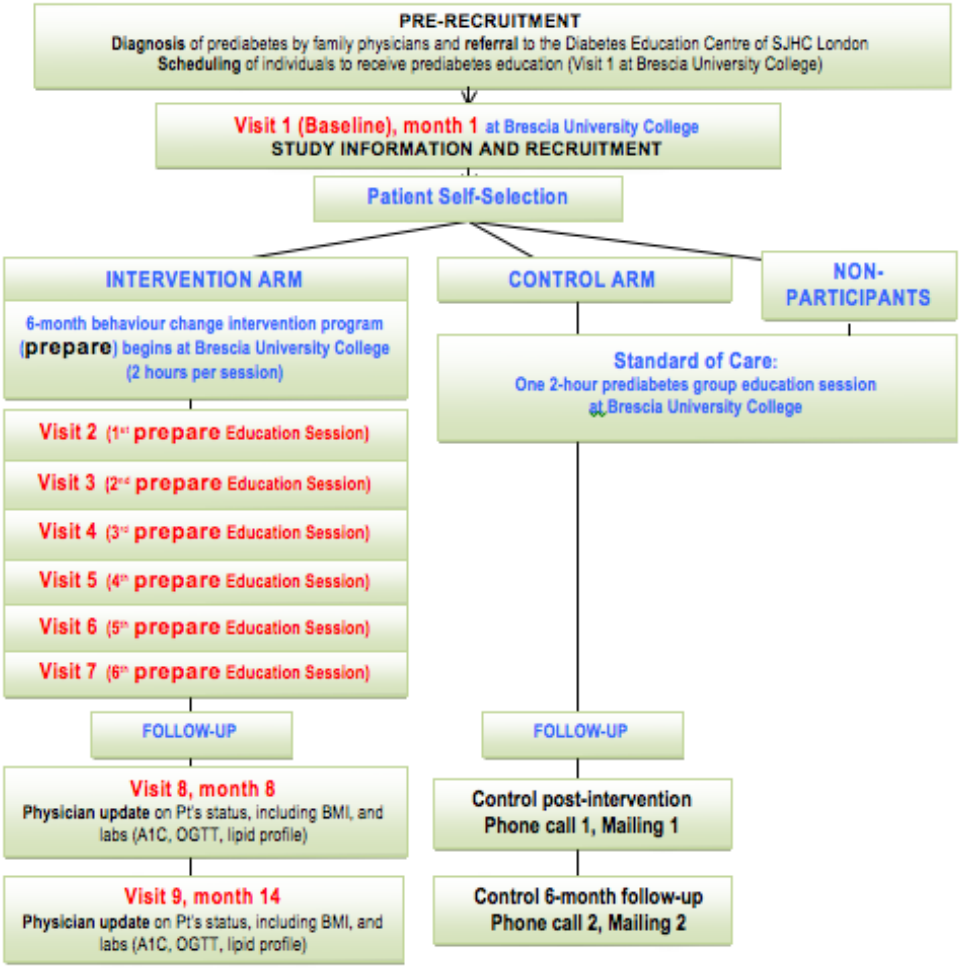
For more information, visit our website: **http://www.brescia.uwo.ca/prediabetes_initiative**

Sincerely,

Dr. Irene Hramiak, MD, FRCP(C)
Chair, Division of Endocrinology & Metabolism
St. Joseph's Health Care London
Diabetes Education Centre: 519-XXX-XXXX

Dr. Isabelle Giroux, PhD, RD, PHEc
Associate Professor and Prediabetes Coordinator
Division of Food & Nutritional Sciences
Brescia University College: 519-XXX-XXXX

Enclosed: prepare Brochure, Poster, Physician's Referral Form, and PAR-Q & You



Appendix I: Recruitment Poster

prepare

for a healthy lifestyle

Prediabetes Research and Education
Promoting Activity & Responsible Eating

Are you...

- 30 years or older?
- from the London area?
- diagnosed with **prediabetes** by a physician?

If you answered "**yes**" to all 3 questions, you are invited to participate in either:

One standard information session

OR

The **prepare** program which is designed to assist individuals with prediabetes in making positive lifestyle changes to help delay or prevent the development of diabetes.

If you want more information, please use the tear offs below to contact us

Research Partners: Brescia University College – Choose to Lead. · St. Joseph's Health Care London · Canadian Diabetes Association · Canadian Centre for Activity and Aging – from research to action

Funding Provided By: The Lawson Foundation

prepare Prediabetes Program
Talk to your doctor and then call
519-661-1600 to book an appointment

Appendix J: Recruitment Brochure

Am I eligible to participate?

Are you...

- 30 years or older?
- from London or the surrounding area?
- diagnosed with prediabetes by a physician?

If you answered "**yes**" to all 3 of these questions , you are invited to participate in the **prepare** program.

How do I sign up for the program?

Contact the Diabetes Education Centre of St. Joseph's Health Care London to register for the next prediabetes education session at **519-661-1600**

Our Partners

Brescia University College

The Diabetes Education Centre of St. Joseph's Health Care London

The Canadian Diabetes Association—Southwest Ontario Regional Leadership Centre

The Canadian Centre for Activity and Aging at The University of Western Ontario

This program is funded by The Lawson Foundation

prepare for a healthy lifestyle

Prediabetes Research and Education Promoting Activity & Responsible Eating

THE PREDIABETES INITIATIVE AND PARTNERSHIP

AN EDUCATION PROGRAM FOR ADULTS WITH PREDIABETES FROM LONDON AND AREA

Starts Early 2011

What happens if I want to participate?

I can choose **either**:

One standard information session

OR

prepare, an expanded intervention program that includes:

- A baseline information session and assessment (month 1).
- Six monthly education sessions emphasizing development of self-management skills (during 2nd to 7th month). Sessions are offered Friday afternoons or Thursday evenings at Brescia University College.
- A post-assessment (8th month).
- A 6-month follow-up after the education sessions (14th month)

prepare for a healthy lifestyle

prepare for a healthy lifestyle

Prediabetes Research and Education Promoting Activity & Responsible Eating

The **prepare** program is designed to assist individuals with prediabetes in making positive lifestyle changes to help them to delay or prevent the development of diabetes.

In addition to participating in the **prepare** program you will be provided with:

- A pedometer
- A self-management toolkit
- Access to drop-in support and monitoring periods
- Optional cooking workshops
- An optional walking program
- A one year membership to the Canadian Diabetes Association
- Access to free parking at Brescia University College

Where is the program offered?

Brescia University College
at The University of Western Ontario
1285 Western Road
London, Ontario, Canada
N6G 1H2

Who can I contact if I have questions?

There is more information on our website: **http://www.brescia.uwo.ca/prediabetes_initiative**

OR

you can contact Gillian Mandich, Project Coordinator at 519-432-8353 ext.28034
Email: gmandich@uwo.ca

prepare for a healthy lifestyle

Appendix K: Phone Script for Clients at Baseline

Patient's Name:_____Subject Code: _____

Phone Script for Clients at Baseline
All Potentially Eligible Participants (Reminder about Visit 1)

Hello, my name is _____ (graduate student/work study student part of the PREPARE research team), and I am calling on behalf of the Diabetes Education Centre of St. Joseph's Health Care London. May I please speak with (patient's name)?

The reason for my call is to remind you of your first prediabetes appointment, which will be held at Brescia University College on _____(date of appointment, i.e. Friday January 28, 2011) from (state timeframe, i.e. 2:00-4:00pm).

You should have received a letter in the mail from us, providing further details about what to wear and what you should bring with you to your first appointment. Did you receive this letter yet?

IF PATIENT ANSWERS YES:
That's great! In the letter you may have seen that we are asking you to please complete the 3-day Food Intake Record and Medication Log provided with your letter and to do so prior to your appointment. When completing a 3-day Food Intake Record, it is really important to pick days that are **typical** of your current eating patterns and provide as much detail as possible. For example, the exact portion sizes and brand names. Do you have any questions about filling out that form at the present time?

If yes, answer questions.
If no, proceed to below.

Just as a final note, the information you provide in this food intake record is crucial for your participation in the PREPARAE program if you would like to participate. It will allow us to assess your current eating habits and provide you with specific feedback on the areas of your diet that might need some improvements. In addition, we will be using these records throughout the program as an education tool, so it is really important to fill them out as accurately as possible. Unfortunately, without this information, we cannot provide you with the best experience in the prepare program and therefore cannot invite you to participate in the program. Hopefully this gives you an incentive to get it completed before we see you on the (date of appointment, i.e. Friday, January 28, 2011), from (state time frame, i.e. 2:00-4:00 PM).

Do you have any questions for me at the present time?
If yes, answer questions.

If no, proceed to closing remarks.

IF PATIENT ANSWERS NO:

Oh okay. Would it be okay if I sent you the letter now?

If yes, see below.

If no, ask if there is a better time to send the information.

How would you like to receive the letter? I can send it by mail or email.
Record method here: mailing address or email address.

In the meantime while you are waiting for your letter, please let me fill you in on some of the important details of the letter.

- Again, your appointment date is:_____ from _____(time)_____.
- If you need to reschedule your appointment for any reason, please call in advance. The number to call is 519-XXX-XXXX.
- The location is at Brescia University College in the St. James Building in Room 135. Brescia is located at 1285 Western Road in London.
- For your appointment, we ask that you wear light comfortable clothing. We will be recording your weight, height, waist circumference, and blood pressure.
- If you wish, you are most welcome to bring a friend, family member, spouse, and/or partner for support.
- Finally, the letter provides you with the opportunity to participate in the PREPARE research study. We are asking all of those interested to please complete the 3-day Food Intake Record and Medication Log prior to coming to your appointment. When completing a 3-day Food Intake Record, it is really important to pick days that are **typical** of your current eating patterns and provide as much detail as possible. For example, the exact portion sizes and brand names. The information you provide in this food intake record is crucial for your participation in the PREPARE program if you would like to participate. It will allow us to assess your current eating habits and provide you with specific feedback on the areas of your diet that might need some improvements. In addition, we will be using these records throughout the program as an education tool, so it is really important to fill them out as accurately as possible. Unfortunately, without this information, we cannot provide you with the best experience in the PREPARE program and therefore cannot invite you to participate in the program. Hopefully this gives you an incentive to get it completed before we see you on the (date of appointment, i.e. Friday, January 7, 2011), from (state time frame, i.e. 2:00-4:00 PM).

Do you have any questions for me at the present time?

If yes, answer questions.

If no, proceed to closing remarks.

SAME CLOSING REMARKS FOR EVERYONE:
Thank you very much for talking with me today and for your interest in receiving education for your prediabetes. We look forward to seeing you soon at your first appointment. Take care.

IMPORTANT: If the patient is not home, please do not leave any information with other members of the household or on voice meal. Kindly ask the household member when the patient can be reached and thank them for their assistance.

For the Graduate Student/Work Study Student to Complete:

Date of Call	Time of Call	Outcome / Notes
1.		
2.		
3.		
4.		

Jennifer Broxterman, RD, MSc candidate (or other graduate student/work study student) to read the questionnaire verbatim and clarify as indicated.

Appendix L: Letter to Clients Scheduled for Baseline Visit

Letter to Clients Scheduled for Baseline Visit

Date

Dear [participant's name],

Thank you for booking your appointment to receive prediabetes education with the Diabetes Education Centre (DEC) of St. Joseph's Health Care London. This letter is to inform you of three options available to you upon your arrival:

6 monthly education sessions
(6 x 2-hour session)

Option #1. prepare: ***P****rediabetes* ***R****esearch and* ***E****ducation* ***P****romoting* ***A****ctivity &* ***R****esponsible* ***E****ating*

- A 6-month program consisting of monthly nutrition and physical activity education sessions (2 hours/session) that includes hands-on activities (i.e. food & exercise demonstrations)
- Ongoing monitoring of your weight, waist circumference, blood pressure, HbA1c, fasting blood sugars and lipids
- Optional cooking classes
- Optional walking group
- Access to a free drop-in clinic with a Registered Dietitian
- prepare is an optional research study (your consent is required)

1 education session
(1 x 2-hour session)

Option #2. Standard Presentation with Some Follow-Up:

- A one-time 2-hr group education session
- A follow-up phone call and mailing at 6 months and 1 year later to follow-up on your health
- This is part of an optional research study (your consent is required)

OR

Option #3. Standard Presentation without Follow-Up:

- A one-time 2-hr group education session
- This is not part of the optional research study and is the current option for patients with Prediabetes in London, ON

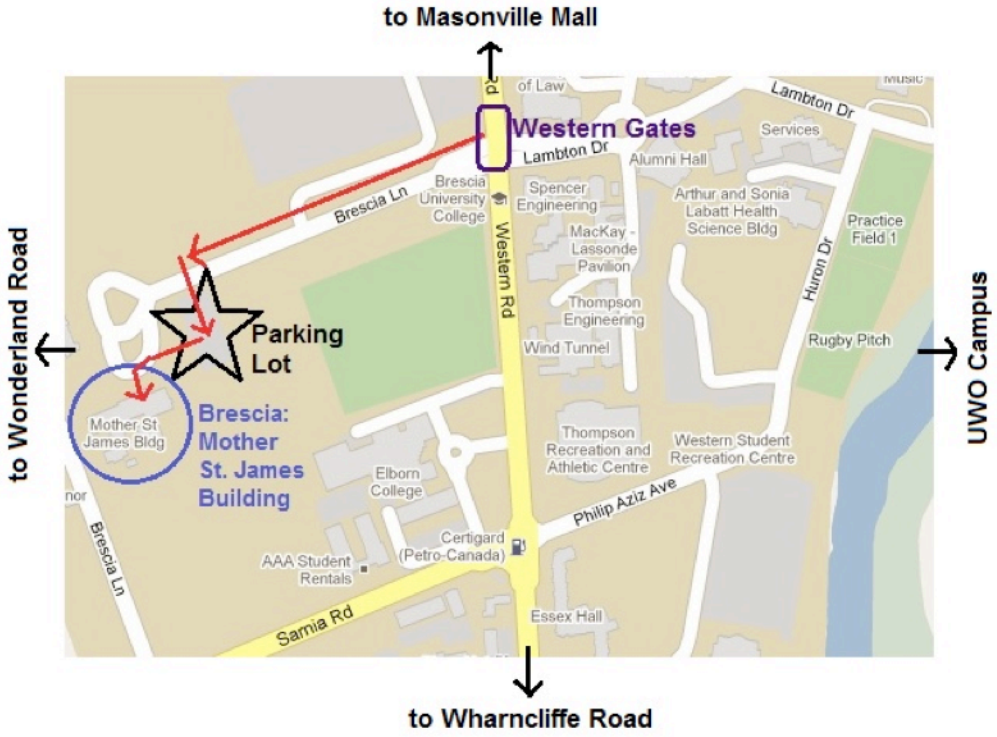
If you are interested in participating in option 1 or 2 (as part of the research study), please read the **Letter of Information** and bring with you the signed **Consent Form**. Regardless of your choice, please fill out and bring the enclosed **3-Day Food Intake Record and Medication Log**, which will be reviewed with all individuals for educational purposes at your visit.

Whatever you decide, you will still receive free nutrition and physical activity education and assistance to help improve your health and manage your prediabetes. Please note all education sessions take place at Brescia University College. Thank you, and we look forward to seeing you soon.

Sincerely,

Dr. Irene Hramiak, MD, FRCP(C)
Chair, Division of Endocrinology & Metabolism
St. Joseph's Health Care London

Dr. Isabelle Giroux, PhD, RD, PHEc
Associate Professor and Prediabetes Coordinator
Division of Food & Nutritional Sciences
Brescia University College

Prediabetes Education Session at Brescia University College	
Date & Time	**e.g. Friday, January 7, 2011 2:00 - 4:00 PM**
Location & Parking	**Brescia University College, St. James Building, Room 135** [redacted] ***Parking:*** *Please park in the lower parking lot (indicated with a star on the map) and display the parking pass enclosed.* 
Telephone	[redacted] (please call in advance if you need to reschedule)
Website	http://www.brescia.uwo.ca/prediabetes_initiative
What to Wear	**Light, comfortable clothing** that will allow you to be easily weighed, have your waist circumference measured, your height collected, and blood pressured taken.
What to Bring	• **Completed 3-Day Food Intake Record and Medication Log:** – Please include all beverages and foods consumed on 2 week days and 1 weekend day. Select days **TYPICAL** for your current eating patterns. – Please record all medications and supplements you are currently taking. – This form will take about 12 minutes to complete per day. • A list of your medications (from the pharmacy) and supplements **OR** pill bottles. • Signed Consent Form IF you are interested in participating in option 1 or 2.
Optional	You can bring a friend, family member, spouse, and/or partner for support

Appendix M: 3-Day Food Intake Record and Medication Log

3-Day Food Intake Record & Medication/Supplement Log

Please keep a record of *everything* you **EAT** and **DRINK** for **3 days**; 2 week days and one weekend day. Include all meals, snacks, and beverages, and the time of day you are eating or drinking. **Please pick days that are TYPICAL for your current eating patterns.**

Please also record your **MEDICATION and SUPPLEMENT schedule** in detail, including: the **name of the drug or supplement**, the **amount** you take, **how often** you take it, **when you started/stopped** the medication or supplement, and **your reason for taking it**.

The purpose of filling out these food and medication records is to help better understand **WHAT** you are eating, **WHEN** you are eating, and **HOW MUCH** you are eating. It also helps the healthcare team understand the role that medications and supplements play in helping you to manage your health conditions. Please be as honest and accurate as you can, as the information you provide will help you better reflect on your eating habits.

FOOD/BEVERAGE RECORDING INSTRUCTIONS:

1. Record all food and beverages consumed during a 24 hour period. Provide the following:

- **Type of Food Eaten:** e.g. chicken noodle soup
- **Brand Name:** e.g. Campbell's, Lipton, Weight Watchers
- **Food or Beverage Characteristics:**
  - **Colour:** e.g. green vs. yellow beans; white vs. whole wheat bread
  - **Fat Content:** % fat (e.g. skim, 1%, 2% or homo milk), leanness of meat (e.g. extra lean ground beef), fat claims (e.g. "light", "low-fat"), was skin removed from poultry?
  - **Freshness:** e.g. fresh, frozen, canned, or dried?
  - **Other Details:** e.g. 25% reduced sodium, "diet" products, etc.
- **Time of Day** you ate or drank

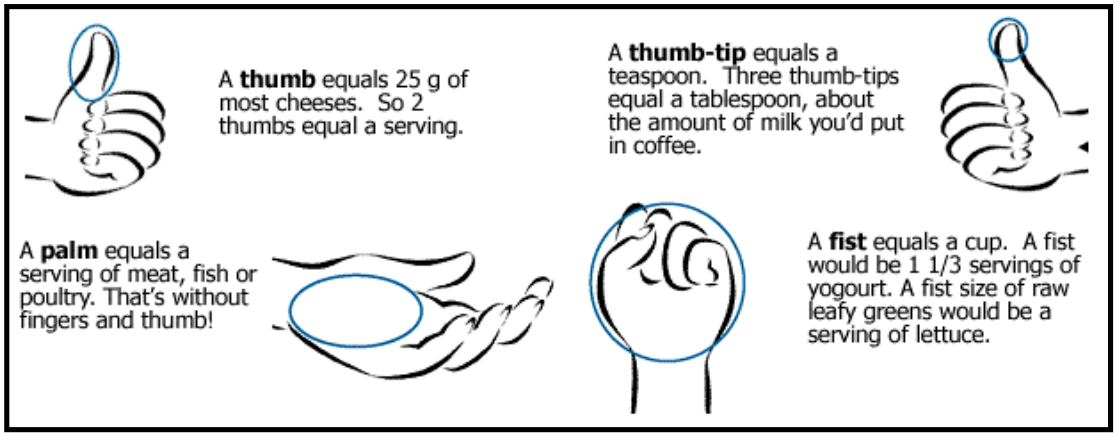
2. Please MEASURE and describe the amount of food eaten as best as possible. Diet records are only reliable with accurate measurements.

- **Always estimate portion sizes of food after cooking.**
- **Use household measures to specify serving sizes.**

  1 cup = 250mL = 8 fluid oz 1 tablespoon (Tbsp) = 15mL
  1 ounce (oz) = 30g 1 teaspoon (tsp) = 5mL
- **Measuring cups (examples):** Put cooked pasta or rice into a measuring cup to record the correct amount before placing it on your plate. Measure your cereal out before pouring into a bowl, and don't forget to measure your milk as well!
- **Teaspoons/tablespoons (examples):** Measure out butter, margarine, mayonnaise, salad dressings, ketchup, mustard, ground flaxseed, sugar, milk/cream, and other condiments, seasonings, and toppings before adding to your food or beverages.

- **Count the number of food items if practical:** e.g.: 20 grapes, 15 baby carrots, 8 medium-sized shrimp, etc.
- **Fluids:** Record amounts in fluid ounces (oz), milliliters (mL), or in cups. Remember 1 cup = 250mL = 8 fl. oz
- **Use food labels to estimate quantities:** Food labels can help you estimate the quantity of food eaten based on weight or volume. For example, write down a 355mL can of pop, ½ of a 60g can of tuna, a 37g granola bar, etc.
- **Use your hand to estimate portion sizes quickly:**

  Whole Thumb = 1 Tablespoon Tip of your Thumb = 1 Teaspoon
  Palm of Your Hand = 3 oz of meat Fist = 1 cup (250mL)



3. Record if anything was ADDED when preparing the food, such as oil (list specific kind), sauce, butter, margarine, or other condiments or seasonings.

4. For COMBINATION DISHES such as lasagna, casseroles, chili, soups, or stews include a description of the main ingredients. E.g. Lasagna: lean ground beef (¼ cup per piece), mozzarella cheese (1 oz per piece), cottage cheese (1 oz per piece), ½ cup tomato sauce, 2 noodles, ¼ cup spinach.

5. Include SNACK FOODS eaten. Don't forget to include candy, chips, cookies, popcorn, ice cream, and beverages such as soft drinks, juice, coffee, or tea.

6. Use the "notes" column to record any additional PRODUCT INFORMATION if available (e.g. 6 crackers – 80 calories, 2.5g fat, 1g fibre, 210mg sodium).

7. Don't forget to write down any ALCOHOLIC BEVERAGES consumed and how much you drank. This includes all wine, beer, and liquor.

When in doubt… include more details!

Current Medication/Supplement Use

Baseline Question: Are you taking any **pills, drugs, or medications?** This includes all over-the-counter and prescribed medications. ☐ Yes ☐ No **If yes,** please list all medications in the table below.

All Follow-Up Visits: Have you had any changes to your medications since your last visit? ☐ Yes ☐ No
If yes, please indicate in the table below which medications you have started or stopped taking, or if the dose or frequency has changed for any current medications.

Name of Medication (Brand Name)	Dose	Frequency	Start Date	Stop Date	Reason for Medication (Medical Problem)
e.g. Lipitor	80 mg	1x / day at bedtime	Jan. 2007	--	High cholesterol

Baseline Question: Are you taking any **supplements?** This includes all over-the-counter and prescribed supplements (e.g. multivitamin, iron, fish oil, etc.). ☐ Yes ☐ No
If yes, please list all supplements in the table below.

All Follow-Up Visits: Have you had any changes to your supplements since your last visit? ☐ Yes ☐ No
If yes, please indicate in the table below which supplements you have started or stopped taking, or if the dose or frequency has changed for any current supplements.

Name of Supplement	Dose	Frequency	Start Date	Stop Date	Reason for Taking Supplement
e.g. Vitamin D	1000 IU	1x / day	Oct. 2010	--	Bone health (osteoporosis)

Sample 1-Day Food Record

Below is an *EXAMPLE* of how to keep accurate records. Include a detailed description and amounts for each item. Remember to record **water**, notes on **product details**, and the **times of day** you ate.

TIME	AMOUNT	DESCRIPTION	NOTES
8am	Large	Coffee	Tim Horton's
	1 Tbsp	Cream	
	2 tsp	Sugar	
11 am	2 slices	Bread, whole wheat	
	2 oz.	Turkey, lunchmeat	Oven-roasted from deli
	1 Tbsp	Mayo (Hellman's)	"light", 4.5g fat per Tbsp
	1 leaf	Romaine Lettuce	
	1 tsp	Becel Margarine	Salt-free
11:30pm	2 cups	water, tap	
2 pm	1 medium	Apple (granny smith)	
	6	Whole wheat crackers (Premium Plus)	80 cals, 2.5g fat, 210mg sodium (from label)
	1"x1" cube	Marble cheese, 35%MF	Crackerbarrel
4pm	1 large	Muffin, blueberry	store-bought
	500mL	Water, tap	
7:30pm	1 patty	Hamburger, BBQ'd (regular ground beef)	M&M Meat Shops (~4oz.)
	1	Hamburger Bun, white bread	
	1 leaf	Iceburg Lettuce	
	2 slices	Tomato, raw	
	1 slice	Red Onion, raw	
	2 Tbsp	Kethcup, Heinz	45 calories per tsp
	1 bottle	Beer (12 oz, 5% alcohol)	Moosehead
10pm	2 cups	Chocolate ice cream	Chapman's

Was this a typical day? If not, why? Usually drink more water (forgot water bottle at home)

Did your take all of your usual medications and supplements as prescribed? ☑ Yes ☐ No

DAILY FOOD RECORD

Subject Code: _____ Date: _____ ☐ Weekday or ☐ Weekend

Please list all food/beverages/water/medications/supplements. Estimate all food/drink amounts accurately.

TIME	AMOUNT	DESCRIPTION	NOTES

Was this a typical day? If not, why?_____

Did your take all of your usual medications and supplements as prescribed? ☐ Yes ☐ No

DAILY FOOD RECORD

Subject Code: _____ Date: _____ ☐ Weekday or ☐ Weekend

Please list all food/beverages/water/medications/supplements. Estimate all food/drink amounts accurately.

TIME	AMOUNT	DESCRIPTION	NOTES

Was this a typical day? If not, why?_____

Did your take all of your usual medications and supplements as prescribed? ☐ Yes ☐ No

DAILY FOOD RECORD

Subject Code: _____ Date: _____ ☐ Weekday or ☐ Weekend

Please list all food/beverages/water/medications/supplements. Estimate all food/drink amounts accurately.

TIME	AMOUNT	DESCRIPTION	NOTES

Was this a typical day? If not, why?_____

Did your take all of your usual medications and supplements as prescribed? ☐ Yes ☐ No

Appendix N: Demographics Questionnaire

Subject Code:_____ Date: _____

Please answer the following questions about yourself. This personal information will be held in strict confidence. Only averages from a large group will be reported at the end of data collection period.

1. What is your age?_____ years old

2. Sex: ○ Male ○ Female

3. How would you classify yourself?
   - ○ Arab ○ Asian ○ African American/Black
   - ○ Caucasian/White ○ First Nations ○ Hispanic
   - ○ Multiracial ○ Pacific Islander ○ Would prefer not to say
   - ○ Other:_____

4. What is your current marital status?
   - ○ Single ○ Married ○ Common-Law
   - ○ Separated ○ Divorced ○ Widowed
   - ○ Would prefer not to say

5. What is the highest level of education you have completed? Please check only one answer.
   - ○ Less than elementary school ○ Elementary school
   - ○ High school ○ Vocational/technical school
   - ○ College ○ University: Bachelor's degree
   - ○ University: Post-graduate degree ○ Professional degree (MD, JD, etc.)
   - ○ Other, please specify_____

6. What is your current employment status?
   - ○ Employed Full-Time ○ Employed Part-Time
   - ○ Retired ○ Student
   - ○ Unemployed Not By Choice ○ Unemployed By Choice
   - ○ Would prefer not to say

7. What is your current household income in Canadian dollars?
   - ○ Under $25,000 ○ $25,000-$49,999 ○ $50,000-$74,999
   - ○ $75,000-$99,999 ○ $100,000-$124,999 ○ $125,000-$149,999
   - ○ $150,000 or more ○ Would prefer not to say

8. How many adults are supported by this household income (including yourself)?
   ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 or more

9. How many children are supported by this household income?
   ○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 or more

End of questionnaire. Thank you for your time!

Appendix O: Lifestyle Questionnaire

Subject Code:_____ Date: _____

1. Do you have a **parent, brother, or sister** who has been diagnosed with **Type 2 diabetes?**
   ○ Yes ○ No

2. If you are female, have you ever **given birth to a baby that weighed over 4 kg or 9 lbs?**
   ○ Yes ○ No ○ Not applicable

3. **If yes,** how many of your children had a birth weight over 4 kg or 9 lbs?
   ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ≥ 6 ○ Not applicable

4. If you are female, were you ever **diagnosed with gestational diabetes** (diabetes that is diagnosed during pregnancy and usually goes away after the baby is born)?
   ○ Yes ○ No ○ Not applicable

5. Please check (✓) which of the following **medical conditions you have (or have had in the past)**:

		Yes	**No**	**I Don't Know**
5.1	Heart disease	○	○	○
5.2	High blood pressure	○	○	○
5.3	High cholesterol or triglycerides	○	○	○
5.4	High blood sugars	○	○	○
5.5	Kidney disease	○	○	○
5.6	Polycystic ovarian syndrome (PCOS)	○	○	○

6. Please indicate your current **smoking status** (choose one):
   ○ Never smoked – I live in an environment with non-smokers
   ○ Never smoked – I live in an environment where others smoke
   ○ Former smoker – I have quit successfully and I live in an environment with non-smokers
   ○ Former smoker – I have quit successfully and I live in an environment where others smoke
   ○ Current smoker – actively trying to quit and I live in an environment with non-smokers
   ○ Current smoker – actively trying to quit and I live in an environment where others smoke
   ○ Current smoker – no intention to quit at this time

7. Since being diagnosed with prediabetes, have you **made any lifestyle changes**?
   ○ Yes ○ No

If yes, please check (✓) which areas of your life you have made changes and specify what actions you have taken or changes you have made:

		Yes	No	Actions Taken / Changes Made
7.1	Alcohol	○	○	
7.2	Diet/Nutrition	○	○	
7.3	Physical Activity	○	○	
7.4	Smoking	○	○	
7.5	Weight Loss	○	○	
7.6	Other (specify):	○	○	

8. Please answer the following questions about your **weight history**.

8.1	Lowest Adult Weight: _____lbs or _____kg
8.2	Highest Adult Weight:_____lbs or _____kg
8.3	Most Stable Adult Weight:_____lbs or _____kg
8.4	Desired Body Weight:_____lbs or _____kg
8.5	Within the last year, has your weight: ○Increased ○Decreased ○Stayed the same
8.6	If you have lost or gained weight within the last year, please tell us how much: _____lbs or _____kg
8.7	How satisfied are you at your current weight? ○ Not satisfied at all ○ Somewhat satisfied ○ Unsure ○ Satisfied ○ Very satisfied

9. Thinking back to the last 7 days, **how many days did you consume alcohol**?

○ none ○ 1 day ○ 2 days ○ 3 days ○ 4 days ○ 5 days ○ 6 days ○ 7 days

10. Thinking back to the last 7 days, how many **standard drinks of alcohol did you consume in total** (over the week)? Note: 1 standard drink = 12 oz beer; 5 oz wine; 3 oz fortified wine; 1.5 oz liquor.

○ none ○ 1-3 ○ 4-6 ○ 7-9 ○ 10-12 ○ 13-14 ○ ≥ 15

11. Please indicate your current **stress level:**

○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10

Not stressed at all — Mildly stressed — Moderately stressed — Severely stressed

12. Please indicate which of the following sentences best describes your cooking (check one):

○ I can boil an egg and cook cheese on toast but I never try anything more advanced.
○ I can prepare simple meals but never cook anything too complicated.
○ I am happy cooking most dishes if I have a recipe to follow.
○ I am a competent cook and feel confident I could prepare most dishes.
○ I regard myself as an expert cook and frequently prepare sophisticated dishes.

End of questionnaire. Thank you for your time!

Appendix P: Session Feedback Form

prepare Session Feedback Form

Visit #: ____ Date: _____ Participant Code: _____

Your feedback is important to us. Please take a few minutes to let us know what you think about your visit today, so we can help serve you better.

Section 1: Format

A. I found the length of the education session today to be

○	○	○
Too long	Just right	Too short

Section 2: Interaction with the prepare team

A. I found the student volunteers were helpful today

○	○	○	○	○
Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

B I enjoyed the interactive nature of the education session today

○	○	○	○	○
Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

Section 3: Nutrition Component on (topic of presentation inserted here)

A. I benefited from the nutrition session on _(topic of presentation inserted here)_ today

○	○	○	○	○
Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

B. I found the educational information provided on _(topic of presentation inserted here) .

○	○	○
Very useful	Useful	Not very useful

C. I enjoyed the food demonstration on _(topic of presentation inserted here)_ today

○	○	○	○	○
Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

D. I will use the information presented today on _(topic of presentation inserted here)_ to help me achieve my health eating goals.

○	○	○	○	○
Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

E. Based on what I experienced today, I feel more confident in making a positive change in my eating habits.

○	○	○	○	○
Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

Section 4: Physical Activity Component on _(topic of presentation inserted here)_

A. I benefited from the physical activity session on _(topic of presentation inserted here)_ today

○	○	○	○	○
Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

B. I found the educational information provided on _(topic of presentation inserted here)_

○	○	○
Very useful	Useful	Not very useful

C. I enjoyed participating in the interactive physical activity session today

○	○	○	○	○
Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

D. I will use the information presented today on _(topic of presentation inserted here)_ to help me achieve my physical activity goals.

○	○	○	○	○
Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

E. Based on what I experienced today, I feel more confident in making a positive change in my physical activity habits.

○	○	○	○	○
Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

Section 6: Overall Feedback

A. I enjoyed the education session today

○	○	○	○	○
Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

B. I would recommend this education session to a friend or family member

○	○	○	○	○
Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

C. ***What I liked most*** about the education session was: _____
_____
_____
_____

D. ***What I liked least*** about the education session was: _____
_____
_____
_____

E. Do you have any other thoughts or comments about the education session today or the **prepare** program you would like to share?_____
_____
_____
_____

Thank you very much for your feedback!

Appendix Q: Overall Feedback Form

Overall Feedback Form

Date: _____ Participant Code: _____

Your feedback is important to us. Your thoughts and opinions are valuable to us as they will help us to determine if **prepare** is a worthwhile program that should continue. In addition, your suggestions for improvements to the program will enable us to offer the best program possible to others and may even set the standard for healthcare in Canada!

Section 1: Overall Evaluation

A. I would recommend this program to a friend or family member

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

B. ***What I liked most*** about my experience with the **prepare** program was:

_____

_____

_____

C. ***What I liked least*** about my experience with the **prepare** program was:

_____

_____

_____

Section 2: Format

A. I found the length of the **prepare** program to be	○ Too long	○ Just right	○ Too short
B. I found the length of the education sessions	○ Too long	○ Just right	○ Too short

C. I found the frequency of the education sessions to be

○	○	○
Too often	Just right	Not often enough

D. I found that the Friday afternoon timing of the education sessions suited my needs

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

E. I found that the Thursday evening timing of the education sessions suited my needs

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

G. I took advantage of the option to corresponding by email ○ Yes ○ No

H. I took advantage of the information on the Brescia prediabetes Web pages ○ Yes ○ No

Section 3: Interaction with the prepare team

A. I found the student volunteers were helpful

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

B. I found the student volunteers were knowledgeable and skilled

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

C. I found the student volunteers were welcoming/friendly

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

D. I valued having a health professional available

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

E. I was treated with respect

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

F. My confidentiality was maintained

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

G I enjoyed the interactive nature of the sessions

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

H. I found the individual "drop in" periods with the dietitian useful ○ not applicable

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

I. I enjoyed the group nature of the program

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

J. Please indicate any other comments you may have about the **interaction** with the staff and volunteers as part of the **prepare** program: _____
_____

Section 4: Facilities

A. I found the location of the sessions suited my needs

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

B. I found the location of the sessions was convenient for me

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

C. I valued the free parking

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

Session 5: Nutrition Component

A. I benefited from the nutrition sessions

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

B. I found the educational information provided during the nutrition sessions

○	○	○
Very useful	Useful	Not very useful

C. I found the amount of information provided at each session to be

○	○	○
Too much	Just right	Not enough

D. I found the information provided during the nutrition sessions easy to understand

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

E. I found the nutrition sessions practical

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

F. I found the nutrition sessions interactive

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

G. I enjoyed the interactive food demonstrations

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

H. I took away some practical ideas from the food demonstrations

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

I. I enjoyed the interactive *optional monthly cooking workshops* ○ not applicable

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

J. I took away some practical ideas from the *cooking workshops* ○ not applicable

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

K. I found the frequency of the *optional* cooking workshops was

○	○	○
Too often	Just right	Not often enough

L. I found that the monthly healthy eating goals kept me on track with respect to my nutrition goals

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

M. I will continue to set healthy eating goals to keep me on track in the future

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

N. I found the monthly food records useful for keeping me on track with my healthy eating goals

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

O. I will continue to record my food intake to help me to stay on track with my healthy eating goals

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

P. I have been able to make positive changes to my diet during the program

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

Q. The nutrition component of **prepare** has enhanced my skills

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

R. I feel confident that I can continue to implement many of the healthy eating strategies I have learned as part of the **prepare** program

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

S. I believe that the fact I was following the **prepare** program had a positive impact on the eating habits of my family member(s). ○ not applicable

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

Section 6: Physical Activity Component

A. I enjoyed the educational information provided during the physical activity sessions

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

B. I found the educational information provided during the physical activity sessions useful

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

C. I found the amount of information provided at each session to be appropriate

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

D. I found the information provided during the physical activity sessions easy to understand

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

E. I enjoyed participating in the interactive physical activity sessions

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

F. I found the interactive physical activity sessions easy to understand

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

F. I found the interactive physical activity sessions easy to follow

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

G. I found the interactive physical activity sessions useful

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

H. I found the physical activity sessions were safe for me

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

I. I enjoyed participating in the *optional* weekly walking program ○ not applicable

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

J. I found that the walking program kept me on track with respect to my physical activity goals

○ not applicable

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

K. I believe the monthly goal setting helped me to stay on track with my physical activity goals

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

L. I will continue to set physical activity goals to keep me on track in the future

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

M. I found the physical activity and step logs useful for keeping me on track with my physical activity goals

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

N. I will continue to keep a physical activity and step log to help me to stay on track with my physical activity goals in the future

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

O. Overall, I feel my participation in the physical activity component of **prepare** has helped me to make positive changes in my physical activity level

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

P. Overall, I feel more confident in my ability to perform physical activity due to my participation in the **prepare** program

○	○	○	○	○
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

Section 7: Follow-Up

A. Would you be interested in receiving long-term follow-up? ○ Yes ○ No

B. If yes, what type of follow-up would you be interested in receiving? Please explain.

_____

_____

Thank you very much for your feedback!

Appendix R: Sample 3-Day Food Intake Record ESHA Analysis

Nutrients	Value	Rcmd	% Rcmd	Nutrients	Value	Rcmd	% Rcmd
Basic Components				Vitamin B12 (mcg)	8	2	324%
Gram Weight (g)	3829			Vitamin C (mg)	360	90	400%
Calories (kcal)	3123	2723	115%	Vitamin D - IU (IU)	862	600	144%
Carbohydrates (g)	289	374	77%	Folate (mcg)	391	400	98%
Protein (g)	139	67	208%	Vitamin K (mcg)	130	120	108%
Fat (g)	159	85	188%	Pantothenic Acid (mg)	10	5	198%
Water (g)	2990	3700	81%	Minerals			
Dietary Fiber (g)	38	38	99%	Calcium (mg)	1017	1000	102%
Total Sugars (g)	109			Iron (mg)	17	8	216%
Saturated Fat (g)	56	27	204%	Magnesium (mg)	362	420	86%
Trans Fatty Acid (g)	1			Phosphorus (mg)	1221	700	174%
Cholesterol (mg)	643	300	214%	Potassium (mg)	4572	4700	97%
Mono Fat (g)	58	30	191%	Selenium (mcg)	133	55	242%
Poly Fat (g)	19	27	70%	Sodium (mg)	3834	1500	256%
Vitamins				Zinc (mg)	13	11	116%
Vitamin A - RAE (RAE)	1232	900	137%	Other Fats			
Vitamin B1 (mg)	2	1	149%	Omega 3 Fatty Acid (g)	1		
Vitamin B2 (mg)	2	1	190%	Other Nutrients			
Vitamin B3 (mg)	31	16	195%	Alcohol (g)	4		
Vitamin B3 - Niacin Equiv (mg)	52	16	324%	Caffeine (mg)	368		
Vitamin B6 (mg)	3	1	210%				

Participant Code: PREPARE-_____ or CONTROL-_____

3d-FIR Dates Analyzed: _____ **Visit:**_____

Macronutrient Distribution Range:

Nutrient	Recommended	Average Intake
Carbohydrate	45-65%	%
Protein	10-35%	%
Fat	20-35%	%
Alcohol	n/a	%
Saturated Fat	Less than 7%	%

Fluid Intake:

Intake	Water	Sweetened Beverages
Day 1		
Day 2		
Day 3		
Average		

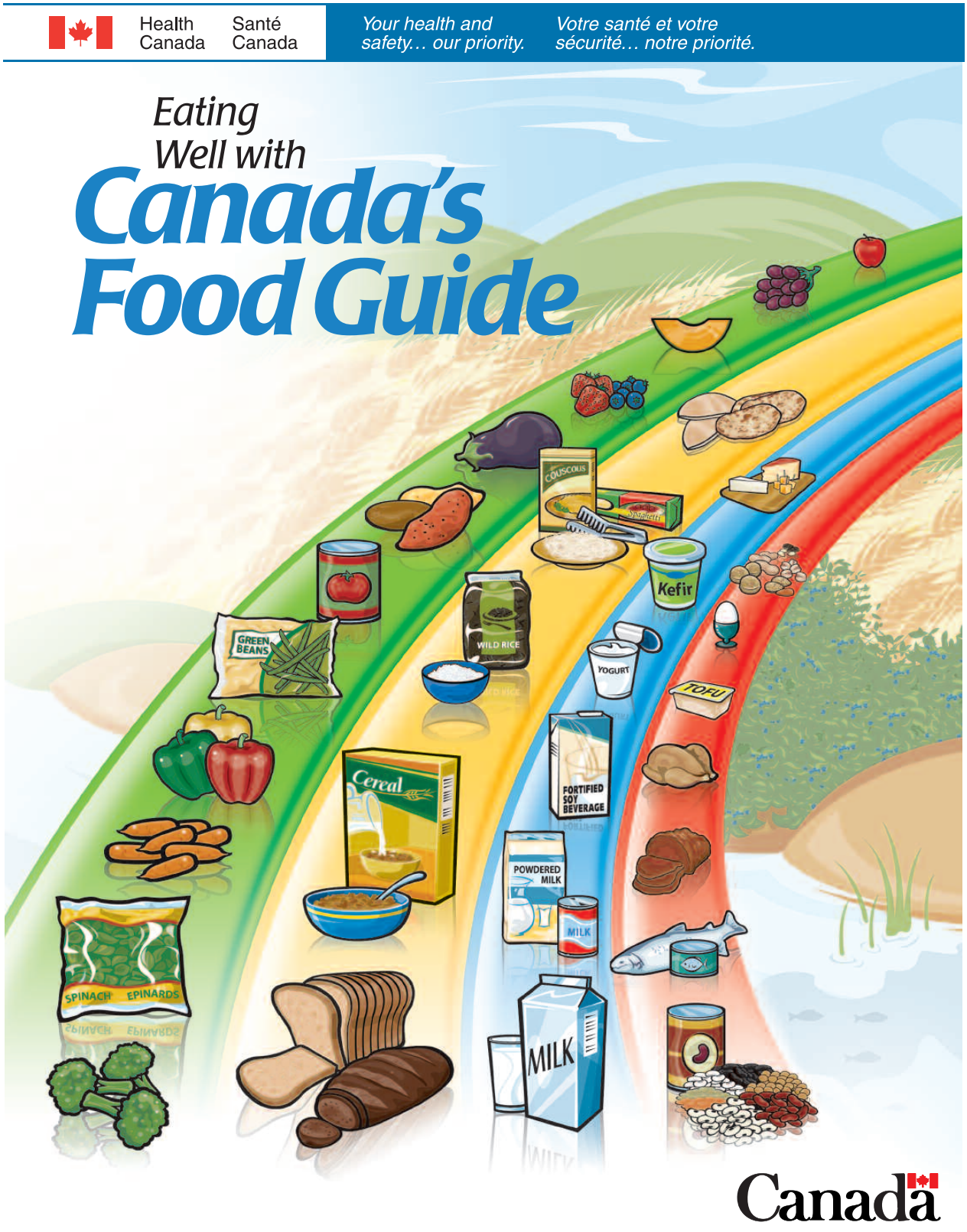
Eating Well with Canada's Food Guide:

	Participant's Intake (# Servings/Day)										
	Grains	Milk & Alt.	Meat & Alt.	Veg. & Fruit	Total Fruit	Whole Fruit	Fruit Juice	Total Veg.	Dark Green Veg.	Orange Veg. & Fruit	Starchy Veg.
Day 1											
Day 2											
Day 3											
Average											

Comments (typical day?):_____

Analyzed By:_____ Date Analyzed:_____

Appendix S: Eating Well with Canada's Food Guide



Recommended Number of Food Guide Servings per Day

	Children			Teens		Adults			
Age in Years	2-3	4-8	9-13	14-18		19-50		51+	
Sex	Girls and Boys			Females	Males	Females	Males	Females	Males
Vegetables and Fruit	4	5	6	7	8	7-8	8-10	7	7
Grain Products	3	4	6	6	7	6-7	8	6	7
Milk and Alternatives	2	2	3-4	3-4	3-4	2	2	3	3
Meat and Alternatives	1	1	1-2	2	3	2	3	2	3

The chart above shows how many Food Guide Servings you need from each of the four food groups every day.

Having the amount and type of food recommended and following the tips in *Canada's Food Guide* will help:

- Meet your needs for vitamins, minerals and other nutrients.
- Reduce your risk of obesity, type 2 diabetes, heart disease, certain types of cancer and osteoporosis.
- Contribute to your overall health and vitality.


What is One Food Guide Serving?
Look at the examples below.
Fresh, frozen or canned vegetables
125 mL (½ cup)
Leafy vegetables
Cooked: 125 mL (½ cup)
Raw: 250 mL (1 cup)
Fresh, frozen or canned fruits
1 fruit or 125 mL (½ cup)
100% Juice
125 mL (½ cup)
Bread
1 slice (35 g)
Bagel
½ bagel (45 g)
Flat breads
½ pita or ½ tortilla (35 g)
Cooked rice, bulgur or quinoa
125 mL (½ cup)
Cereal
Cold: 30 g
Hot: 175 mL (¾ cup)
Cooked pasta or couscous
125 mL (½ cup)
Milk or powdered milk (reconstituted)
250 mL (1 cup)
Canned milk (evaporated)
125 mL (½ cup)
Fortified soy beverage
250 mL (1 cup)
Yogurt
175 g
(¾ cup)
Kefir
175 g
(¾ cup)
Cheese
50 g (1 ½ oz.)
Cooked fish, shellfish, poultry, lean meat
75 g (2 ½ oz.)/125 mL (½ cup)
Cooked legumes
175 mL (¾ cup)
Tofu
150 g or
175 mL (¾ cup)
Eggs
2 eggs
Peanut or nut butters
30 mL (2 Tbsp)
Shelled nuts and seeds
60 mL (¼ cup)
Oils and Fats
• Include a small amount – 30 to 45 mL (2 to 3 Tbsp) – of unsaturated fat each day. This includes oil used for cooking, salad dressings, margarine and mayonnaise.
• Use vegetable oils such as canola, olive and soybean.
• Choose soft margarines that are low in saturated and trans fats.
• Limit butter, hard margarine, lard and shortening.

Make each Food Guide Serving count…
wherever you are – at home, at school, at work or when eating out!

- **Eat at least one dark green and one orange vegetable each day.**
  - Go for dark green vegetables such as broccoli, romaine lettuce and spinach.
  - Go for orange vegetables such as carrots, sweet potatoes and winter squash.
- **Choose vegetables and fruit prepared with little or no added fat, sugar or salt.**
  - Enjoy vegetables steamed, baked or stir-fried instead of deep-fried.
- **Have vegetables and fruit more often than juice.**

- **Make at least half of your grain products whole grain each day.**
  - Eat a variety of whole grains such as barley, brown rice, oats, quinoa and wild rice.
  - Enjoy whole grain breads, oatmeal or whole wheat pasta.
- **Choose grain products that are lower in fat, sugar or salt.**
  - Compare the Nutrition Facts table on labels to make wise choices.
  - Enjoy the true taste of grain products. When adding sauces or spreads, use small amounts.

- **Drink skim, 1%, or 2% milk each day.**
  - Have 500 mL (2 cups) of milk every day for adequate vitamin D.
  - Drink fortified soy beverages if you do not drink milk.
- **Select lower fat milk alternatives.**
  - Compare the Nutrition Facts table on yogurts or cheeses to make wise choices.

- **Have meat alternatives such as beans, lentils and tofu often.**
- **Eat at least two Food Guide Servings of fish each week.***
  - Choose fish such as char, herring, mackerel, salmon, sardines and trout.
- **Select lean meat and alternatives prepared with little or no added fat or salt.**
  - Trim the visible fat from meats. Remove the skin on poultry.
  - Use cooking methods such as roasting, baking or poaching that require little or no added fat.
  - If you eat luncheon meats, sausages or prepackaged meats, choose those lower in salt (sodium) and fat.

Enjoy a variety of foods from the four food groups.

Satisfy your thirst with water!

Drink water regularly. It's a calorie-free way to quench your thirst. Drink more water in hot weather or when you are very active.

* Health Canada provides advice for limiting exposure to mercury from certain types of fish. Refer to www.healthcanada.gc.ca for the latest information.

Advice for different ages and stages…

Children

Following *Canada's Food Guide* helps children grow and thrive.

Young children have small appetites and need calories for growth and development.

- Serve small nutritious meals and snacks each day.
- Do not restrict nutritious foods because of their fat content. Offer a variety of foods from the four food groups.
- Most of all... be a good role model.

Women of childbearing age

All women who could become pregnant and those who are pregnant or breastfeeding need a multivitamin containing **folic acid** every day. Pregnant women need to ensure that their multivitamin also contains **iron**. A health care professional can help you find the multivitamin that's right for you.

Pregnant and breastfeeding women need more calories. Include an extra 2 to 3 Food Guide Servings each day.

Here are two examples:

- Have fruit and yogurt for a snack, or
- Have an extra slice of toast at breakfast and an extra glass of milk at supper.

Men and women over 50

The need for **vitamin D** increases after the age of 50.

In addition to following *Canada's Food Guide*, everyone over the age of 50 should take a daily vitamin D supplement of 10 µg (400 IU).

How do I count Food Guide Servings in a meal?

Here is an example:

Vegetable and beef stir-fry with rice, a glass of milk and an apple for dessert		
250 mL (1 cup) mixed broccoli, carrot and sweet red pepper	=	2 **Vegetables and Fruit** Food Guide Servings
75 g (2 ½ oz.) lean beef	=	1 **Meat and Alternatives** Food Guide Serving
250 mL (1 cup) brown rice	=	2 **Grain Products** Food Guide Servings
5 mL (1 tsp) canola oil	=	part of your **Oils and Fats** intake for the day
250 mL (1 cup) 1% milk	=	1 **Milk and Alternatives** Food Guide Serving
1 apple	=	1 **Vegetables and Fruit** Food Guide Serving

Eat well and be active today and every day!

The benefits of eating well and being active include:

- Better overall health.
- Lower risk of disease.
- A healthy body weight.
- Feeling and looking better.
- More energy.
- Stronger muscles and bones.

Be active

To be active every day is a step towards better health and a healthy body weight.

It is recommended that adults accumulate at least 2 ½ hours of moderate to vigorous physical activity each week and that children and youth accumulate at least 60 minutes per day. You don't have to do it all at once. Choose a variety of activities spread throughout the week.

Start slowly and build up.

Eat well

Another important step towards better health and a healthy body weight is to follow Canada's Food Guide by:

- Eating the recommended amount and type of food each day.
- Limiting foods and beverages high in calories, fat, sugar or salt (sodium) such as cakes and pastries, chocolate and candies, cookies and granola bars, doughnuts and muffins, ice cream and frozen desserts, french fries, potato chips, nachos and other salty snacks, alcohol, fruit flavoured drinks, soft drinks, sports and energy drinks, and sweetened hot or cold drinks.

Read the label

- Compare the Nutrition Facts table on food labels to choose products that contain less fat, saturated fat, trans fat, sugar and sodium.
- Keep in mind that the calories and nutrients listed are for the amount of food found at the top of the Nutrition Facts table.

Limit trans fat

When a Nutrition Facts table is not available, ask for nutrition information to choose foods lower in trans and saturated fats.

Nutrition Facts

Per 0 mL (0 g)

Amount	% Daily Value
Calories 0	
Fat 0 g	**0** %
Saturates 0 g	**0** %
+ Trans 0 g	
Cholesterol 0 mg	
Sodium 0 mg	**0** %
Carbohydrate 0 g	**0** %
Fibre 0 g	**0** %
Sugars 0 g	
Protein 0 g	

Vitamin A	0 %	Vitamin C	0 %
Calcium	0 %	Iron	0 %

Take a step today…

- ✓ Have breakfast every day. It may help control your hunger later in the day.
- ✓ Walk wherever you can – get off the bus early, use the stairs.
- ✓ Benefit from eating vegetables and fruit at all meals and as snacks.
- ✓ Spend less time being inactive such as watching TV or playing computer games.
- ✓ Request nutrition information about menu items when eating out to help you make healthier choices.
- ✓ Enjoy eating with family and friends!
- ✓ Take time to eat and savour every bite!

For more information, interactive tools, or additional copies visit Canada's Food Guide on-line at:
www.healthcanada.gc.ca/foodguide

or contact:

Publications
Health Canada
Ottawa, Ontario K1A 0K9
E-Mail: publications@hc-sc.gc.ca
Tel.: 1-866-225-0709
Fax: (613) 941-5366
TTY: 1-800-267-1245

Également disponible en français sous le titre : Bien manger avec le Guide alimentaire canadien

This publication can be made available on request on diskette, large print, audio-cassette and braille.

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Appendix T: Eating Well with Canada's Food Guide
What is a Food Guide Serving of… Vegetables and Fruit

Health Canada Santé Canada

Your health and safety… our priority. *Votre santé et votre sécurité… notre priorité.*

Eating Well with **Canada's Food Guide**

What is a Food Guide Serving of…

Vegetables and Fruit

Dark Green and Orange Vegetables

Asparagus 125 mL, ½ cup, 6 spears	**Mesclun mix** 250 mL, 1 cup – raw	
Beans, green 125 mL, ½ cup	**Mustard greens** 250 mL, 1 cup – raw	
Bok choy/Chinese cabbage (Choi sum) 125 mL, ½ cup – cooked	**Okra** 125 mL, ½ cup	
Broccoli 125 mL, ½ cup	**Peas** 125 mL, ½ cup	(starchy vegetable)
Brussels sprouts 125 mL, ½ cup, 4 sprouts	**Pepper, sweet, green** 125 mL, ½ cup, ½ medium	
Carrots 125 mL, ½ cup, 1 large	**Pumpkin** 125 mL, ½ cup	
Chard 125 mL, ½ cup	**Seaweed** 125 mL, ½ cup	
Dandelion greens 250 mL, 1 cup – raw	**Snow peas** 125 mL, ½ cup	
Edamame (soy beans) 125 mL, ½ cup	**Spinach** 250 mL, 1 cup – raw	
Endive 250 mL, 1 cup	**Squash** 125 mL, ½ cup	(starchy vegetable)
Fiddleheads 125 mL, ½ cup	**Sweet potato** 125 mL, ½ cup	(starchy vegetable)
Kale/collards 250 mL, 1 cup – raw	**Yam** 125 mL, ½ cup	(starchy vegetable)
Leeks 125 mL, ½ cup, ½ leek	**Zucchini** 125 mL, ½ cup	
Lettuce, romaine 250 mL, 1 cup – raw		

Canada

What is a Food Guide Serving of...

More Vegetables and Fruits

Some orange coloured fruit can be substituted for an orange vegetable. See the fruit marked with an asterisks (*)

 **Apple** 1 medium	 **Eggplant** 125 mL, ½ cup	 **Pear** 1 medium
 **Apricot, fresh *** 3 fruits	 **Fig, fresh** 2 medium	 **Peppers, bell** 125 mL, ½ cup, ½ medium
 **Avocado** ½ fruit	 **Fruit juice** 125 mL, ½ cup	 **Pineapple** 125 mL, ½ cup, 1 slice
 **Bamboo shoots** 125 mL, ½ cup	 **Grapefruit** ½ fruit	 **Plantain** 125 mL, ½ cup
 **Banana** 1 medium	 **Grapes** 20 fruits	 **Plum** 1 fruit
 **Beans, yellow** 125 mL, ½ cup	 **Guava** 125 mL, ½ cup, 1 fruit	 **Potato** (starchy vegetable) 125 mL, ½ cup, ½ medium
 **Beets** 125 mL, ½ cup	 **Honeydew** 125 mL, ½ cup	 **Radishes** 125 mL, ½ cup
 **Berries** 125 mL, ½ cup	 **Kiwi** 1 large fruit	 **Rhubarb** 125 mL, ½ cup
 **Bitter melon** 125 mL, ½ cup, ½ pod	 **Kohlrabi** 125 mL, ½ cup	 **Tomato** 125 mL, ½ cup
 **Cabbage** 125 mL, ½ cup	 **Lettuce (example: iceberg or butterhead)** 250 mL, 1 cup – raw	 **Tomato sauce** 125 mL, ½ cup
 **Cantaloupe *** 125 mL, ½ cup	 **Lychee** 10 fruits	 **Turnip** 125 mL, ½ cup
 **Cauliflower** 125 mL, ½ cup, 4 flowerets	 **Mango *** 125 mL, ½ cup, ½ fruit	**Vegetable juice** 125 mL, ½ cup
 **Celery** 1 medium stalk	 **Mixed vegetables** 125 mL, ½ cup	 **Watermelon** 125 mL, ½ cup
 **Chayote** 125 mL, ½ cup	**Mushrooms** 125 mL, ½ cup	
Cherries 20	**Nectarine *** 1 fruit	
Corn (starchy vegetable) 1 ear, 125 mL, ½ cup	**Orange** 1 medium	
Cucumber 125 mL, ½ cup	**Papaya *** ½ fruit	
Dried fruit 60 mL, 1/4 cup	**Peach *** 1 medium	

Appendix U: Procedure for Physical Measurements

RESPECT OF PRIVACY AND CONFIDENTIALITY

When measuring anthropometrics, it is important to ensure that the **privacy and confidentiality of participants** are always respected. To do this, you must ensure that measurements are taken on a one-on-one basis (just you and the participant present). Also, it is very important that you explain to the participant exactly what you are going to be doing and to allow them the opportunity to ask any questions that they may have.

STATURE (STANDING HEIGHT)

Stature, or standing height, can be measured for subjects who are cooperative and able to stand without assistance. A stadiometer (height rod) will be used in this study to determine an accurate height for each subject. This measurement will take about 2 minutes.

How to Set-Up a Stadiometer

Stadiometers must be stable, calibrated and dedicated to the purpose. This requires:

- A vertical board with an attached metric ruler (when assembling the stadiometer, ensure that the tiny icons at the top and bottom of each piece fit together with the piece that has the same corresponding icon. For example, put the top of the piece with the * symbol into the bottom of the piece that has the same * symbol)
- An easily moveable horizontal headpiece that can be brought into contact with the most superior part of the head. Ensure that the flat side of the headpiece faces the floor.
- A wide and stable platform or firm uncarpeted floor as the base

How to Measure Stature Using a Stadiometer

Step 1. Ask the subject to remove the following items:

- Shoes
- Hair ornamentation (clips, headbands, barrettes, etc.)
- Bulky outer layers (minimal clothing is best)

Step 2. Position the subject as follows:

- Stand with heels together
- Arms to the side
- Legs straight
- Shoulders relaxed
- Head in the Frankfort horizontal plane ("look straight ahead", make sure the chin is parallel to the floor)
- The following four body points should be gently touching the stadiometer vertical board: head, shoulder blades, buttocks, and heels

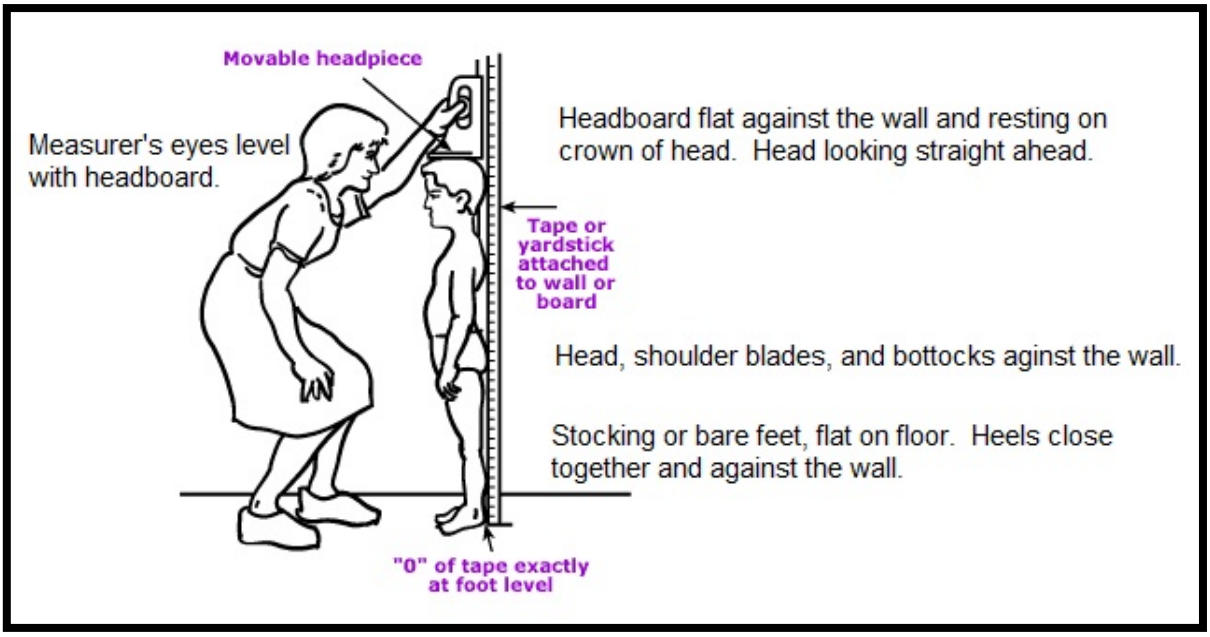
Note: Some people may not be able to touch all four points against the stadiometer because of obesity, protruding buttocks, or curvature of the spine. Rather than creating an embarrassing situation by trying to force a subject into a physically impossible position, have the subject touch two or three of the four points to the vertical surface of the stadiometer. Also make sure that the points are just touching, and that the person is not leaning on the stadiometer.

Step 3. Just before the measurement is taken, the subject should:

- Relax and maintain an erect posture ("stand up tall" and ensure that the chin is parallel to the floor and arms are at the participants' sides).

Step 4. Collect the stature measurement as follows:

- Lower the headboard to the highest point of the head with enough pressure to compress the hair.
- Eye level of the observer should be level with the headboard to avoid errors caused by parallax.
  Parallax: Is a difference in the apparent reading of a measurement scale when viewed from various points not in a straight line with the eye.
- Read the measurement to the nearest 0.1 cm (1/8").
- Repeat the measurement one more time to ensure accuracy and average the two readings.
- If the initial two measurements are more than 0.5 cm apart, perform another measurement and take an average measurement between the two closest measurements.



WEIGHT (CURRENT BODY WEIGHT)

Weight will be collected using an electronic scale. This measurement will take about 2 minutes.

How to Set Up an Electronic Scale

- Ensure that the scale is set up on a hard flooring surface and is as level as possible.

How to Measure Weight Using an Electronic Scale

Step 1. Ask the subject to remove the following items:

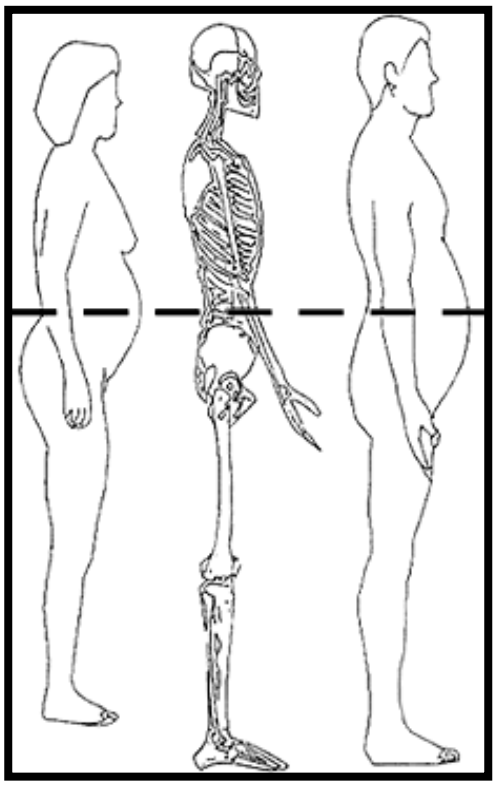
- Shoes
- Bulky outer layers (minimal clothing is best)
- Heavy items in pockets / on the person (cell phone, wallet, coins, keys, heavy belts)

Step 2. Collect the weight measurement as follows:

- Turn the electronic scale on.
- Ask the subject to stand still in the middle of the scale's platform without touching anything.
- Body weight should be equally distributed on both feet.
- Read the weight to the nearest 100 g (0.1 kg).
- Repeat the measurement one more time to ensure accuracy and average the two readings.
- If the two measurements are more than 100 g (0.1 kg) apart, perform another measurement and take an average measurement between the two closest measurements.

Considerations:

- The scale should be placed on a flat, hard surface that will allow it to sit securely without rocking or tipping.
- The scale will be calibrated monthly.
- Ideally, individuals should be weighed after voiding (going to the bathroom) and dressed in lightweight clothing.
- The scale will be placed in a spot where adequate privacy will be provided.
- While participants have the right to ask for their current measurement value, do not tell the participant how optimal their weight is.



WAIST CIRCUMFERENCE

The United States National Institute of Health (NIH) recommends using waist circumference to assess abdominal fat content. It is a valuable guide in assessing health risk in persons categorized as normal or overweight (in terms of BMI) and provides an independent prediction of risk over and above that of BMI. This measurement will take about 6 to 8 minutes.

<u>How to Measure Waist Circumference Using a Measuring Tape</u>

Step 1. Ask the subject to remove the following items:

- Outer clothing that restricts or may interfere with the measurement (e.g. the placement of the measuring tape against bare skin, compressing the abdomen, etc.)

Step 2. Collect the waist circumference measurement as follows:

- Locate the right iliac crest by using the fingertips to gently feel for the highest point of the hip bone on the subject's right side. Make a small mark with a pen on the subject's skin.
- Locate the lowest right rib. Make a small mark with a pen on the subject's skin.
- Find the midway point between the iliac crest and lowest right rib, and use this as the reference point for which to measure the subject's waist circumference.
- Place an inelastic, flexible measuring tape in a horizontal plane (parallel to the floor) around the abdomen at the midway point between the iliac crest and lowest right rib.

- The tape should be snug but should not compress the skin.
- Ensure that the participant is standing with their feet hip width apart and that their arms are at their sides.
- Have the participant take a breath and exhale. You can also ask the participants to talk (e.g. ask them their favorite movie), as this helps with relaxation.
- Take the reading.
- Record the measurement to the nearest 0.1 cm.
- Repeat the measurement one more time to ensure that an accurate measurement and average the two readings.
- If the two measurements are more than 0.5 cm apart, perform another measurement and take an average between the two closest measurements.

BLOOD PRESSURE

This measurement will take about 7 to 10 minutes (including 5 minutes to sit and relax).

How to Take Blood Pressure Using a Blood Pressure Cuff

Step 1. Ask the subject to remove the following items:

- Any outer clothing restricting easy access to an arm and interfering with the placement of blood pressure cuff against the bare skin of the upper arm.

Step 2. Ask the subject to sit and relax:

- The individual will be asked to sit comfortably in a chair that supports his/her back and beside a table that supports his/her arm.
- A pillow or towel will be used to ensure that the centre of the cuff is at heart level.
- The legs of the individuals will not be crossed.
- The correct size cuff (i.e. S, M, L, XL) will be placed around a bare arm. The cuff will be placed on the anterior part of the arm. The bottom of the cuff will rest approximately two fingers above the elbow. The tube that connects the cuff to the machine will sit on the table.
- The individual will rest and relax for 5 minutes.

Step 3. Measure the blood pressure:

- Blood pressure will be measured and recorded by a member of the research team.
- The individual will relax for 1-2 minutes.
- A second reading of the blood pressure will be done and the average between the two measurements recorded.

Reference: The Canadian Hypertension Education Program (CHEP) http://hypertension.ca/

Considerations:

- The participant should not talk during the measurement.
- The participant's arm and fingers should remain still (i.e. no wiggling their fingers).
- The breath of the participant should be normal (i.e. no holding of the breath or breathing deeply).
- Try to minimize distractions around the participant during the measurement (i.e. no loud noises or exciting events that would elevate the heart rate of the participant).

Appendix V: Focus Group Questions

PREPARE Visit 8 Focus Group Questions

Hello everybody and welcome. My name is _____, and I will be leading today's focus group discussion. Assisting me is _____, and she will be helping me with the discussion and will help us to stay on track so we don't go over the hour. The purpose of today's discussion is to find out your thoughts and ideas about the prediabetes PREPARE program that you joined in May of 2011.

Please be aware that there are no right or wrong answers to the questions being asked of you. We will be recording this discussion with a tape recorder to make sure we catch all of your important comments. The information you provide will be grouped together into themes and we will be looking at your feedback as a group overall, and will not be connecting any individual comments to anyone in particular from the group. Whether you came a lot to the PREPARE sessions or very little, we would really like to hear more about why that was to help us improve the program in the future. Please feel free to be as open and honest as you wish with you answers. Are there any questions? If no, then let's begin.

1. What parts of the PREPARE program did you enjoy? **(5 minutes)**
    a. What did you find most helpful?

2. What parts of the PREPARE program did you not enjoy? **(5 minutes)**
    a. What did you not find helpful?

3. Are there any areas in your life that you have changed since getting involved with the PREPARE program? **(9 minutes)**
    a. Fruits & Vegetables
    b. Physical activity
    c. Following Canada's Food Guide

4. What are the most valuable things you have learned about being healthy from this program? **(8 minutes)**
    a. Did you learn anything new you could use from the education sessions?

5. What challenges did you face in participating fully in the PREPARE program? **(12 minutes)**
    a. Time of day, day of week?
    b. Length of the sessions?
    c. Frequency of the session? (i.e. 1x/month, more/less often?)
    d. Parking? Transportation?

   e. Location?
   f. Financial constraints?
   g. Communication?
   h. Social support or lack of?

6. We offered some "extras" to the PREPARE program that we're looking for feedback on. What did you think about: **(10 minutes)**
   a. The CCAA (Canadian Centre for Activity and Aging) physical activity program
   b. The goal setting activity
   c. The healthy snack
   d. The optional cooking workshops
   e. The optional walking program

7. If you could change any parts of the program, what would you change and why? **(10 minutes)**
   a. How can we make it better for future participants?
   b. Any final comments you wish to share?

Thank you so much for participating in this discussion. Your comments have been most informative and greatly appreciated.

Appendix W: Attendance Log

Legend:	**Attendance Classification:**
V = Visit CW = Cooking Workshop C- = Control participant P- = PREPARE participant c = cancelled Y = visit or cooking workshop was attended n/a = not applicable	**PREPARE high attendee (n = 25)**, attended ≥ 3 of 6 PREPARE education visits (Visits 2-7); received ≥ 50% of the PreDM education offered **PREPARE low attendee (n = 11)**, attended only 1-2 of 6 PREPARE education visits (Visits 2-7); received < 50% of the PreDM education offered **PREPARE non-attendee (n = 12)**, did not attend any of the PREPARE education visits (Visits 2-7), received 0% of the PreDM education offered **CONTROL complete (n = 8)**, submitted package of information at Visit 1 and 6-month F/U **CONTROL incomplete (n = 7)**, submitted package of information at Visit 1, did not submit 6-month F/U package by mail

PREPARE Attendance

Study ID	Base-line	6 Prediabetes Education Sessions						1-mo F/U	Total Visits Atten-ded	Cooking Workshops							Total CW Atten-ded
	V1	V2	V3	V4	V5	V6	V7	V8		CW 1	CW 2	CW 3	CW 4	CW 5	CW 6	CW 7	
P-1001	Y	Y	Y	Y	Y				5				c				0
P-1002	Y	Y					Y		3				c				0
P-1003	Y	Y	Y	Y	Y			Y	6	Y	Y	Y	c	Y		Y	5
P-1004	Y	Y	Y				Y		4				c				0
P-1005	Y								1				c				0
P-1006	Y	Y	Y		Y	Y	Y	Y	7				c				0
P-1007	Y		Y						2				c				0
P-1008	Y	Y							2				c				0
P-1009	Y								1				c				0
P-1010	Y								1				c				0
P-1011	Y		Y	Y	Y	Y	Y	Y	7				c				0
P-1012	Y	Y	Y	Y	Y	Y	Y	Y	8	Y	Y	Y	c	Y	Y		5
P-1013	Y	Y		Y					3	Y	Y		c				2
P-1014	Y	Y	Y	Y	Y	Y	Y	Y	8				c				0
P-1015	Y	Y	Y	Y	Y	Y	Y	Y	8				c				0
P-1016	Y								1				c				0
P-1017	Y	Y	Y	Y					4				c				0
P-1018	Y	Y		Y	Y			Y	5				c				0
P-1019	Y	Y	Y				Y	Y	5	Y			c				1
P-1020	Y	Y		Y					3				c				0
P-1021	Y	Y						Y	3				c				0
P-1022	Y	Y							2				c				0
P-1023	Y	Y					Y	Y	4	Y			c				1
P-1024	Y	Y	Y	Y	Y	Y	Y	Y	8	c		Y	Y			Y	3
P-1025	Y	Y							2	c							0
P-1026	Y	Y							2	c							0
P-1027	Y	Y	Y	Y	Y	Y	Y	Y	8	c		Y		Y			2
P-1029	Y	Y	Y		Y			Y	5	c	Y						1
P-1030	Y								1	c							0
P-1032	Y	Y	Y	Y					4	c	Y	Y					2
P-1033	Y								1	c							0
P-1035	Y	Y	Y	Y		Y	Y	Y	7	c	Y	Y		Y	Y	Y	5
P-1036	Y								1	c							0
P-1037	Y	Y	Y	Y	Y	Y		Y	7	c			Y				1
P-1038	Y								1	c							0
P-1039	Y	Y	Y	Y	Y	Y	Y	Y	8	c	Y	Y	Y	Y	Y	Y	6
P-1040	Y							Y	2	c							0
P-1041	Y	Y	Y	Y	Y	Y		Y	7	c	Y	Y		Y			3
P-1042	Y	Y	Y						3	c	Y						1
P-1043	Y	Y	Y	Y	Y	Y	Y	Y	8	c	Y		Y		Y	Y	4
P-1044	Y	Y	Y	Y	Y	Y	Y	Y	8	c	Y	Y	Y				3
P-1045	Y	Y	Y	Y	Y	Y	Y	Y	8	c	Y	Y	Y	Y			4
P-1046	Y	Y		Y	Y	Y	Y	Y	7	c	Y						1
P-1047	Y	Y	Y	Y	Y				5	c							0
P-1048	Y	Y	Y		Y	Y	Y	Y	7	c							0
P-1049	Y								1	c							0
P-1050	Y								1	c							0
P-1051	Y								1	c							0
n	**48**	**34**	**25**	**22**	**20**	**16**	**18**	**23**	**n/a**	**5**	**13**	**10**	**6**	**7**	**4**	**5**	**n/a**

PREPARE Attendance
with Sub-Classification of High Attendees, Low Attendees, Non Attendees

Study ID	Base-line	6 Prediabetes Education Sessions						1-mo F/U	Total Visits Atten-ded	Cooking Workshops							Total CW Atten-ded
	V1	V2	V3	V4	V5	V6	V7	V8		CW 1	CW 2	CW 3	CW 4	CW 5	CW 6	CW 7	
P-1001	Y	Y	Y	Y	Y				5				c				0
P-1002	Y	Y					Y		3				c				0
P-1003	Y	Y	Y	Y	Y			Y	6	Y	Y	Y	c	Y		Y	5
P-1004	Y	Y	Y				Y		4				c				0
P-1005	Y								1				c				0
P-1006	Y	Y	Y		Y	Y	Y	Y	7				c				0
P-1007	Y		Y						2				c				0
P-1008	Y	Y							2				c				0
P-1009	Y								1				c				0
P-1010	Y								1				c				0
P-1011	Y		Y	Y	Y	Y	Y	Y	7				c				0
P-1012	Y	Y	Y	Y	Y	Y	Y	Y	8	Y	Y	Y	c	Y	Y		5
P-1013	Y	Y		Y					3	Y	Y		c				2
P-1014	Y	Y	Y	Y	Y	Y	Y	Y	8				c				0
P-1015	Y	Y	Y	Y	Y	Y	Y	Y	8				c				0
P-1016	Y								1				c				0
P-1017	Y	Y	Y	Y					4				c				0
P-1018	Y	Y		Y	Y			Y	5				c				0
P-1019	Y	Y	Y				Y	Y	5	Y			c				1
P-1020	Y	Y		Y					3				c				0
P-1021	Y	Y						Y	3				c				0
P-1022	Y	Y							2				c				0
P-1023	Y	Y					Y	Y	4	Y			c				1
P-1024	Y	Y	Y	Y	Y	Y	Y	Y	8	c		Y	Y			Y	3
P-1025	Y	Y							2	c							0
P-1026	Y	Y							2	c							0
P-1027	Y	Y	Y	Y	Y	Y	Y	Y	8	c		Y		Y			2
P-1029	Y	Y	Y		Y			Y	5	c	Y						1
P-1030	Y								1	c							0
P-1032	Y	Y	Y	Y					4	c	Y	Y					2
P-1033	Y								1	c							0
P-1035	Y	Y	Y	Y		Y	Y	Y	7	c	Y	Y		Y	Y	Y	5
P-1036	Y								1	c							0
P-1037	Y	Y	Y	Y	Y	Y		Y	7	c			Y				1
P-1038	Y								1	c							0
P-1039	Y	Y	Y	Y	Y	Y	Y	Y	8	c	Y	Y	Y	Y	Y	Y	6
P-1040	Y							Y	2	c							0
P-1041	Y	Y	Y	Y	Y	Y		Y	7	c	Y	Y		Y			3
P-1042	Y	Y	Y						3	c	Y						1
P-1043	Y	Y	Y	Y	Y	Y	Y	Y	8	c	Y		Y		Y	Y	4
P-1044	Y	Y	Y	Y	Y	Y	Y	Y	8	c	Y	Y	Y				3
P-1045	Y	Y	Y	Y	Y	Y	Y	Y	8	c	Y	Y	Y	Y			4
P-1046	Y	Y		Y	Y	Y	Y	Y	7	c	Y						1
P-1047	Y	Y	Y	Y	Y				5	c							0
P-1048	Y	Y	Y		Y	Y	Y	Y	7	c							0
P-1049	Y								1	c							0
P-1050	Y								1	c							0
P-1051	Y								1	c							0
n	**48**	**34**	**25**	**22**	**20**	**16**	**18**	**23**	**n/a**	**5**	**13**	**10**	**6**	**7**	**4**	**5**	**n/a**

CONTROL Attendance

Study ID	Base-line	6 Prediabetes Education Sessions						1-mo F/U	Total # of Con-tacts	Cooking Workshops							Total CW Atten-ded
	V1	V2	V3	V4	V5	V6	V7	V8		CW 1	CW 2	CW 3	CW 4	CW 5	CW 6	CW 7	
C-2001	Y	n/a	n/a	n/a	n/a	n/a	n/a		1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
C-2002	Y	n/a	n/a	n/a	n/a	n/a	n/a	Y	2	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
C-2003	Y	n/a	n/a	n/a	n/a	n/a	n/a	Y	2	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
C-2004	Y	n/a	n/a	n/a	n/a	n/a	n/a	Y	2	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
C-2005	Y	n/a	n/a	n/a	n/a	n/a	n/a		1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
C-2006	Y	n/a	n/a	n/a	n/a	n/a	n/a		1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
C-2007	Y	n/a	n/a	n/a	n/a	n/a	n/a	Y	2	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
C-2008	Y	n/a	n/a	n/a	n/a	n/a	n/a	Y	2	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
C-2009	Y	n/a	n/a	n/a	n/a	n/a	n/a	Y	2	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
C-2010	Y	n/a	n/a	n/a	n/a	n/a	n/a	with-drew	1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
C-2101	Y	n/a	n/a	n/a	n/a	n/a	n/a		1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
C-2012	Y	n/a	n/a	n/a	n/a	n/a	n/a		1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
C-2013	Y	n/a	n/a	n/a	n/a	n/a	n/a		1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
C-2014	Y	n/a	n/a	n/a	n/a	n/a	n/a	Y	2	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
C-2015	Y	n/a	n/a	n/a	n/a	n/a	n/a		1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
n	**15**	**n/a**	**n/a**	**n/a**	**n/a**	**n/a**	**n/a**	**7**	**n/a**	**n/a**	**n/a**	**n/a**	**n/a**	**n/a**	**n/a**	**n/a**	**n/a**

Note: C-2010 withdrew from the study at the 1-month F/U point due to a diagnosis of colon cancer.

CONTROL Attendance (Scored)

Study ID	Base-line	6 Prediabetes Education Sessions						1-mo F/U	Total # of Con-tacts	Cooking Workshops							Total CW Atten-ded
	V1	V2	V3	V4	V5	V6	V7	V8		CW 1	CW 2	CW 3	CW 4	CW 5	CW 6	CW 7	
C-2001	Y	n/a	n/a	n/a	n/a	n/a	n/a		1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
C-2002	Y	n/a	n/a	n/a	n/a	n/a	n/a	Y	2	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
C-2003	Y	n/a	n/a	n/a	n/a	n/a	n/a	Y	2	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
C-2004	Y	n/a	n/a	n/a	n/a	n/a	n/a	Y	2	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
C-2005	Y	n/a	n/a	n/a	n/a	n/a	n/a		1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
C-2006	Y	n/a	n/a	n/a	n/a	n/a	n/a		1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
C-2007	Y	n/a	n/a	n/a	n/a	n/a	n/a	Y	2	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
C-2008	Y	n/a	n/a	n/a	n/a	n/a	n/a	Y	2	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
C-2009	Y	n/a	n/a	n/a	n/a	n/a	n/a	Y	2	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
C-2010	Y	n/a	n/a	n/a	n/a	n/a	n/a	with-drew	1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
C-2101	Y	n/a	n/a	n/a	n/a	n/a	n/a		1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
C-2012	Y	n/a	n/a	n/a	n/a	n/a	n/a	Y	1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
C-2013	Y	n/a	n/a	n/a	n/a	n/a	n/a		1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
C-2014	Y	n/a	n/a	n/a	n/a	n/a	n/a	Y	2	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
C-2015	Y	n/a	n/a	n/a	n/a	n/a	n/a		1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
n	**15**	**n/a**	**n/a**	**n/a**	**n/a**	**n/a**	**n/a**	**8**	**n/a**	**n/a**	**n/a**	**n/a**	**n/a**	**n/a**	**n/a**	**n/a**	**n/a**

Appendix X: Overall Program Feedback Form Responses

Program Feedback Form

Date: **December 2011 & March 2012**
COHORTS 1& 2 (22 participants)

Your feedback is important to us. Your thoughts and opinions are valuable to us as they will help us to determine if **prepare** is a worthwhile program that should continue. In addition, your suggestions for improvements to the program will enable us to offer the best program possible to others and may even set the standard for healthcare in Canada!

Section 1: Overall Evaluation

A. I would recommend this program to a friend or family member

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
0/22	0/22	2/22	4/22	15/22	1/22
0%	0%	9%	18%	68%	5%

B. ***What I liked most*** about my experience with the **prepare** program was:

- Student interaction.
- Information on healthy foods, what fatty foods are, and sodium.
- All of the information given, and the way the girls explained. Loved the exercise sessions. All girls were very friendly and helpful.
- Questions were answered.
- The nice people who put on the program - lots of good information.
- The exercise ideas & snack ideas.
- How important it is to eat well and exercise.
- How friendly and helpful everyone was.
- The information that we were given, so that we may be able to stop diabetes or delay it.
- Learning about the nutritional side - what can be in certain food types that you aren't aware of.
- Positive atmosphere.
- Learning about healthy choices & how to balance my diet. Also learning how to read & understand nutrition labels.
- It was interesting and very informative.
- Education.
- Informative.
- Hands on cooking classes.
- Information on diet and food values.
- Cooking classes & recipes.
- Education portion - tips on foods.
- No response provided (x 3 participants)

C. ***What I liked least*** about my experience with the **prepare** program was:

- Paperwork. Not enough feedback from all that paperwork.
- Loose pieces given out with no order in folder. (Give info out to put in binders, in sections per week.)
- None of it. Loved all my visits. Learned a lot. Thank you so much!
- Handouts at start - there were a lot.

- It took too much time, was not self-paced (info came in a slow trickle), and there was limited personal feedback on a week-to-week basis. It was not personalized. The food log was tedious (in its current form).
- Goal setting.
- The long questionnaires and food logs.
- Time filling out forms.
- There wasn't anything that I found I liked least.
- Too basic.
- Gym exercises.
- Individual attention.
- Filling out forms.
- Weather prevented me from coming to cooking class.
- Group physical activity.
- Nothing. (x 2 responses)
- No response provided (x 5 participants)

Section 2: Format

A. I found the length of the **prepare** program to be

○ Too long	○ Just right	○ Too short	Left Blank
3/22	18/22	0/22	1/22
14%	82%	0%	4%

B. I found the length of the education sessions

○ Too long	○ Just right	○ Too short	Left Blank
3/22	17/22	1/22	1/22
14%	77%	5%	4%

C. I found the frequency of the education sessions to be

○ Too often	○ Just right	○ Not often enough	Left Blank
1/22	17/22	3/22	1/22
5%	77%	14%	4%

D. I found that the Friday afternoon timing of the education sessions suited my needs

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
1/22	2/22	6/22	5/22	5/22	3/22
4%	9%	27%	23%	23%	14%

E. I found that the Thursday evening timing of the education sessions suited my needs

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
1/22	2/22	1/22	13/22	4/22	1/22
5%	9%	5%	59%	18%	4%

G. I took advantage of the option to corresponding by email

○ Yes	○ No	Left Blank
6/22	16/22	0/22
27%	73%	0%

H. I took advantage of the information on the Brescia prediabetes Web pages

○ Yes	○ No	Left Blank
4/22	18/22	0/22
18%	82%	0%

Section 3: Interaction with the prepare team

A. I found the student volunteers were helpful

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
0/22	0/22	0/22	6/22	16/22	0/22
0%	0%	0%	27%	73%	0%

B. I found the student volunteers were knowledgeable and skilled

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
0/22	0/22	0/22	13/22	9/22	0/22
0%	0%	0%	59%	41%	0%

C. I found the student volunteers were welcoming/friendly

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
0/22	0/22	0/22	5/22	17/22	0/22
0%	0%	0%	23%	77%	0%

D. I valued having a health professional available

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
0/22	0/22	1/22	6/22	14/22	1/22
0%	0%	5%	27%	64%	4%

E. I was treated with respect

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
0/22	0/22	0/22	6/22	16/22	0/22
0%	0%	0%	27%	73%	0%

F. My confidentiality was maintained

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
0/22	0/22	2/22	6/22	13/22	1/22
0%	0%	9%	27%	59%	5%

G I enjoyed the interactive nature of the sessions

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
0/22	0/22	5/22	6/22	11/22	0/22
0%	0%	23%	27%	50%	0%

H. I found the individual "drop in" periods with the dietitian useful

○ not applicable	○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
14/22	0/22	0/22	1/22	4/22	2/22	1/22
64%	0%	0%	4%	18%	9%	5%

I. I enjoyed the group nature of the program

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
0/22	1/22	5/22	11/22	5/22	0/22
0%	4%	23%	50%	23%	0%

J. Please indicate any other comments you may have about the **interaction** with the staff and volunteers as part of the **prepare** program:

- Everyone was great.
- There was no personalized feedback to speak of.
- Great staff + volunteers.
- Everyone was very helpful and pleasant.
- Found them all to be very knowledgeable & extremely friendly.
- Staff and volunteers always cheerful & helpful - thanks!
- No response provided (x 16 participants)

Section 4: Facilities

A. I found the location of the sessions suited my needs

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
0/22	0/22	2/22	10/22	10/22	0/22
0%	0%	9%	45%	46%	00%

B. I found the location of the sessions was convenient for me

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
0/22	0/22	2/22	11/22	9/22	0/22
0%	0%	9%	50%	41%	0%

C. I valued the free parking

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
0/22	0/22	1/22	7/22	13/22	1/22
0%	0%	4%	32%	59%	5%

Session 5: Nutrition Component

A. I benefited from the nutrition sessions

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
0/22	1/22 "Too basic"	0/22	9/22	12/22	0/22
0%	4%	0%	41%	55%	0%

B. I found the educational information provided during the nutrition sessions

○ Very useful	○ Useful	○ Not very useful	Left Blank
15/22	6/22	1/22	0/22
68%	27%	5%	0%

C. I found the amount of information provided at each session to be

○ Too much	○ Just right	○ Not enough	Left Blank
3/22 "Too detailed – K.I.S.S." "Not well organized"	15/22	3/22	1/22
14%	68%	14%	4%

D. I found the information provided during the nutrition sessions easy to understand

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
0/22	0/22	1/22	16/22	5/22	0/22
0%	0%	4%	73%	23%	0%

E. I found the nutrition sessions practical

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
0/22	0/22	1/22	16/22	5/22	0/22
0%	0%	4%	73%	23%	0%

F. I found the nutrition sessions interactive

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
0/22	0/22	5/22	12/22	4/22	1/22
0%	0%	23%	55%	18%	4%

G. I enjoyed the interactive food demonstrations

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
0/22	1/22	3/22	9/22	8/22	1/22
0%	4%	14%	41%	36%	5%

H. I took away some practical ideas from the food demonstrations

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
0/22	0/22	2/22	11/22	8/22	1/22
0%	0%	9%	50%	36%	5%

I. I enjoyed the interactive *optional monthly cooking workshops*

○ not applicable	○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
8/22	0/22	0/22	2/22	3/22	9/22	0/22
36%	0%	0%	9%	14%	41%	0%

J. I took away some practical ideas from the *cooking workshops*

○ not applicable	○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
8/22	1/22	0/22	1/22	4/22	8/22	0/22
36%	5%	0%	5%	18%	36%	0%

K. I found the frequency of the *optional* cooking workshops was

○ Too often	○ Just right	○ Not often enough	Left Blank
0/22	15/22	1/22	6/22
0%	68%	5%	27%

L. I found that the monthly healthy eating goals kept me on track with respect to my nutrition goals

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
0/22	1/22	4/22	14/22	2/22	1/22
0%	5%	18%	64%	9%	4%

M. I will continue to set healthy eating goals to keep me on track in the future

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
0/22	0/22	2/22	15/22	5/22	0/22
0%	0%	9%	68%	23%	0%

N. I found the monthly food records useful for keeping me on track with my healthy eating goals

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
2/22 "Feedback would have been appreciated if more integrated with my personal record intake."	0/22	1/22	13/22	5/22	1/22
9%	0%	4%	59%	23%	5%

O. I will continue to record my food intake to help me to stay on track with my healthy eating goals

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
2/22 "Not in the fashion requested in this study."	1/22	4/22	13/22	2/22	0/22
9%	5%	18%	59%	9%	0%

P. I have been able to make positive changes to my diet during the program

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
0/22	0/22	2/22	14/22	6/22	0/22
0%	0%	9%	64%	27%	0%

Q. The nutrition component of **prepare** has enhanced my skills

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
0/22	0/22	3/22	13/22	5/22	1/22
0%	0%	14%	59%	23%	4%

R. I feel confident that I can continue to implement many of the healthy eating strategies I have learned as part of the **prepare** program

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
0/22	0/22	2/22	16/22	3/22	1/22
0%	0%	9%	73%	14%	4%

S. I believe that the fact I was following the **prepare** program had a positive impact on the eating habits of my family member(s).

○ not applicable	○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
8/22	0/22	1/22	3/22	7/22	3/22	0/22
36%	0%	4%	14%	32%	14%	0%

Section 6: Physical Activity Component

A. I enjoyed the educational information provided during the physical activity sessions

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
0/22	3/22	2/22	12/22	5/22	0/22
0%	14%	9%	54%	23%	0%

B. I found the educational information provided during the physical activity sessions useful

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
1/22	1/22	4/22	10/22	5/22	1/22
4%	5%	18%	45%	23%	5%

C. I found the amount of information provided at each session to be appropriate

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
1/22	1/22	4/22	12/22	3/22	1/22
4%	4%	18%	55%	14%	5%

D. I found the information provided during the physical activity sessions easy to understand

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
1/22	0/22	3/22	12/22	6/22	0/22
4%	0%	14%	55%	27%	0%

E. I enjoyed participating in the interactive physical activity sessions

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
1/22	3/22	3/22	9/22	6/22	0/22
4%	14%	14%	41%	27%	0%

Fa. I found the interactive physical activity sessions easy to understand

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
0/22	0/22	2/22	12/22	7/22	1/22
0%	0%	9%	55%	32%	4%

Fb. I found the interactive physical activity sessions easy to follow

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
0/22	0/22	3/22	11/22	7/22	1/22
0%	0%	14%	50%	32%	4%

G. I found the interactive physical activity sessions useful

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
2/22	2/22	2/22	11/22	4/22	1/22
9%	9%	9%	50%	18%	5%

H. I found the physical activity sessions were safe for me

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
0/22	1/22	2/22	11/22	7/22	1/22
0%	4%	9%	50%	32%	5%

I. I enjoyed participating in the *optional* weekly walking program

○ not applicable	○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
18/22	1/22	1/22	0/22	0/22	1/22	1/22
82%	4%	5%	0%	0%	4%	5%

J. I found that the walking program kept me on track with respect to my physical activity goals

○ not applicable	○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
17/22	2/22	0/22	1/22	0/22	1/22	1/22
77%	9%	0%	4%	0%	5%	5%

K. I believe the monthly goal setting helped me to stay on track with my physical activity goals

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
1/22	2/22	3/22	11/22	4/22	1/22
4%	9%	14%	50%	18%	5%

L. I will continue to set physical activity goals to keep me on track in the future

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
0/22	0/22	3/22	14/22	5/22	0/22
0%	0%	14%	64%	22%	0%

M. I found the physical activity and step logs useful for keeping me on track with my physical activity goals

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
1/22	1/22	2/22	12/22	5/22	1/22
4%	4%	9%	55%	23%	5%

N. I will continue to keep a physical activity and step log to help me to stay on track with my physical activity goals in the future

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
1/22	1/22	4/22	11/22	4/22	1/22
4%	5%	18%	50%	18%	5%

O. Overall, I feel my participation in the physical activity component of **prepare** has helped me to make positive changes in my physical activity level

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
1/22	0/22	4/22	11/22	5/22 "Only the tip about 10,000 steps per day. Nothing else."	1/22
4%	0%	18%	50%	23%	5%

P. Overall, I feel more confident in my ability to perform physical activity due to my participation in the **prepare** program

○ Strongly disagree	○ Disagree	○ Neither agree or disagree	○ Agree	○ Strongly agree	Left Blank
2/22	1/22	4/22	10/22	4/22	1/22
9%	4%	18%	46%	18%	5%

Section 7: Follow-Up

C. Would you be interested in receiving long-term follow-up?

○ Yes	○ No	Left Blank
19/22	1/22	2/22 "? – Depends on what it entails."
86%	5%	9%

D. If yes, what type of follow-up would you be interested in receiving? Please explain.

- Blood work and food intake records.
- One-on-one.
- Measures - blood sugar test and physical parameters.
- 6 monthly, perhaps weight and waist measurements.
- Only weigh-in, measurements, BMI follow-up.
- All my results – blood work.
- Email updates and new recipes. More education and activity sessions every 3 to 6 months.
- Emails of nutritional ideas or any new updates or views on how to "fight" prediabetes.
- New developments, new recipes & food info.
- Phone call.
- Physical exercise - diet - weight loss.
- No response provided (x 11 participants)

Thank you very much for your feedback!

Curriculum Vitae

Name: Jennifer Broxterman, RD

Post-secondary Education and Degrees:

Queen's University (Life Sciences)
Kingston, Ontario, Canada
2003-2007 B.Sc.

The University of Western Ontario (Foods & Nutrition)
London, Ontario, Canada
2007-2009 B.Sc.H.

London Health Sciences Centre (Accredited Dietetic Internship)
London, Ontario, Canada
2009-2010 R.D.

The University of Western Ontario (Foods & Nutrition)
London, Ontario, Canada
2010-2012 M.Sc.

Honours and Awards:

Ontario Graduate Scholarship
2010-2012

Brescia University College, Young Alumni Award of Merit
London, Ontario, Canada
2011

Related Work Experience:

CEO & Private Practice Registered Dietitian
NutritionRx
2010-present

Contract Professor
Brescia University College, Dept. of Foods & Nutritional Sciences
London, Ontario, Canada
2011-present

Course Assistant (Teaching Assistant)
The University of Western Ontario
2010-2011

Publications:

Palmer, M., Paramore, J., Broxterman, J., Goss, P., & Parulekar, W. (2007). Efforts to increase activation of sites in a clinical trial involving re-randomization. *Clinical Trials, 4*(408), 34.

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Conference Abstracts:

Broxterman, JN., Burke, N., Craig, L., Orchard, C., & Giroux, I. (2011). The Prediabetes Initiative and Partnership student experiential interdisciplinary learning in London, Ontario. *National Health Sciences Students Association 2011 Conference.*

Giroux, I., Dworatzek, PDN., Battram, DS., Colby, P., Mathyssen, J., Broxterman, JN., Mandich, G., & Hramiak, I. (2011). Genesis of the "Prediabetes Initiative and Partnership." *Dietitians of Canada 2011 Conference.*

Shier, A., Giroux, I., Broxterman, JN., Colby, P., Battram, DS., Dworatzek, PDN., Mandich, G., & Hramiak, I. (2012). Cooking workshop experience of middle and older adults participating in the PREPARE prediabetes lifestyle intervention program. *Canadian Diabetes Association 2012 Conference.*

Broxterman, JN., Giroux, I., Battram, DS., Dworatzek, PDN., Mandich, GE., Colby, P., Mathyssen, J., & Hramiak, I. (2012). Impact of a pilot group lifestyle behaviour change program ("PREPARE") on nutritional and health characteristics in adults with prediabetes. *Canadian Diabetes Association 2012 Conference.*