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University of Alberta

Lifestyle Intervention for Individuals with Type 2 Diabetes

By

Sian Hoe Cheong 

A thesis submitted to the Faculty of Graduate Studies and Research in partial fulfillment of the requirements for the degree of Master of Science

In

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Abstract:

The First Step Program (FSP) has been successful in increasing the physical activity among individuals with Type 2 Diabetes (T2D). This study determined the effects of combining a simple nutrition message of eating more low glycemic index (GI) foods with the simple FSP message of walking more (the First Step First Bite Program, FSFB) on health outcomes in T2D individuals vs. the FSP alone. After 16 weeks (n = 19/group), both groups had increased their walking by about 31 minutes/day. In the FSFB vs. FSP groups respectively, waist and hip girths decreased by 3.7 ± 0.5 vs. 5.9 ± 0.9 cm and 2.2 ± 0.5 vs. 3.7 ± 0.6 cm ($p<0.01$ over time, both groups). FSFB participants increased low GI foods by 2.2 ± 0.7 servings/day ($p<0.01$); FSP did not. Simple messages delivered in the FSFB over a short period of time in a group setting were successful in promoting lifestyle change.

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Abbreviations:

A1C	Glycosylated hemoglobin
ACSM	American College of Sports Medicine
ADA	American Diabetes Association
ASCN	American Society for Clinical Nutrition
BMI	Body mass index
CDA	Canadian Diabetes Association
CVD	Cardiovascular disease
DCCT	Diabetes Control and Complication Trial
DEXA	Dual energy X-Ray absorptiometry
DPP	Diabetes Prevention Program
FSFB	First Step First Bite Program
FSP	First Step Program
FPG	Fasting plasma glucose
HDL	High density lipoprotein
IFP	Impaired fasting glucose
IGT	Impaired glucose tolerance
LDL	Low density lipoprotein
NIH	National Institute of Health
GI	Glycemic index
OGTT	Oral glucose tolerance test
PAI-1	Plasminogen activator inhibitor-1
PG	Plasma glucose
RD	Registered Dietitian
RN	Registered Nurse
T1D	Type 1 diabetes
T2D	Type 2 diabetes
TG	Triglycerides
UKPDS	United Kingdom Prospective Diabetes Study
VO_{2max}	Maximal oxygen uptake
2hPG	2-hour-plasma-glucose

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Chapter 1: Introduction

1.1 Rationale:

Healthy eating and physical activity are cornerstones in the management of Type 2 Diabetes (T2D). A recent position statement by the American Diabetes Association (ADA), North American Association for the Study of Obesity, and American Society for Clinical Nutrition (ASCN) continues to emphasize the importance of lifestyle interventions involving healthy eating and physical activity in T2D management (Klein, et al, 2004). Numerous studies have demonstrated that combining both nutrition and physical activity, i.e. lifestyle modification, can improve the metabolic control of T2D (Kelley, et al, 2004; Wolf, et al, 2004; Goldhaber-Fiebert, et al, 2003; Toobert, et al, 2003; Krook, et al, 2003; Sone, et al, 2002; Gaede, et al, 2001; Agrus-Collins, et al, 1997). However, there continues to be a need for programs that are effective and easy to implement.

Recent clinical practice guidelines released by the Canadian Diabetes Association (CDA) suggested that individuals with diabetes should follow a healthy diet as outlined in Canada's Food Guide for Healthy Eating, and when possible, replace foods that have a high glycemic index (GI) with foods that have a lower GI (CDA, 2003). Today, evidence exists in supporting a positive role of low GI diets or foods in improving the metabolic control of T2D (Brand-Miller, et al 2003; Jarvi, et al, 1999; Frost, et al, 1994; Fontvielle, et al, 1992; Wolever, et al, 1992a, b; Brand, et al, 1991;Jenkins, et al, 1988). A meta-analysis conducted by Brand-Miller showed that consumption of a low GI diet can potentially reduce haemoglobin A1C (A1C) concentrations by 0.43 unit compared with a high GI diet (Brand-Miller, et al, 2003). A recent evidence-based technical review by the

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CDA has given evidence for the use of low GI foods in improving the glycemic control in individuals with T2D a Grade B, Level 2 (Kalergies, et al, 2005). Stemming from this recommendation, CDA has developed and released its new GI education teaching tools (described in subsequent chapters), to help diabetes educators and individuals with diabetes incorporate low GI foods as part of a healthy eating plan in managing diabetes.

Physical activity guidelines and recommendations have been established for both the general population and for people with T2D (Sigal, et al, 2004; CDA, 2003; ADA and ACSM, 1997; Health Canada and Canadian Society for Exercise Physiology, 1998; NIH Consensus Development Panel on Physical Activity and Cardiovascular Health, 1996; Pate, et al, 1995). Specifically, the CDA recommends that individuals with T2D should "accumulate at least 150 minutes of moderate-intensity aerobic exercise each week" (CDA 2003). Physical activity of moderate intensity includes brisk walking, biking, raking leaves, swimming, dancing and water aerobics (Health Canada and Canadian Society for Exercise Physiology, 1998). Despite the well-known benefits of physical activity on the management of T2D, the prevalence of sedentary behaviour or low physical activity levels among individuals with T2D is high (Nelson, et al, 2002; Hays, et al 1999; Ford, et al, 1995).

Previously, Dr. Catrine Tudor-Locke and colleagues developed a pedometer-based walking program called the First Step Program (FSP) that has been shown to be successful at helping people with T2D increase their physical activity (Tudor-Locke, et al, 2002; Tudor-Locke, et al, 2004). The FSP is a facilitated, behaviour-modification program designed to help people with T2D increase their physical activity. It is based on the principles of self-efficacy and social support, and uses goal setting, self-monitoring

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and feedback (using a pedometer) to help achieve this (Tudor-Locke, et al, 2001, Tudor-Locke, et al, 2000). The FSP has undergone rigorous evaluation and has been shown to be acceptable to diabetes educators, peer leaders and people with T2D (Tudor-Locke, et al, 2000).

Despite significant increases in physical activity observed among the FSP participants, the changes in physiological health indicators, such as fasting glucose, insulin and plasma lipids, resting heart rate and blood pressure, body weight, hip and waist girths, and oral glucose tolerance observed over the 24 weeks of the study were small (Tudor-Locke, et al, 2004). It is possible that given the self-directed nature of the FSP, participants did not increase their physical activity enough to cause changes in these indicators. Furthermore, the FSP does not provide any dietary advice or information that may help to optimize glycemic control, and lower the risk of cardiovascular disease (CVD). Therefore, it is likely that a greater magnitude of health benefits could be observed if participants were to make changes in dietary intake at the same time increase their physical activity.

It remains of paramount importance to develop, implement, critically evaluate, and disseminate programs that may be effective in helping people with T2D make lifestyle changes that facilitate the management of this condition. Dr. Tudor-Locke and colleagues have previously demonstrated success with the FSP in terms of encouraging physical activity. Incorporating a simple nutritional message and a feedback/motivational tool regarding dietary intake into the FSP, in a manner that is parallel to the simple physical activity message and a pedometer as the

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feedback/motivational tool encouraging physical activity, may provide complementary strategies to manage glycemia and reduce CVD factors in this population.

1.2 Purpose:

The overall purpose of this First Step First Bite (FSFB) research project was to examine whether a lifestyle modification program that incorporates both a simple nutritional message of "eat more low GI foods" and a simple physical activity message of "walk more", positively affects glycemic control in people with T2D. The effects of the FSFB, were compared to those of the FSP (i.e. physical activity message alone), to determine the impact of combining the nutrition and physical activity messages compared to the impact of physical activity message alone.

1.3 Hypothesis:

We hypothesized that upon the completion of the FSFB, participants in this group would increase their daily intake of low GI food in addition to increasing in their physical activity. Consequently, such lifestyle changes would lead to improvements in health parameters.

The specific hypotheses of this project were:

1. The improvements in physiological health indicators (i.e. glycemic control, body weight, waist and hip girths, resting blood pressure, resting heart rate and percentage body fat/body fat mass) would be greater in the FSFB participants, compared to FSP participants at the end of the research study.

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2. Participants in the FSFB would increase their daily intake of low GI foods compared to the FSP participants.

1.4 Objectives:

The objectives of this study were to compare changes in glycemic control and other health indicators in people with T2D who received the FSFB vs. FSP.

The specific objectives of this project were:

1. To compare the effects of participating in the FSFB vs. the FSP alone on steps/day, A1C, waist girth, hip girth, body weight, body composition resting blood pressure, resting heart rate and dietary intake (specifically macronutrients, the average daily intakes of low GI foods, fruits and vegetables, and milk products).

2. To evaluate the effect of FSFB on the average daily intake of low GI foods.

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Chapter 2: Literature review

2.1 Definition of Type 2 Diabetes:

Type 2 Diabetes (T2D), previously known as adult-onset diabetes or non-insulin-dependent diabetes, is a metabolic disease caused by defective insulin secretion, defective insulin action or both (ADA, 2004; CDA, 2003; Meltzer, et al, 1998). The disease is characterized by hyperglycemia. Classical symptoms of hyperglycemia include polyuria, polydypsia, weight loss (sometimes accompanied by polyphagia) and blurred vision. In some cases, chronic hyperglycemia may result in growth retardation and susceptibility to certain infections (ADA, 2004; CDA, 2003). Chronic hyperglycemia can result in long-term micro- and macro-vascular complications including retinopathy, nephropathy, neuropathy and CVD (ADA, 2004, CDA, 2003).

2.2 Pathophysiology:

The pathophysiology of T2D involves insulin resistance and insulin deficiency or an inadequate compensatory insulin secretory response (ADA, 2004; Guthrie, et al, 2004; Bardsley, et al, 2004). Insulin resistance, where the cells (particularly muscle and fat cells) become less sensitive to insulin, may be the first defect in T2D; and this process may begin a long time before the onset symptoms of hyperglycemia or T2D (ADA, 2004; Guthrie, et al, 2004).

Insulin is a protein hormone produced by the beta cells in the islets of Langerhans in the pancreas. It helps to control blood glucose concentrations by promoting glucose transport from the circulation into peripheral tissues. It also inhibits gluconeogenesis and

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glycogenolysis in the liver (Bardsley, et al, 2004; Guthrie, et al, 2004). One theory of how insulin resistance may lead to a decrease in beta cell function suggests that the beta cell may increase its production of insulin to maintain a normal blood glucose concentration. This can lead to hyperinsulinemia. If hyperinsulinemia persists, the beta cell will exhaust and cease to produce sufficient insulin to maintain normal blood glucose concentrations (Bardsley, et al, 2004; Guthrie, et al, 2004).

Insulin resistance is prevalent in people who are obese, but not all obese individuals will get T2D (Guthrie, et al, 2004). Only obese individuals with a genetic propensity for reduced pancreatic or beta cell function are at increased risk for T2D.

2.3 Prevalence and Risk Factors:

The incidence of T2D has been increasing at an alarming rate in North America (Boyle, et al, 2001; Mokdad, et al, 2000; Mokdad et al, 2001). The prevalence of diabetes rose from 4.9% in 1990 to 7.3% in 2000, and it is estimated to be at 8.7% in 2002 (ADA, 2004; Mokdad, et al, 2000; Mokdad, et al, 2001). Globally, Wild and colleagues projected that the number of people with diabetes will rise from 171 million in 2000 to 366 million in 2030 (Wild, et al, 2004). The increasing number of individuals with T2D is due to population growth, aging, urbanization, increasing incidence of obesity and inactivity (Boyle, et al, 2001; Wild, et al, 2004). Some of the major risk factors associated with T2D are summarized in Table 2.1.

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2.4 Screening and Diagnosis:

Mass screening for T2D in the general population is not suggested by the CDA due to its low cost-effectiveness (CDA, 2003). Instead, the recent CDA Clinical Practice Guidelines (CDA, 2003) recommend targeted screening of all individuals 40 years old or older for T2D every 3 years and more frequent for individuals who are at risk for T2D (CDA, 2003). Risk factors for T2D are outlined in Table 2.1.

The diagnostic criteria for diabetes (Type 1 or Type 2) are summarized in Table 2.2. Under these criteria, an individual has diabetes if they have any of the following: a casual plasma glucose (PG) ≥11.1 mmol/L with symptoms of diabetes mellitus or a fasting plasma glucose (FPG) ≥ 7.0 mmol/L. When a FPG is between 5.7 and 6.9 mmol/L, and there is a high suspicion of T2D or impaired glucose tolerance (IGT), a 2-hour-plasma-glucose (2hPG) in a 75g-oral-glucose-tolerance-test (OGTT) should be conducted (ADA, 2004; CDA 2003). A 2hPG (in an OGTT) value of ≥11.0 mmol/L is indicative of T2D.

The term "pre-diabetes" has been used to describe both impaired fasting glucose (IFG) and IGT. Table 2.3 shows the diagnostic criteria for IFG and IGT. Individuals with pre-diabetes are at high risk of developing T2D and its complications, including microvascular and macrovascular complications, and are also at risk for Metabolic Syndrome (CDA, 2003). Metabolic Syndrome, or Syndrome X, is a clustering of CVD and T2D risk factors, including abdominal obesity, hypertriglyceridemia, low levels of high-density lipoprotein cholesterol (HDL), hyperuricemia, plasminogen activator inhibitor 1 (PAI-1), hypertension and resistance to insulin-stimulated glucose uptake

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(Grundy, 2005; Kutschman RF, et al, 2004; Reaven, 1993). Individuals who have Metabolic Syndrome are at risk of developing diabetes and CVD.

2.5 Diabetes Management:

T2D is a chronic condition that requires on-going medical care and patient self-management education through the balance of lifestyle and medication. This process requires a multi- and inter-disciplinary team effort that includes diabetes health care professionals and the patient (ADA, 2004; CDA, 2003; Wolever, et al, 1999). Diabetes care is most effective when on-going support such as education and comprehensive care are delivered (CDA, 2003). The following sections describe some of the major aspects of diabetes management which include lifestyle modification addressing nutrition and physical activity, and medication. Due to the focus of this research project, particular attention will be placed on lifestyle interventions in T2D, specifically nutrition therapy and physical activity.

2.5.1.a Role of lifestyle modification in T2D prevention:

Evidence exists today demonstrating that individuals at high risk for T2D, who have achieved desired lifestyle changes, can reduce their risk of T2D. In recent years, there have been several studies demonstrating that intensive lifestyle interventions can ameliorate or reduce the incidence of diabetes among the population of people with IGT.

Two landmark studies have demonstrated the importance of sustained changes in lifestyle in reducing the development of T2D among IGT individuals. These were the Finnish Diabetes Prevention Study and the Diabetes Prevention Program (DPP). In the Finnish Diabetes Prevention Study (Tuomilehto, et al, 2001), 522 participants with IGT

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were randomized to either the control or intervention group. Each participant in the intervention group was offered seven sessions with a nutritionist during the first year of the study, followed by one session every three months thereafter. Participants in the intervention group also received individual guidance on increasing their level of physical activity which included supervised, progressive, individually-tailored training sessions. By the fourth year of the study, the cumulative incidence of T2D was 11% in the intervention group, and 23% in the control group. When compared to the control group, there was a significant 58% reduction in the risk of T2D in the intervention group ($p<0.001$).

The DPP had an experimental design that was similar to the Finnish Diabetes Prevention Study, and the results of both studies were similar (DPP Research Group, 2002). The DPP included a lifestyle intervention arm, as well as a metformin arm in the study. In the DPP, 3234 people with IGT were randomly assigned to one of three groups: standard lifestyle recommendations plus metformin (85mg bid), standard lifestyle recommendations plus placebo (bid), or an intensive lifestyle modification program. A 20-30 minute individual session was offered to the participants who were assigned to the standard lifestyle recommendations. The intensive lifestyle intervention group received a 16-lesson program, which covered nutrition, physical activity and behaviour modifications, with the goal of achieving and maintaining a weight reduction of 7% of initial body weight, and engaging at least 150 minutes/week of physical activity with moderate intensity. The program, was delivered by case managers on an individual basis during the first 24-week of the study, followed by subsequent monthly individual and group sessions. A 58% and 31% reduction of T2D was found in the lifestyle and the

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metformin groups respectively, when compared to the placebo group. When compared to the metformin and placebo groups at the end of the trial, not only was there a significant reduction in the incidence of T2D in the intensive lifestyle intervention group (as mentioned above), but a significant reduction of 5.6 kg in weight ($p<0.001$ for group comparison) was attained as well. These two studies clearly showed that individuals with IGT can reduce their risk of T2D by more than 50% if lifestyle modification is achieved.

As demonstrated in the Finnish Diabetes Prevention Study and the DPP, a combination of nutritional and physical activity interventions has a major role in reducing the incidence of T2D among those at high risk for the disease. The magnitude of such reduction was even greater compared to pharmacological intervention. People who are at risk of developing T2D should consider a lifestyle modification as a means of T2D prevention.

2.5.1.b Lifestyle intervention as a means of T2D management:

Lifestyle modification involving both nutrition and physical activity are the cornerstones in the management of T2D. A recent statement by the ADA, North American Association for the Study of Obesity and ASCN continued to emphasize the importance of lifestyle intervention in T2D management (Klein, et al, 2004). Specifically, these groups advocate the role of weight management or healthy body weight via lifestyle modification in the management of T2D. Ample evidence exists in supporting the role of lifestyle modification in improving health outcomes or reducing the CVD risk factors of individuals with T2D. Table 2.4 is a summary of several lifestyle intervention trials reviewed in the treatment of T2D.

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Optimal glycemic control is pivotal in reducing long-term complications in T2D. Ample evidence exists where a lifestyle modification program can improve glycemic control in individuals with T2D; a sample of the studies in this area is summarized in Table 2.4. In Goldhaber-Fiebert's study, a 12-week randomized controlled lifestyle intervention trial, using a community-based and group-centred public health approach was effective in improving the glycemic control among a group of Costa Ricans with T2D (Goldharber-Fiebert, et al, 2003). The lifestyle intervention included 11 weekly nutrition classes, and 12 weeks of a 60-minute group walking session, three times a week, at each community health centre. The thirty three participants in the treatment group improved their FPG and A1C values significantly, when compared to the 28 participants in the control group (Table 2.4).

Most studies to date have used a structured/supervised and intensive lifestyle intervention to evaluate the effectiveness of lifestyle interventions in improving T2D management. The effectiveness of a weight-loss and exercise program targeted specifically at older African Americans with T2D was assessed by Agrus-Collins and colleagues (Agrus-Collins, et al, 1997). Sixty four African-Americans aged >55 years were randomized to either the intervention or a usual care group. In the intervention group, 12 weekly group sessions (60 minutes of nutrition education followed by 30 minutes of physical activity) and 1 individual session were held in the first 3 months of the intervention. Then, six bi-weekly group sessions were offered during the subsequent 3 months of the intervention. In addition to the nutrition education, an exercise physiologist provided a one-on-one evaluation and exercise prescription for each of the participants in the intervention group. At the 6th month, participants in the intervention

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group achieved significant net reductions of -2.4% ($p<0.01$) for A1C values and -2.4 kg ($p<0.01$) in weight, compared to the usual care group.

Using a similarly structured and supervised Mediterranean lifestyle intervention program, Toobert and associates found that post-menopausal women with T2D could make comprehensive lifestyle changes, leading to improved glycemic control (Toobert, et al, 2003). The Mediterranean Lifestyle Program consisted of a diet low in saturated fat but high in mono-unsaturated fats. The physical activity component included 30 minutes of moderate aerobic activity per day, and twice a week of resistance exercise. A total of 245 women completed the trial. Women who were assigned to the Mediterranean Lifestyle program achieved a significant reduction in A1C values (-0.4%, $p = 0.02$) and BMI (-0.37 kg/m^2, $p = 0.02$) when compared to the control group.

In addition, a research study conducted by Kelley and associates showed that Orlistat, a weight loss medication, when combined with a 6-month lifestyle modification program, produced similar improvements in A1C values as a lifestyle intervention alone (Kelley, et al, 2004). In this study, a total of 39 participants with T2D met with a nutritionist weekly, who encouraged them to increase their physical activity levels and adhere to a healthy diet. Those who were assigned to the Orlistat group were instructed to take 120 mg of Orlistat before each meal; those assigned to the lifestyle intervention alone group received a placebo instead. Even though the Orlistat group achieved significantly better improvements in fasting insulin and free fatty acid concentrations in comparison to the lifestyle alone intervention group, the magnitude of improvement for the majority of the measured parameters was similar in the two groups (Table 2.4). This shows that with a lifestyle alone intervention, significant improvements in health

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outcomes, such as weight and FPG, can be achieved among the participants with T2D. The addition of Orlistat to a lifestyle modification program may further improve some health indicators, and may be useful as an adjunct therapy to diabetes management. Krooks and colleagues investigated the effectiveness of a residential lifestyle modification program for people with T2D who had not responded well to conventional diabetes management strategies (Krook, et al, 2003). One hundred and thirty nine women and one hundred and sixty five men were referred to this study by their physicians and participated in the residential lifestyle modification program, after failing to achieve optimal diabetes control through primary care settings or conventional management programs. The residential program consisted of an initial period and two follow-up periods during the 31 weeks of the study, in a treatment centre. During the residential period, participants spent a total of 3.5 weeks in the treatment centre and took part in a structured, supervised lifestyle intervention program. The program addressed nutritional and exercise aspects of T2D management, and also taught participants how to cope with stress. At the end of the study, the participants showed a significant reduction in A1C (-1.13 ± 0.12 %, $p<0.001$), weight (-2.82 ± 0.32 kg, $p>0.0001$), systolic (-3.10 ± 0.57 mmHg, $p<0.001$) and diastolic pressure (-4.21 ± 0.54 mmHg, $p<0.001$) when compared to baseline. These studies revealed that structured/supervised and intensive lifestyle modification over approximately 6 months can induce an improvement in glycemic control and reduce the risks of CVD.

The studies reviewed above suggest that lifestyle modification programs are effective over a relatively short time (<6 months). There are fewer studies that have evaluated effectiveness of such programs for longer period of time. In a long-term study by

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Vanninen et al, 78 individuals with T2D were randomly assigned to a usual care or an intervention group (Vanninen, et al, 1992). Besides receiving basic diabetes education (which involves in nutrition and exercise prescription), the intervention group also received bi-monthly follow-up visits with a multidisciplinary team of a physician, a dietitian (RD) and a nurse (RN) for up to 12 months. At the 12^{th} month, only the intervention group had reduced their fasting plasma insulin and increased their serum HDL concentrations significantly when compared to their baseline values.

A similar lifestyle intervention program was delivered in the ICAN study (Wolf, et al, 2004). However, in the ICAN study, intervention and follow-ups occurred 10 times throughout the 12-month study period, and participants worked with an RD rather than a whole diabetes team. A total of 147 participants were randomized to either the usual care group or the intervention group. At the end of the ICAN study, those in the intervention group lost a significant -2.4 ± 1.0 kg body weight ($p<0.05$ between groups) and -5.5 ± 1.0 cm waist circumference ($p<0.001$ between groups) when compared to the usual care group.

The Power Trial, another 12-month long lifestyle modification trial, also investigated the impact of lifestyle modification in T2D management (Mayer-Davis, et al, 2004). A total of 187 participants were randomly assigned to an intensive-lifestyle intervention, or a reimbursable-lifestyle intervention or a usual care group. The intensive-lifestyle intervention was based on the DPP and consisted of weekly meetings, up to 4 months and provided a core curriculum emphasizing diet and exercise to promote weight loss and T2D management. It was followed by regular follow-up visits for the remaining 8 months. Meanwhile, the reimbursable-lifestyle intervention provided lifestyle

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interventions for nutrition and physical activity that were delivered in a time frame allotted for Medicare reimbursement. Overall, this reimbursement group received four 1-hour sessions over the course of the 12-month study. At 12 months, the primary outcome measure, weight, was significantly reduced (-2.2 ± 0.4 kg, $p<0.001$) in the intensive-lifestyle group, but not in the reimbursement group, when compared to the baseline. Other secondary outcomes such as A1C and lipid profiles were not measured at 12-months.

Lifestyle modification in the management of T2D is a life long commitment. The research studies mentioned above provide evidence that long-term lifestyle interventions that are 1 year in duration can improve glycemic control and reduce risks of CVD. There are two studies that are more than 1 year in length, and these have demonstrated that adherence to lifestyle modifications for more than one year, with regular follow-up by health care professionals, had a continuing benefits in the management of T2D (Sone, et al, 2002; Gaede, et al, 2001). The Japan Diabetes Complications Study is a randomized, nationwide, multi-centre prospective study involving >2000 Japanese with T2D (Sone, et al, 2002). In this study, individuals assigned to the intervention group received intensive lifestyle intervention, involving diet and physical activity, and bi-weekly follow-up from a RN-educator during the study period. In addition, physicians regularly monitored participants' adherence to lifestyle changes. Meanwhile, the conventional treatment group received usual care with monitoring consistent with the usual care. The interim report of the study at the 3rd year revealed a modest, yet significant improvement of A1C values in the intervention group compared to the conventional treatment group at year 3 (7.53 ± 1.19 vs. 7.70 ± 1.23 %, $p<0.01$). In addition, Gaede and associates provided a

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similar lifestyle intervention program to their 80 study participants (N= 160 for total sample at randomization), except that this study has less frequent follow-up visits, i.e. at least 4 times/year, than the Japan Diabetes Complication Study (Gaede, et al, 2001). Eighty participants assigned to the usual care group received no special intervention and regular follow-up. At the end of the study, with a mean follow-up time of 3.8 years, participants in the intervention group reduced their A1C values, fasting triglycerides (TG) and total cholesterol significantly, compared to the usual group (all at $p<0.001$). These two research studies showed that with regular follow-ups, lifestyle modification can continue to have a positive impact on glycemic control for up to 3 years.

Clearly, lifestyle interventions incorporating both nutrition and physical activity can be a powerful approach in improving health outcomes in people with T2D. With on-going follow-ups by health care professionals, these improvements can be maintained in long term. Therefore, clinicians and people with T2D should consider lifestyle modification as a key part of diabetes management.

2.5.2 Nutrition Therapy:

The overall goal of diabetes management is to assist individuals with T2D and their support members to gain the necessary skills, knowledge and resources to achieve optimal health and well-being. A RD plays a key role in the diabetes health care team, where he/she should be responsible for helping people with T2D adopt appropriate nutrition management strategies (ADA, 2002; American Dietetic Association, 2003; CDA, 2003; Pastors, et al, 2002; Pastors, et al, 2003; ADA, 2001; Wolever, et al, 1999). The goals of nutrition therapy are to improve or maintain the nutritional status, physiological health, quality of life, and prevent and treat both the acute and long term

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complications of T2D by balancing food intake with endogenous and/or exogenous insulin levels (ADA, 2002; CDA, 2003; Wolever, et al, 1999). It is well documented that nutrition therapy can improve diabetes management, such as glycemic control (Ash, et al, 2003; Miller, et al, 2002; Pastors, et al, 2002; Pi-Sunyer, et al, 1999; Franz, et al, 1995; Laitinen, et al, 1993; Hartwell, et al, 1986; Rabkin, et al, 1983). Optimal glycemic control which includes a post-meal blood glucose that is as close to the normal range as possible is key to reducing the long term complications in both Type 1 diabetes (T1D) and T2D (1993 UKPDS Study Group, 1998; Ohkubo, et al, 1995).

Generally, people with T2D should be consuming a healthy diet following the principles of Canada's Food Guide to Healthy Eating. This means that the nutrition advice for individuals with T2D is similar to that of healthy individuals. The principles of Canada's Guidelines for Healthy Eating include (Health Canada, 1992): 1. Enjoy a variety of foods, 2. Emphasize cereals, breads, other grain products, vegetables and fruit, 3. Choose lower-fat dairy products, leaner meats and foods prepared with little or no fat, 4. Achieve and maintain a healthy body weight by enjoying regular physical activity and healthy eating, 5. Limit salt, alcohol and caffeine.

Table 2.5 summarizes some important nutritional considerations for people with T2D. When consuming a well-balance diet, vitamin and/or mineral supplementation is not necessary for individuals with T2D except for individuals who have inadequate food intake or special needs, such as vegans and women during pregnancy (ADA, 2004; CDA, 2003; Wolever, et al, 1999). Individuals with T2D should consume the amount of protein recommended to the general population, i.e. ~0.86g/kg/day. In addition, calorie intake from fat should account for <30% of the energy requirements, with the emphasis on

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choosing foods that are rich sources of monounsaturated fatty acids. Dietary carbohydrates from grain products, vegetables, fruits, legumes, milk products and added sugar should represent 50-55% of one's energy intake; out of this 50-55%, added sugar should comprise <10% of energy intake/day. Low glycemic index (GI) foods should be chosen more often to optimize glycemic control in individuals with T2D. The simple nutrition message of "choose more low GI foods" was incorporated into the FSFB study as part of the lifestyle intervention in managing T2D. The following section will briefly discuss the concept of GI and review available evidence, suggesting that a diet rich in low GI foods improves the management of T2D.

2.5.2.a Nutritional management of diabetes using low GI diet:

2.5.2.a.i GI-Background and definition:

Evidence indicates that delaying carbohydrate absorption using either a diet rich in low GI foods or a pharmacological carbohydrate digestion/absorption inhibitor (i.e. Acarbose) can prevent the development of T2D in healthy people (Salmeron, et al, 1997a, b) and in those at high risk for T2D (Chiasson, et al, 2002). Achievement of such control requires an intensive approach to diabetes management which includes nutrition therapy (The DCTT Research Group, 1993). To improve glycemic control, especially in the post-prandial state requires balancing dietary intake with endo- and/or exogenous insulin level and is a critical part of the nutritional management of diabetes.

In the 1980's, Dr. David Jenkins and colleagues devised the concept of GI for classifying the glycemic response to carbohydrate-containing foods (Jenkins, et al, 1984; Jenkins, et al, 1981). GI is used to describe the extent of the acute rise in blood glucose concentration after consumption of 50g of available carbohydrate in a test food relative to

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the rise evoked following the ingestion of the equivalent amount of carbohydrate in a reference food, usually glucose or white bread (Ludwig, et al, 2002; Jenkins, et al, 1984; Jenkins, et al, 1981). It is expressed as the incremental area under the blood glucose response curve, above baseline[1], over a period of 2 to 3 hours, in comparison to a reference food (Figure 2.1) (Wolever, et al, 1991; Jenkins, et al, 1981; Jenkins, et al, 1984, Kalergis, et al, 2005). Foods that are considered to have a high GI, such as white bread, will result in a rapid rise in blood glucose whereas foods that are considered to have a low GI, such as spaghetti, will result in a slower rise in blood glucose. To simplify the interpretation of GI, the CDA has divided the food according to 3 GI reference points: high (GI>70), medium (55-69), and low (<55) (CDA, 2003). The calculation of the GI can be expressed as follows (Kalergis, et al, 2005; Jenkins, et al., 1984):

$$GI = \frac{\text{Incremental blood glucose area of test carbohydrate}}{\text{Incremental blood glucose area of reference carbohydrate}} x100$$

Today, extensive listings of GI values for some major foods are available for researchers and diabetes educators (Foster-Powell, et al, 2002; Foster-Powell, et al, 1995; Wolever, et al, 1994).

2.5.3.a .ii. Controversies surrounding the use of GI in diabetes management:

The ADA currently does not endorse the use of GI in the nutritional management of diabetes (ADA, 2002, Franz, et al, 2001; Franz et al, 1999; Franz, et al, 1994; Nantel, 2003). One of the reasons ADA does not recommend the use of GI is the belief that the concept would complicate the life of individuals with diabetes by severely limiting food choices (Franz, et al, 1994). However, there is no evidence for this. Contrary to this, a

[1] The incremental area under the blood glucose response curve does not include values which fall below baseline.

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study completed by Gilbertson and associates showed that nutrition advice, with an emphasis on low GI foods, not only improved A1C levels, but it also had no increase in the risk of hypoglycemia, as well as no decrease in the quality of life among children with T1D (Gilbertson, et al, 2003). In the study, a total of 104 children with T1D were randomized to either the carbohydrate-exchange-diet group or the low GI diet group. In the carbohydrate-exchange-diet group, parents and children were taught about carbohydrate counting or the "exchange list"; in the low GI diet group, parents and children were provided with flexible dietary instruction based on the food pyramid, with a focus on low GI foods. At 12 months, there were significant differences between the two dietary regimen groups ($p<0.01$). Children in the low GI diet group achieved significantly lower A1C levels ($7.77 \pm 0.79\%$) compared to the carbohydrate-exchange diet group ($8.76 \pm 1.07\%$). A quality-of-life questionnaire revealed that twice as many caregivers in the low GI diet group, as opposed to the carbohydrate-exchange-diet group (51 vs. 24% of caregivers respectively, $p=0.02$) reported that the children were not experiencing difficulties in selecting their own meals. A study by Frost's et al (research methods and physiological health improvements are described below), provided dietary instruction with an emphasis on low GI foods to study participants with T2D in an intervention similar to that in Gilbertson's study (Frost, et al, 1994). At the end of the intervention, dietary analysis revealed significantly lower meal GI values in the low GI diet group compared to the control group ($p<0.001$). The authors in the study concluded that "... it is possible for patients diagnosed as having T2D to reduce significantly the GI of the diet following dietary education", and that the success of this "may be due to the advice being seen as simple and positive, ... rather than the more negative general advice

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which often encourages restraint from a number of foods" (Frost, et al, 1994). This evidence demonstrates that incorporating the low GI concept into nutrition education for caregivers and individuals with diabetes is not as complex as expected.

A small group of studies has demonstrated that a low GI diet has no beneficial impact on glycemic control among individuals with T2D, and that the GI of a food does not predict the glycemic response in the context of a mixed meal (Hollenbeck, et al, 1988; Coulston, et al, 1984). In the study by Hollenbeck et al, the effects of three test meals under the categories of low, intermediate and high GI values (per meal) on plasma glucose and insulin responses were examined. On the test day, nine study volunteers with T2D consumed the aforementioned test meals. The same category of test meals were fed at breakfast, lunch and supper (i.e. low, intermediate and high-GI days), after an overnight fast, in a random order within 2-week period. Blood samples were drawn hourly for measurement of plasma glucose and insulin concentrations for a total duration of 12 hours. Analyses showed that the mean PG response area was significantly reduced ($p<0.05$) by about 7% on the low-GI day compared with the intermediate or high-GI days; mean total plasma insulin response area was about 16% lower on the low-GI day when compared with the intermediate or high-GI days ($p<0.05$). The authors stated that "whether these changes in glycemic excursion are deemed to be clinically significant is obviously a matter of individual judgment, but we feel that the magnitude of the differences ... is not sufficient to recommend that patients modify their diets to take [GI concept into account]". Subsequently, the authors concluded that "... there is little clinical benefit to be gained by designing meals based on GI". Nevertheless, the data in

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this study appeared to suggest otherwise since a small, but significant difference was observed following the different diets.

Meanwhile, Coulston's study suggested that the concept of GI may be limited because differences between the glycemic responses of foods do not apply to mixed meals (Coulston, et al, 1984). In this study, eight study participants with T2D were fed with four different test meals. The sources of carbohydrate that made up the test meals (60% of the total carbohydrates) were baked potatoes, rice, spaghetti and lentils. The sources and amount of protein and fat were held constant in these test meals. The study participants consumed all the test meals in a random order within a 2-week period. The areas under the PG and insulin response curves (including the areas both above and below baseline level) showed no differences between the rice, spaghetti and lentil test meals. However, these three test meals had a significantly lower PG and insulin response curves when compared to the baked potato meals (all at $p<0.01$). The failure to observe significant differences among the three aforementioned test meals led the Stanford group to conclude that "evidence at this time fails to support the view that menu planning for diabetics must be drastically modified in order to take advantage of the GI of different carbohydrate-rich foods". The discrepancy in conclusions between this group of researchers and others is likely attributable to the different methods used in determining the glycemic response. Coulston et al estimated the glycemic response based on total, rather than the incremental, area under the curve. When the GI was originally developed, it was based on the incremental area of the blood glucose response curve, above baseline (Wolever, et al, 1991; Jenkins, et al, 1981; Jenkins, et al, 1984). Thus, this method of calculating glycemic response might commit to a Type II (statistical) error if the expected

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difference is small, i.e. if there was a significantly lower glycemic response after consuming a low GI diet when compared to a high GI diet (Wolever, 1997). Reanalysis of the Stanford group's data by Wolever and associates, using the original method of estimating glycemic response, supported the contention that the GI in predicts the glycemic response to a mixed meal (Wolever, et al, 1986).

There is considerable evidence to support the utility of the GI of individual foods in predicting the glycemic and insulin responses in a mixed meal situation, especially in the presence of fat and protein. Wolever and associates were the first ones who demonstrated that the GI concept can be applied to mixed meals containing more than one carbohydrate source, and mixed meals containing fat and protein (Wolever, et al, 1985). In that study, six healthy participants consumed three different types of mixed meals in a random order after an overnight fast. The test meals contained 50 g of available carbohydrate from navy beans (GI = 56) or 50 g of available carbohydrate from white bread (GI = 100), while the mixed meal contained equal amounts of available carbohydrate from white and navy beans (25 g of each). The results showed that the observed GI of the navy beans and bread mixed meal was virtually identical to the predicted value[2] (77 vs. 78 respectively). This means that the predicted GI of the mixed meal using individual food GI values did not differ from the observed GI. As for mixed meals containing fat and protein, another two mixed meals were tested using different amounts of macronutrients. In the first set of studies, four different meals, each containing 69-83 g of carbohydrate, 20-29 g of protein and 13-21 g of fat (total calorie: 473-610 kcal/meal) were given to eight individuals with T2D; in the other set of the

[2] The GI of navy beans was 56, and the GI of white bread was 100. The mixed meal contained equal amount of carbohydrates from navy beans and white bread. Hence, the predicted GI of the meal should be: 25 g/50 g * 56 + 25 g/ 50 g * 100 = 78

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studies, five different meals each containing higher amounts of macronutrients than the previous, i.e. 84-89 g carbohydrate, 31-38 g protein, 25-26 g fat (total calorie: 685-742 kcal/meal), were fed to 10 healthy participants, 12 people with T1D and 10 people with T2D. The results from the PG area under the curve indicated a significant correlation between the predicted GI and the observed GI ($r = 0.957$, $p<0.05$) for the first four meals; for the five meals that provided a higher content of macronutrients, the predicted GI values correlated significantly with reported glycemic response in people with T1D ($r = 0.928$, $p<0.01$), those with T2D ($r = 0.920$, $p<0.01$) and in healthy individuals ($r = 0.928$, $p<0.01$).

Using a similar method, Collier and colleagues (Collier, et al, 1986) also demonstrated that the predicted GI for 5 different mixed meals (50% carbohydrate, 30% fat, 20% protein), when fed to 6 individuals with T2D, correlated significantly with observed mean glycemic response ($r = 0.988$, $p<0.01$). Chew and associates fed six different test meals to eight healthy individuals, and results attained were similar to those of Wolever and Collier's studies (Chew, et al, 1988). They observed a significant correlation of ($r= 0.88$, $p<0.01$) between the observed glycemic response and the predicted mean GI value. A more recent study by Wolever and associates also concluded that approximately 90% of the variability of the observed mean glucose and insulin responses following the ingestion of carbohydrates in a meal was explained by the predicted glucose response (i.e. predicted GI) (Wolever, et al, 1996). In the study, eight normal individuals were given 5 different mixed meals. Significant correlations between the predicted and observed responses for capillary glucose ($r = 0.929$, $p = 0.02$), plasma glucose ($r = 0.950$, $p = 0.01$), and plasma insulin ($r = 0.956$, $p = 0.01$) were observed. All

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of these studies were successful in demonstrating that the predicted GI in a mixed meal predicts the glycemic and insulin responses in people with and without diabetes. Therefore, they provided sound evidence of the applicability of using GI in planning diets for individuals with T2D in the context of mixed meals.

Thus, despite the controversies surrounding the clinical utility of GI, there is evidence that demonstrates that individuals with diabetes can integrate the GI concept into their diabetes management and that the concept of GI remains relevant in the context of mixed meals. Most importantly, a large number of studies to-date have demonstrated that incorporating a low GI diet can help improve glycemic control in people with T2D (described below).

2.5.2.a.iii Evidence of a low GI diet in improving glycemic control in individuals with T2D:

The GI concept in the nutritional management of diabetes is being advocated and endorsed by many diabetes and health organizations world wide, such as the World Health Organization, and diabetes associations in Europe, Australia, Canada and South Africa (Kalergis, et al, 2004; CDA 2003; Nantel, 2003; Nutrition Subcommittee of the Diabetes Care Advisory Committee of Diabetes UK, 2003; The Diabetes and Nutrition Study Group of the European Association for the Study if Diabetes, 2000; Wolever, et al, 1999; Perlstein, et al, 1997). Ample evidence exists in supporting the use of low GI diets in the management of T2D (Jenkins, et al, 2002; Ludwig, et al, 2002; Brand-Miller, 1994). Table 2.6 contains a summary of studies that have demonstrated positive effects of a low GI diet in the management of T2D.

Most studies assessing the effectiveness of a low GI diet in individuals with T2D have utilized a randomized crossover design with two dietary periods (i.e. low and high

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GI diet). In addition, food provision (i.e. feeding trial), lasting from 2 to 6 weeks, was generally part of the intervention. Jenkins and associates provided their volunteers, who had T2D, with 2 weeks of pre-weighed portions of either high or low GI foods (Jenkins, et al, 1988). Subjects experienced significant reductions in fasting blood glucose and serum fructosamine over the 2 week diet period when they consumed the low GI diet. Using a similar study design, Wolever and colleagues conducted two separate trials, involving a 2-week, and a 6-week, feeding trial with a crossover design. They found significant reductions in serum fructosamine and cholesterol levels when subjects were consuming the low vs. high GI diet (Wolever, et al, 1992a, b) (see Table 2.6). In another study, when a low GI diet was used for up to 24 days, improvements in glycemic control were observed when compared to the high GI diet (Jarvi, et al, 1999). In this study, 20 participants with T2D completed a feeding trial using a crossover design. At the end of the feeding trial, subjects in the low GI diet group achieved lower serum fructosamine levels compared to the high GI diet group (356 ± 75 vs. 347 ± 72 μmol/L, $p = 0.05$). Therefore, under controlled conditions, using crossover designs, these studies demonstrated that a low GI diet can effectively improve glycemic control among individuals with T2D.

Aside from the aforementioned feeding trials, dietary intervention via counseling, with a focus on a low GI diet, has shown promising results as well. A total of 18 individuals with T1D and T2D (n=6 for T2D) were prescribed with and instructed to follow a low GI diet and then a high GI diet (with a washout period between the two diets) or vice versa for 5 weeks each (Fontivielle, et al, 1992). At the end of the low GI dietary intervention, participants experienced significant reductions in serum

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fructosamine, fasting blood glucose and 2h PG when compared to when they followed the high GI diet. Using a similar design but a longer period of intervention, i.e. a 12-week crossover study, subjects with T2D consuming a diet low in GI achieved a significantly lower A1C values at the end of the study (7.0 ± 0.3%) when compared to when they consumed the diet high in GI (7.9 ± 0.5%, $p<0.05$) (Brand, et al, 1991). In another study by Frost and associates, this time involving 51 participants, about half of whom were assigned to the diet counseling group. Those in the diet counseling group attained a significant improvement in serum fructosamine concentrations compared with their baseline values (i.e. from 3.8 ± 0.2 to 3.2 ± 0.2 mmol/L, $p<0.05$) at the end of the 12-week trial (Frost, et al, 1994). In contrast, the serum fructosamine level remained unchanged in the control group throughout the trial (from 3.6 ± 0.2 to 3.6 ± 0.2 mmol/L). The difference between the groups was also significant ($p<0.05$). These studies demonstrate that glycemic control can be improved when individuals with T2D are instructed and encouraged to adhere to a low GI diet. A meta-analysis conducted by Brand-Miller and colleagues showed that consumption of a low GI diet can potentially reduce the A1C by 0.43 percent versus a high GI diet (Brand-Miller, et al, 2003).

In short, when the GI of a diet is manipulated as part of a clinical feeding trial, an improvement in glycemic control can be attained in as early as 2 weeks. Moreover, when free living individuals with T2D are encouraged to follow a low GI diet, improvements in glycemic control can be observed within a similar time frame. Inclusion of a low GI diet concept into diabetes education may be warranted. The recent technical review by the CDA concluded that "1. The use of low GI foods helps optimize glycemic control in adults with T2D" and "2. The use of low GI diets has a clinically useful effect on

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glycemic control in both T1D and T2D" (Kalergis, et al, 2005). Therefore, choosing low GI foods over high GI foods can help improve glycemic control among individuals with T2D.

2.5.2.a.iv Implementing GI in the nutritional management of diabetes:

In the study by Brand et al (1999, reviewed above), participants who were counseled to adhere to a low GI diet managed to achieve significantly lower average dietary GI values compared to the ones with a high GI diet (77 ± 3 and 91 ± 1 units respectively, $p<0.01$) (Brand, et al, 1991). This 15% drop in the overall GI value was followed by a modest improvement in glycemic control. Data from this study indicates that a 15 percent drop in GI was attained by exchanging half of the carbohydrate-containing foods, from high to low GI (Brand-Miller, et al, 1999). The CDA and the Dietitians Association of Australia have suggested that these changes could, in practice, be implemented by including at least one low GI food choice at each meal or by including two low GI food choices into a daily diet (CDA, 2003; Perlstein, et al, 1997). Variation in the precise message about GI can lead to flexibility in the meal plan for individuals with T2D, which may help with adherence.

There have been several examples of educational strategies that have evolved to help people with T2D increase their consumption of low GI foods (see Table 2.7). For example, legumes have been shown to be useful in reducing the GI of the diet (Trout, et al, 1993). Thus, recipes and dishes that include legumes can be used to lower the total GI of a meal. Most whole grain products, fruits, vegetables and milk products generally have a GI rating that is considered low-moderate. A healthy diet that emphasizes a variety of foods from these food groups should be encouraged.

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2.5.3. Physical activity:

Physical activity has long been considered a cornerstone in the management of T2D (Boule, et al, 2001; Eriksson, 1999). Physical activity can help improve the management of T2D by improving cardio-respiratory fitness, glycemic control, insulin resistance, lipid profiles, blood pressure and weight management (ADA, 2004; Sigal, et al, 2004; CDA, 2003; Boule, et al, 2001; Eriksson, 1999).

The ADA and the American College of Sports Medicine (ACSM) recommend physical activities at an intensity of 50-80% of maximal aerobic capacity ($V0_2$ max), 3-4 times a week, for 30-60 minutes, and suggest that this may result in great improvement in both glycemic control and insulin sensitivity in individuals with diabetes (ADA and ACSM, 1997.) Both associations also endorsed the 1996 Surgeon General's Report on Physical activity and Health, in which it was recommended that individuals should accumulate 30 minutes of moderate physical activity on most, if not all, days of the week. This recommendation is similar to the recent recommendations updated by Sigal and colleagues (Sigal, et al, 2004). Specifically, Sigal et al suggested that individuals with T2D should get "at least 150 min/week of moderate-intensity aerobic physical activity and/or at least 90 min/week of vigorous aerobic exercise", and that "the physical activity should be distributed over at least 3 days/week and with no more than 2 consecutive days without physical activity". Here in Canada, Health Canada has put forward a similar pubic health message, where it recommends that the general population accumulate 30 minutes of moderate physical activity, such as brisk walking, biking, raking leaves, swimming, dancing and water aerobics, 4 days a week, or 60 minutes of light physical activity, such as light walking, volleyball, easy gardening and stretching (Health Canada

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and Canadian Society for Exercise Physiology, 1998). Individuals with T2D should be encouraged to follow Canada's Physical Activity Guide and accumulate at least 30 minutes of moderate-intensity of physical activity most days of the week to better manage their T2D. This message is consistent with the recent practice guidelines released by the CDA, which states that individuals with T2D "should accumulate at least 150 minutes of moderate-intensity aerobic exercise each week, spread over at least 3 nonconsecutive days of the week, or, if willing, should be encouraged to accumulate ≥4 hours of exercise per week" (CDA, 2003).

Walking is the most popular and convenient mode of physical activity among overweight, middle-aged and elderly people with diabetes (CDA, 2003; Tudor-Locke, et al, 1998; Ford, at al, 1995). It can be performed any time of the day, in most places, and without significant associated cost. This research study implemented a program called the FSP, a physical activity program designed to increase walking for people with T2D. The following section will briefly discuss some of the studies examining the role of walking in T2D prevention and management.

2.5.3.a. Walking—A means of physical activity in the prevention and management of T2D:

It has been reported that individuals with T2D are more likely to participate in walking as a form of physical activity compared to other physical activities such as golfing, dancing, weight lifting, yoga, basketball and skiing (Tudor-Locke, et al, 1998; Ford, et al, 1995). There are several studies demonstrating that walking alone can be used to reduce the risk of T2D, and can also improve health outcomes, including mortality, for people with T2D.

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Hu and colleagues used data from the Nurses' Health Study Cohort to determine whether walking can reduce the risk of T2D to the same degree as vigorous physical activity in women (Hu, et al, 1999). Among 70,102 participants surveyed at baseline (i.e. year 1986), 1419 cases of T2D were identified at the 8-year follow-up point. After adjusting for confounding factors, the relative risks of developing T2D among the participants across quintiles of total physical activity[3] (least to most) were 1.0, 0.84, 0.87, 0.77 and 0.74 ($p<0.001$ across the quintiles); the relative risks of developing T2D across the quintiles for moderate-intensity physical activity were 1.0, 0.95, 0.80, 0.81, 0.74 ($P=0.01$). Results from this study have been used to suggest that moderate-intensity physical activity such as walking may be equally effective as vigorous activity in reducing the risk of T2D.

This epidemiological evidence can further be supported by a clinical trial, in which Swart and associates demonstrated that overweight women who walked 10,000 steps/day could reduce the risk of T2D by improving glucose tolerance and blood pressure (Swartz, et al, 2003). In a 12-week study, 18 women who were inactive (4491 ± 2269 steps/day) and at high risk for T2D completed a 4-week control period (i.e. no physical activity) followed by 8 weeks of physical activity intervention. During the physical intervention, the women were instructed to achieve a goal of 10,000 steps/day (the same goal that was used in Yamanouchi's et al study described below). At the end of the intervention, the women not only achieved an average steps of 9213 ± 362 per day, but they also improved their 2hPG values, systolic and diastolic pressure compared to the control period ($p<0.01$).

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[3] Quintile was based on total energy expenditure on physical activity, expressed in Metabolic Equivalent Task (MET)-Hours per week.

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Several studies have examined health outcomes in people with T2D who have engaged in regular activity. Yamanouchi and colleagues examined the effectiveness of walking combined with nutrition therapy on insulin sensitivity in obese T2D individuals during 6-8 weeks duration (Yamanouchi, et al, 1995). In the study, a total of 24 obese participants with T2D were recruited and randomized to either diet intervention group (n = 10) or diet-and-exercise group (n = 14). All participants were admitted to the hospital during the study period. The diet intervention for both groups involved a supervised food intake of 1,000-1,600kcal/day[4]. Both groups were given a pedometer; the diet intervention group was told to continue with their regular physical activity routine prior to hospitalization, but the diet-and-exercise group was instructed to walk a minimum of 10,000 steps/day. At the end of the study, participants in the diet intervention group walked 4,500 ± 290 steps/day, whereas participants in the diet-and-exercise group walked 19,200 ± 2,100 steps/day. Weight loss in both the diet intervention group and diet-and-exercise group (-4.2 ± 0.5 kg and -7.8 ± 0.8 kg respectively, $p<0.01$) was significantly different from the baseline, but the diet-and-exercise group lost significantly more body weight than the diet group ($p<0.01$ vs. diet intervention). When compared to the baseline, the diet-and-exercise group also showed significant improvement in insulin sensitivity as measured by a hyperinsulinemic, euglycemic clamp.

Inspired by Yamanouchi's study, Tudor-Locke developed the FSP (details of which are in Chapter 1 & 4). In the first FSP study, Tudor-Locke and associates demonstrated that an average increase of approximately 3000 steps/day from baseline improved waist girth ($p<0.01$) and systolic pressure ($p<0.05$) over time among the T2D

[4] Kcal intake on each participant was determined by subtracting 1,000kcal from the participant's usual self-reported food intake.

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participants (Tudor-Locke, et al, 2002). In the following controlled outcome evaluation of the FSP, Tudor-Locke and associates found similar results, where a significant increase of approximately 3000 steps/day vs. at baseline ($p = 0.025$) improved waist girth (Tudor-Locke, et al, 2004). In addition, Walker and colleagues investigated the effects of regular self-paced walking on CVD risk factors among postmenopausal women with T2D (Walker, et al, 1999). A total of 11 participants were recruited to the 12-week study. During the intervention, the participants were instructed by qualified personnel to walk at least 60 minutes/day, 5 times a week at a self-selected pace. At the end of the 12-week, the women reported walking for 4.1 ± 1.6 hour/week and they exhibited significant improvements (over time) in estimated VO_{2max} (from 18.7 ± 3.2 to 21.8 ± 4.9 ml/kg/minute respectively, $p<0.05$), body weight (from 77.9 ± 13.0 to 76.4 ± 12.3 kg, $p<0.05$), total cholesterol (from 5.50 ± 0.94 to 4.81 ± 0.67 mmol/L, $p<0.001$), LDL cholesterol (from 3.13 ± 0.86 to 2.64 ± 0.45 mmol/L, $p<0.05$), A1C (from 7.78 ± 1.37 to 7.19 ± 1.59%, $p<0.05$), and fasting glucose (from 9.29 ± 3.82 to 8.24 ± 3.16 mmol/L, $p<0.05$) and fasting insulin concentrations (from 90.6 ± 35.4 to 88.2 ± 27.0 pmol/L, $p<0.05$).

Improvements in the CVD risk factors and health outcomes seen in the aforementioned studies may be critical in reducing mortality in individuals with T2D. Two epidemiological studies demonstrated that moderate levels of activity or walking can reduce the overall mortality among adults with diabetes (Gregg, et al, 2003; Batty, et al, 2002). Gregg and colleagues used the 1990 & 1991 National Health Interview Survey to investigate the association between walking and the risk for all-cause and CVD mortality among individuals with diabetes. Using data from 2896 adults, after controlling

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for confounding factors (e.g. smoking, BMI, age), they found that individuals with T2D who walked at least 2 hours/week had a 39% lower all-cause mortality rate and a 34% lower CVD mortality rate. The authors estimated that, among individuals with T2D, one death per year may be prevented for every 61 individuals who chose to walk at least 2 hours/week; if 145 of these individuals chose the same effort, then one death/year resulting from CVD may be prevented. Batty and associates observed similar results and they concluded that moderately active men with either T2D or IGT had significantly lower all-cause and CVD mortality when compared to those who were inactive (Batty, et al, 2002). These men were classified as moderately active if they participated in leisure activities such as walking, gardening and woodwork. The conclusions were derived from a sample of 6408 men in the Whitehall study database, a study that examined the cardio-respiratory disease and diabetes among middle-aged, British male, civil servants.

Walking can be a safe, convenient and accessible form of physical activity for individuals with T2D. Regular walking not only may reduce the risk of T2D, but it may improve T2D management of CVD risk factors. Therefore, individuals with T2D who are sedentary, should be encouraged, at least, to walk regularly, i.e. 30 minutes most days of the week, as per the Canada Physical Activity Guide to Healthy Active Living, as part of their management of T2D.

2.5.4 Pharmacological management in achieving optimal glycemic control:

It has been suggested that a lifestyle intervention should be the initial step in treating T2D (CDA, 2003; Meltzer, et al, 1998). When this non-pharmacological approach is inadequate in achieving optimal T2D management (i.e. glycemic control), a

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more aggressive approach involving the use of oral hypoglycemia agent(s) is warranted (CDA, 2003).

Generally, a combination of different oral hypoglycemic agents at sub-maximal doses produces a more rapid and better glycemic control than only one oral hypoglycemic agent at maximal dose (i.e. monotherapy) (CDA, 2003). In fact, due to the progressive deterioration of beta cell function, many patients might require more than one oral hypoglycemic agent to achieve optimal blood glucose control (CDA, 2003). Table 2.8 summarizes oral hypoglycemic agents available in Canada and some therapeutic considerations when prescribing to individuals with T2D.

Initiation of insulin therapy is usually seen in patients when diet, exercise and oral hypoglycemic agents are no longer effective or are contraindicated. In clinical practice, single injection of low dose intermediate-acting or long-acting insulin at bed time in addition to oral hypoglycemic agents can be effective in controlling blood glucose levels. This approach has been associated with better glycemic control, less weight gain and incidence of nocturnal hypoglycemia (CDA, 2003). Insulin therapy is also used during the presence of persistent, marked hyperglycemia, such as illness, pregnancy stress, infection, a medical procedure or surgery.

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2.6 Summary:

T2D is a complex, chronic disease and the incidence of this disease is dramatically increasing. It has been described as the health epidemic of the 21st century. When it is not well-controlled, T2D is associated with long term complications such as retinopathy, nephropathy and CVD. Today, management of T2D includes the use of nutrition therapy, physical activity and pharmacotherapy. Among these avenues of therapy, lifestyle interventions, involving nutrition and physical activity, play a significant role in the prevention and management of T2D. Specifically, lifestyle intervention not only improves the glycemic control, but it can facilitate improvement of other health outcomes, such as weight management, lipid profiles and blood pressure. Individuals with T2D are strongly recommended to adopt a healthy eating pattern and incorporate active living as part of their T2D management strategy.

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Table 2.1: Risk factors for T2D (adapted from ADA, 2004; CDA, 2003)

- Age ≥ 40 years old
- BMI ≥ 25 kg/m^2
- Abdominal obesity
- Acanthosis Nigricans
- Family history of diabetes (i.e. first-degree relative)
- Inactivity
- Ethnicity (e.g. Aboriginals, African-Americans, Asians)
- History of IFG or IGT
- History of Gestational Diabetes Mellitus or delivery of a macrosomic infant (i.e. > 4 kg)
- Hyptertension
- Dyslipidemia
- Polycystic Ovarian Syndrome
- History of vascular disease
- Schizophrenia

Table 2.2: Diagnosis of T2D (adapted from CDA, 2003; ADA, 2004)

1. Symptoms of diabetes plus casual PG ≥ 11.1 mmol/L. Symptoms of diabetes include polyuria, polydipsia and unexplained weight loss; casual is defined as any time of the day without regard to time since the last meal.

   or

2. FPG≥ 7.0 mmol/L. Fasting is defined as no caloric intake for at least 8 hours.

   or

3. 2hPG in a 75g-OGTT≥ 11.1 mmol/L.

Note: In an absence of unequivocal hyperglycemia with acute metabolic decompensation, these criteria should be confirmed by repeated testing on a different day. The OGTT is not recommended for routine clinical use

Table 2.3: Diagnostic Criteria for IFG, IGT and diabetes (adapted from CDA, 2003)

	FPG (mmol/L)		2hPG in a 75g OGTT (mmol/L)
IFG	6.1-6.9		------
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

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Table 2.4: Summary of lifestyle intervention trials in the treatment of T2D reviewed

Reference	Type of intervention	Study Length	No. of subject (completed)	Significant findings
Vanninen, et al, 1992	-RCT (usual care or lifestyle intervention)	12 months	N=78 T2D subjects	-Both males and females in the lifestyle intervention group improved fasting plasma insulin and serum HDL level vs. baseline (all at $p<0.05$)
Agrus-Collins et al, 1997	-RCT (Control or lifestyle intervention)	6 months	N=64 African-Americans with T2D	-Significant net improvement in the intervention vs. control group in weight (-2.4 kg) and A1C (-2.4 %) (all at $p<0.05$)
Gaede et al, 2000	-RCT (Control or lifestyle , including smoking cessation)	3.8 years	N=149 T2D subjects with mirco-albuminuria	-Lifestyle group had significant reductions vs. control group, in A1C (7.6 vs. 9.0 %), fasting triglycerides (1.8 vs. 2.7 mmol/L) and total CHO (4.8 vs. 5.5 mmol/L) ($p<0.001$ for all)
Sone, et al, 2002	-RCT (Control or lifestyle intervention)	Data on 3rd year	N=2205 T2D subjects	- Treatment group improved A1C vs. control group (7.62 ± 1.20 vs. 7.78 ± 1.27 %, $p<0.001$)
Goldhaber-Fiebert, et al, 2003	-RCT (control or lifestyle intervention)	12 weeks	N=61 overweight, T2D subjects	-Compared to control, treatment group improved weight (+0.4 ± 2.3 vs. -1.0 ± 2.2 kg,), fasting PG (+16 ± 78 vs. -19 ± 55 mg/dl), A1C (-0.04 ± 2.3 vs. -1.8 ± 2.3 %) (all at $p<0.05$)
Toobert et al, 2003	-RCT (Control or lifestyle including stress management)	6 months	N=279 post-meno pausal T2D female	- 0.4 % reduction in AIC and the 0.37 in BMI in the treatment group vs. control group ($p<0.01$)
Krook et al, 2003	-Clinical trial -Lifestyle intervention, with stress management	31 weeks	N=487 T2D who failed the conventional care	-Reductions in A1C (-1.13%), weight (-2.2 kg), systolic (-3.1 mmHg) and diastolic pressure (-4.21 mmHg) vs. baseline (all $p<0.0001$)
Kelly, et al, 2004	-RCT (lifestyle intervention + placebo-IntP or plus Orlistat-IntO)	6 months	N=39 obese subjects with <5 years history of T2D	-IntP group lost significant weight (-9.4 ± 1.3 kg), FPG (-3.3 ± 0.4 mg/dl), A1C (-0.97 ± 0.39 %) vs. baseline (all at $p<0.01$). IntO group achieved similar significant improvement in these outcomes when compared to baseline -IntP vs. IntO, IntO improved significantly in fasting insulin and free fatty acids ($p<0.05$)
Mayer-Davis, et al 2004	-Randomized clinical trial (intensive, moderate lifestyle intervention or usual care)	12 months	N=152 overweight, T2D participants	-Over time, only the intensive group lost 2.2 kg ($p<0.05$) -Over time, both intensive and moderate groups reduced in A1C (-1.56 %, $p<0.0001$ vs. -0.843, $p<0.05$, respectively)
Wolf, et al, 2004	-RCT (usual care or lifestyle intervention)	12 months	N=118 T2D	-Compared to control group, treatment group lost -2.4 kg of weight ($p<0.05$) and -5.5 cm of waist ($p<0.001$)

Table 2.5: Major nutritional considerations for management of T2D (CDA, 2003; Wolever, Barbeau, Charron, et al, 1999)

Carbohydrate (50-55% of energy):

- Include whole grains, vegetables, fruits and dairy
- Choose low glycemic index foods more often
- Up to 10% of energy intake from sucrose is acceptable
- Fructose consumption of >60g is not recommended
- Non-nutritive sweeteners such as saccharin, aspartame, acesulfame potassium, cyclamates and sucralose are acceptable
- Intake of up to 10g/day of sugar alcohols is acceptable

Protein (15-20% of energy):

- *Usual protein intake of ~0.86g/kg/day is recommended*
- Vegetable protein should be considered as a alternative to animal protein

Fat (<30% of energy):

- Intake of saturated fats and trans fatty acids should be <10% of energy intake
- Polyunsaturated fats should provide <10% of energy requirement
- Whenever possible, monounsaturated fats should be used
- Include foods rich in polyunsaturated omega-3-fatty acids and plant oils
- Fish rich in omega-3-fatty acids should be recommended at least once per week

Alcohol:

- Should be limited to 5% of total energy intake or 2 drinks/day, whichever is less
- Individuals with dyslipidemia, hypertension and liver impairment should avoid alcohol consumption
- Individuals using insulin and/or insulin secretagogues should be aware of delayed hypoglycemia (up to 14 hours) after alcohol consumption

Vitamin and mineral supplementation:

- Daily vitamin and mineral requirements should come from a well-balanced diet
- Routine supplementation is not necessary

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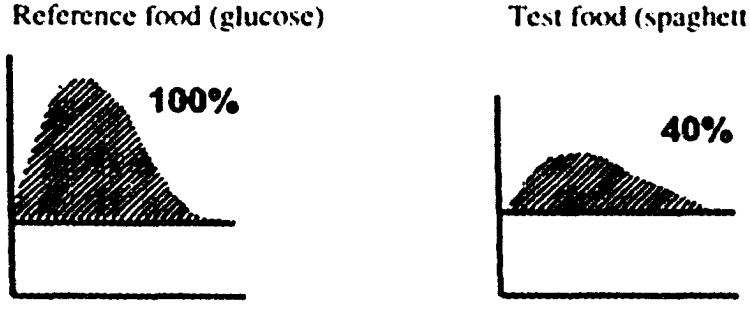
Figure 2.1: The 2-hour blood glucose response of 50 g glucose vs. spaghetti (adapted from http://www.glycemicindex.com)



X-axis: time; Y-axis: blood glucose levels.
The effect of a food on blood glucose levels is calculated using the area under the curve (shaded area). The area under the curve after consumption of the test food is compared with the same after consumption of a reference food (usually 50 grams of pure glucose or 50 grams of carbohydrate portion of white bread)

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Table 2.6: Studies demonstrating positive effects of a low GI diet on glycemic control among individuals with T2D

Reference	Intervention	Duration	Participants (completed)	Major findings
Jenkins, et al, 1988	-Randomized crossover feeding study (partial) with hypo-caloric diet	-Two 2-week interventions (either low or high GI diet)	-N=8 T2D subjects -n=6 were taking insulin	-Only the low GI group achieved significant improvements in fasting BG (%Δ: -30 ± 6%, p<0.005) and AIC (%Δ: -6.6 ± 2.6%, p<0.05) when compared to baseline
Brand, et al, 1991	-Randomized crossover study -Dietary counseling provided	-Two 12-week interventions (either low or high GI group)	-N=16 well-controlled T2D subjects	-A1C was significantly lower (p<0.05) in the low GI group vs. the high GI group (7.0 ± 0.3 vs. 7.9 ± 0.5% respectively); the 8-h plasma glucose profile (area under the curve above fasting) was lower in the low GI vs. high GI group (128 ± 23 vs. 148 ± 22 mmol/h/L, p<0.05 respectively)
Fontvieille, et al, 1992	-Randomized crossover study	-Two 5-week interventions (either low or high GI diet	-12 T1D and 6 T2D well-controlled (N=18) subjects	-The low GI achieved better improvement vs. the high GI group in: fructosamine (3.4 ± 0.4 vs. 3.9 ± 0.9 mmol/L, p<0.05), fasting BG (9.6 ± 2.7 vs. 10.8 ± 2.8 mmol/L, p<0.02), 2hPG (10.3 ± 2.5 vs. 11.6 ± 2.9 mmol/L, p<0.02) and serum TG (1.2 ± 0.6 vs. 1.5 ± 0.9 mmol/L, p<0.05)
Wolever, et al, 1992a	-Randomized crossover feeding (partial) study	-Two 6-week interventions (low or high GI diet)	-N=6 overweight, T2D subjects	-Serum frustosamine and total cholesterol were lower in the low GI group vs. the high GI group (i.e. 4.61 ± 0.48 vs. 5.02 ± 0.60 mM, p<0.05, and 6.12 ± 0.76 vs. 6.57 ± 0.83mM , p<0.01, respectively)
Wolever, et al, 1992b	-Randomized crossover, feeding study (partial)	-Two 2-week interventions (either low or high GI diet)	-N=15 T2D subjects	-Significant decrease in the low GI vs. high GI: fasting fructosamine (3.17 ± 0.12 vs. 3.28 ± 0.16 mmol/L, p< 0.05), cholesterol (5.5 ± 0.4 vs. 5.9 ± 0.5 mmol/L, p<0.02), urinary C-peptide excretion (2.05 ± 0.3 vs. 2.93 ± 0.49 nmol/mmol creatinine, p<0.02)
Frost, et al, 1994	-RCT -Treatment: emphasis on low GI foods	-12 weeks	-N= 51 newly diagnosed T2D subjects	-Within group comparison, only the low GI diet reduced in fructosamine (3.8 ± 0.2 to 3.2 ± 0.2 mmol/L, p<0.05) and cholesterol (6.2 ± 0.3 to 5.5 ± 0.3 mmol/L, p< 0.05)
Jarvi, et al, 1999	-Randomized crossover, feeding study	- Two 24-day interventions (either low or high GI diet)	-N= 20 T2D subjects	-Low GI vs. high GI diet: serum fructosamine (347 ± 72 vs. 356 ± 75 µmol/L, p<0.05), 9-hr plasma response curve on profile day (-31% in the low GI diet, p<0.05), area under the curve for plasma insulin (-27% in the low GI diet, p<0.01), LDL cholesterol (2.87 ± 0.7 vs. 3.13 ± 0.9, respectively p<0.002), PAI-1 (9.4 ± 11.0 vs. 20.2 ± 16.1 U/ml, p<0.01)

Table 2.7: Consumer tips on how to include low GI foods to lower the GI of the diet (Adapted from the Dietitians of Canada, "Glycemic Index: the new buzz word, but what is it really?", 2004)

- Include one low GI food per meal or at least two low GI foods daily
- Base two of your daily meals on low GI food choices
- Include legumes such as lentils, beans, barley in your meals, dishes and recipes
- Most whole grain products, fruits, vegetables and milk products have low GI. Enjoy a variety of foods from these food groups everyday, with an emphasis on low fat choices
- Too much of a good thing may not be a good thing. So, watch your portion sizes even when you are using low GI foods
- Some low GI foods, such as chocolate, are mostly fat and sugar. They give little nutritional value to your diet. Make food choices based on overall nutrition and health value, not just on GI

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Table 2.8: Oral hypoglycemic agents for use in the Management of T2D (Adapted from the CDA 2003 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada, CDA, 2003)

Class	Generic/Trade Name	Therapeutic Considerations
Sulfonylureas	• Gliclazide (Diamicron®) • Glimepiride (Amryl™) • Glyburide (Diabeta®, Euglucon®)	• Hypoglycemia and weight gain are common, especially with Glyburide • Consider using other class of agent first if patient is at risk of hypoglycemia (e.g. elderly)
Biguanide	• Metformin (Glucophage®)	• Contraindicated in patients with renal or hepatic dysfunction, or cardiac failure • Associated with some gastrointestinal (GI) side effects • Associated with less weight gain than sulfonylureas
Alpha-Glucosidase Inhibitor	• ACARBOSE (PRANDASE®)	• Not recommended as initial therapy in patients with severe hyperglycemia (A1C> 9.0%) • Associated with GI side effects • Mostly used in combination with other oral hypoglycemic agents
Insulin Secretagogue	• Nateglinide (Starlix®) • Repaglinide (GlucoNorm®)	• Reduces postprandial glycemia • Associated with less hypoglycemia in the context of missed meals
Thiazolidinediones (TZD)	• Rosiglitazone (Avandia®) • Pioglitazone (Actos®)	• Contraindicated in patients with hepatic dysfunction or significant cardiac failure • Requires 6 to 12 weeks to achieve maximum effect • May induced mild edema, fluid retention • Combination with insulin is currently not approved in Canada

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Chapter 3: Development of FSFB educational materials and details of recruitment and screening

3.1 Background:

Healthy eating and physical activity are pivotal in the management of T2D. Previously, Dr. Catrine Tudor-Locke and colleagues developed a physical activity intervention program called the FSP to help individuals with T2D increase their physical activity (Tudor-Locke, et al, 2000). It was based on the principles of self-efficacy and social support (under the framework of social cognitive theory) and the common clinical practices of goal-setting and feedback (Tudor-Locke, et al, 2001; Tudor-Locke, et al, 2000). The underlying premise was that physical activity, specifically walking, could be gradually increased throughout the day. Inspired by the work of Yamanouchi and colleagues (Yamanouchi, et al, 1995), Tudor-Locke et al felt that the pedometer was an ideal tool for goal setting, self-monitoring, feedback and motivation. The FSP has undergone rigorous evaluation and has been shown to be acceptable to diabetes educators and individuals with T2D. Building on this, a lifestyle intervention program, FSFB, has been developed.

The FSFB combines the physical activity message of the FSP with a simple nutritional message of "choose more low GI foods". The goal of the FSFB program is to increase physical activity and increase the number of low GI foods eaten daily, to positively affect metabolic control.

This chapter summarizes the development of the educational materials of the FSFB research study, including the "GI Track". It also provides more detail on the

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recruitment and screening of study candidates. An overview of the FSFB research study, including major results and the conclusions, can be found in the next chapter.

3.2 Development of FSFB educational materials:

The FSP comes with a facilitator manual and a participant workbook (Canadian Centre for Activity and Aging, 2001). The FSFB participant workbook was developed (Appendix A) following the general format of the FSP, with questions and homework exercises specifically focused on GI.

The nutrition behaviour targeted in the FSFB was to promote the intake of low GI over high GI foods. The nutrition education component was accomplished by using 2 new GI educational materials developed by the CDA: "The Glycemic Index Explained" PowerPoint presentation and "The Glycemic Index" (CDA, 2003) client handout (Appendix B). The first meeting in the FSFB was identical to that in the FSP, where the participants learned how to use a pedometer and established a baseline level of their steps/day. In addition, they learned to use personal goal-setting, self-monitoring and feedback to increase their physical activity. In the second meeting, the FSFB facilitator (SHC), who in this case was an RD, started the session by briefly reviewing the principles of healthy eating in the management of T2D using Canada's Food Guide to Healthy Eating (Health Canada, 1992). Next, the GI concept was introduced using the CDA presentation. At the end of the GI presentation, the "GI Track" tool (the dietary monitoring tool developed for the FSFB, described below) was presented to participants. The participants were taught how to use the "GI Track", and establish their baseline levels of daily intake of low GI foods. Participants discussed different strategies to

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increase their intake of low GI foods. Samples of menus and recipes incorporating low GI foods or ingredients were provided. In addition, snacks provided during the group meetings incorporated low GI food items (Appendix C) to reinforce the low GI message. This also provided an opportunity for participants to taste some low GI foods. At the end of each group meeting, participants set their realistic daily goals for the number of low GI foods they would try to achieve during the following week. Strategies to cope with "high risk" situations (e.g. situations that are not conducive to choosing low GI foods over high GI foods) were discussed. Suggestions to prevent and deal with relapse were part of the nutrition teaching as well.

The "GI Track" (Figure 3.1) was developed based on a commonly used dietary monitoring tool, the "FoodTrack, √ Check on Balance" (©BC Dairy Foundation, 1994) and served as a tool for the participants to monitor their daily low GI foods intake, while providing feedback and enhancing motivation. The "GI Track" was designed to be carried easily to facilitate monitoring of low GI food intake. On the front of the "GI Track", low GI food items were categorized according to the four major food groups found in the Canada's Food Guide to Healthy Eating (Health Canada, 1992). On the back, it provided examples of common low GI foods. These examples were taken from the extensive published listings of GI values for some major foods (Foster-Powell, et al, 2002; Foster-Powell, et al, 1995; Wolever, et al, 1994). The participants put a check mark on the "GI Track" whenever they consumed a serving of low GI food during snack or meal time. At the end of the day, FSFB participants simply summed up the number of check marks and recorded this number on a provided calendar. The GI Track was laminated so that it could be reused. Each "GI Track" came in an envelope, and with a

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water-soluble marker. During its development, the "GI Track" was critically reviewed by the nutrition professors, RDs, technicians and graduate students in the Department of Agricultural, Food and Nutritional Science for its convenience, simplicity, readability and practicality.

3.3 Recruitment of study participants:

Two major recruitment strategies were employed in this study to obtain a total minimum of 40 study participants: 1. Referral from the Edmonton Regional Diabetes Education Program and diabetes education centres in Edmonton, 2. Recruitment from the general Edmonton community via mass media or presentations to groups of people with diabetes. These strategies are described below. The inclusion criteria for this study are summarized in Chapter 4.

3.3.1 Diabetes education program or centre

In the previous FSP research studies, study participants were recruited through diabetes education centres (Tudor-Locke, et al, 2002; Tudor-Locke, et al, 2004). With this in mind, the initial recruitment strategy had the Edmonton Regional Diabetes Education Program and diabetes education centres refer potential study participants to the study.

With the assistance from a FSP facilitator, who is also a diabetes nurse educator at a local community hospital, 9 major diabetes education centres or programs across the Edmonton were identified (Table 3.1). Key contacts for each diabetes education centre or program were identified and approval to contact them was obtained. The FSFB study coordinator (SHC) contacted designated diabetes educators to set up meetings to provide

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an overview of the study and to explain the recruitment process. This recruitment process was approved by the ethics committee of the Faculty of Agriculture, Forestry, and Home Economics and the Health Research Ethics Board, University of Alberta.

A letter to the diabetes educators was prepared, providing an overview of the FSFB study and explaining the recruitment process. A "recruitment package" (Appendix D), consisting of the aforementioned letter, copies of the recruitment advertisement, the inclusion criteria, the summary of the FSFB research study, the information on the screening and the study intervention was prepared and given to all diabetes education centres or programs to facilitate the recruitment process. Weekly emails or phone calls were made to these diabetes educators to answer any possible concerns and to acknowledge their valuable contributions to the recruitment process.

3.3.2 Mass media and presentations to people with diabetes:

Previous lifestyle modification studies have used the media, primarily through advertisements, as a recruitment strategy (Kelley, et al, 2004; Agurs-Collins, et al, 1997; Hartwell, et al, 1986). The FSFB research study employed similar strategies to enhance the recruitment effort. A recruitment advertisement, where interested individuals could tear off the FSFB contact information easily (Appendix E), was developed so that it could be placed in some of the pharmacies in Edmonton. The rationale for choosing a pharmacy as a venue to put up the recruitment advertisement was that individuals with T2D who are on oral hypoglycemic agent(s) would most likely get their medication through local drug stores. After consultation with different pharmacies in the city, one major national pharmacy chain was chosen as the location for these ads. This was because the approval process of putting up an advertisement in any single pharmacy from this chain of store

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was done through a designated staff person, for all of the pharmacy stores in the City of Edmonton.

The study coordinator also contacted several local television stations to explore if these television stations would be interested in featuring the FSFB research study in one of their health news or reports. Two television stations[5], expressed interest in featuring the research study. An interview by one of these TV stations took place on April 26th, 2004, at the University of Alberta, Agriculture/Forestry Centre, and the program was aired on the same day during the evening news. The interview by another TV station took place on April 27th, 2004, at the venue of the TV station. The program was aired the same evening, every 15 minutes for 24-hours. One of the principle investigators for the FSFB research study, completed both television interviews[6].

In addition to the efforts described above, a press release was done to increase the exposure of the FSFB research study in the local media. The press release (Appendix F), completed with the assistance of Cynthia Strawson, Director of Communications, Faculty of Agriculture, Forestry and Home Economics, was forwarded to all major local TV stations and newspapers on May 3rd, 2004. Subsequently, a popular local TV station (different from the above two TV stations) and a local community newspaper were interested in the research study. The TV station completed an interview[2] with Dr. Rhonda Bell, on May 6th, 2004; the local community newspaper did a phone interview with Dr. Rhonda Bell the week of May 24th, 2004, and the research study was featured in the newspaper on May 27th, 2004 (Appendix G).

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[5] Cynthia Stawson, Director of Communications, Faculty of Agriculture, Forestry and Home Economics, helped the study coordinator (SHC) contacted an appropriate person in the one of local TV stations, who was interested in featuring the study.

[6] Tom McGee, a graduate of the FSP and one of the few FSP facilitators in Edmonton, participated in the A-Channel and CFRN television interviews.

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The final recruitment effort ended during the CDA Edmonton Annual Diabetes Forum on May 15th, 2004, at the Chateau Louis Hotel and Conference Centre. A recruitment poster (Appendix H) was developed to recruit potential candidates attending the forum. A summary of the results of the recruitment strategies employed is shown in Table 3.2.

3.4 Screening process:

The purpose of the screening process was to ensure that all study participants met the inclusion criteria for the study. Candidates who contacted the study coordinator or the assistant and expressed interest in the FSFB research study, were asked to attend a screening session. During the screening session, the inclusion criteria checklist (given to the diabetes educators) was used to check the eligibility for the research study. As well, all potential study participants were instructed to wear an electronic pedometer (Yamax, SW 200, Japan) for 3 consecutive days, which included one weekend day and two weekdays. If the average steps/day, calculated from these 3 days, was <8,800, the screened participant was eligible to take part in the research study. This cut-off point was used previously (Tudor-Locke, et al, 2004). Prior to use, pedometers were checked and calibrated according to the method described previously (Tudor-Locke, et al, 2001). In addition to the pedometer monitoring, all candidates who came to the screening session were taught how to complete the 3-day food record. Instruction was accomplished by using food models available in the Human Nutrition Research Centre and the examples in the 3-day food record.

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During the screening period, potential participants completed both a demographic questionnaire and the stages-of-change questionnaire for physical activity and dietary behaviour (participants also completed the stages-of-change questionnaire at the end of the intervention) (Appendix I). The questionnaire used in assessing the stage-of-change for physical activity was similar to one used previously (Tudor-Locke, et al, 2002; Marcus, et al, 1994). The questionnaire on the stage-of-change in dietary behaviour was developed based on a previously published questionnaire (Campbell, et al, 1994). In this questionnaire, questions were structured to assess the readiness to change the intake of vegetables and fruits, fiber and fat. This questionnaire consisted of only a four-stage scale: pre-contemplation, contemplation, preparation and action/maintenance. Action and maintenance stages were combined in the questionnaire as the length of the FSFB research study did not permit for a longer follow-up to assess maintenance of change.

3.5 Results:

3.5.1 Recruitment:

Table 3.2 provides a summary of the recruitment strategies. A total of 182 interested candidates called and inquired about the research study. Out of these calls, 66 individuals were eligible for the screening procedure. A total of 56 candidates completed the screening procedure; 10 candidates who did not complete the screening procedure either did not return their pedometer readings, or decided not to enter the study during the screening period. Reasons for not entering the research study included time conflict, change of jobs and the loss of interest. Out of the 56 people who completed the screening

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protocol, 12 had an average steps/day > 8,800, thus leaving 44 candidates eligible for the study. These final 44 candidates were recruited for the study.

3.5.2 Demographics:

Table 3.3 is a summary of the demographic information of the study participants. Results reported here are based on the 44 participants who were recruited for the study. Demographic information on the 38 participants who completed the study can be found in Chapter 4. Basically, participants recruited for the study were in their mid-50s. Diagnosis of T2D had occurred on average within the previous 4 years. Gender was approximately equally distributed in both groups. Thirty nine of the 44 participants were on at least one oral hypoglycemic agent, and 40 of them did not smoke at the time of screening. The majority of the participants had at least a high school diploma (84 %), and 75 % of them were working, either full- or part-time. Only 3 participants expressed concerns about taking part in the research project. The most common concern was not being able to keep up with the program. In addition, a majority of the participants indicated that they did not follow any specific dietary regime. For those who were following a diet regime, most cited their diet regime as a "diabetic diet". Not including the diabetes, the most commonly reported health problems among all participants were hypertension (45 % for both FSP and FSFB), high cholesterol (FSP=41 %, FSFB=45 %) and arthritis (FSP=27 %, FSFB=23 %).

3.5.3 Stages of change:

With respect to the physical activity stages of change, for the total sample before the intervention, 2% of the participants were in the pre-contemplation stage, 41 % were in the contemplation stage, 34 % were in preparation stage, 16 % were in action stage, and 7

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% were in maintenance stage (Table 3.4). Results at 16th week, based on those who completed the study, showed that most of the participants (>90 %) were in the preparation, action or maintenance stage (Table 3.5). Meanwhile, at baseline, majority of the participants (about 90 %) in the study were either in the preparation or action/maintenance stage of change for dietary behaviour at baseline (Table 3.4). Results at 16th week, based on those who completed the study, demonstrated similar results, where majority of the participant (i.e. >90 %) were still in the preparation or action/maintenance stage (Table 3.5). No further analysis was conducted to compare the differences between the groups in regards to the stages-of-change for both the physical activity and dietary behaviour.

3.6 Conclusion:

The first recruitment strategy utilized in this study was not as effective as anticipated. More than 4 weeks after the meetings with the diabetes educators across the city, only 6 phone calls had been received from the interested candidates. No calls were received from signs posted in the Pharmacies. The recruitment strategy that yielded the largest response from the community was the media approach. Sixty seven percent of the interested callers heard about the research study on television. Specifically, immediately after the all three television stations featured the FSFB research study in their health report news, over a 100 phone calls and messages were received in a 5-day period. All these efforts resulted in a total of 30 participants recruited for the first cohort of the research study. The first cohort of the study started in the week of May 31st, 2004.

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The article on the FSFB research study featured in the local community newspaper was also a successful recruitment strategy. Consequently, a total of 53 phone calls were received from the public who read about the study in the newspaper. A total of 14 participants (with one participant recruited from the CDA Edmonton Diabetes Forum) took part in the second cohort of the research study. This second cohort started the intervention in the week of June 14th, 2004.

The in-person screening procedure took an average of one hour per participant. The screening process was important in determining the eligibility for each candidate, because most of the participants were recruited from the general public or community, where a considerable number of them could be ineligible for various reasons. Out of the 175 calls received from the public (as a result of the media, including The Edmonton Sun), only 59 callers, or 34 %, were considered eligible to proceed to the screening procedure after careful telephone screening. Reasons for ineligibility from the screening procedure were: did not have T2D, were receiving insulin treatment to manage T2D, were on an exercise program/physically active, unable to travel to University of Alberta to attend group meetings/out of town, had no prior diabetes education, were of age 70 or more, and were not able to commit to group meetings.

At the time of screening, more than 50 % of the participants considered themselves engaged in some form of physical activity (regardless of the frequency and duration). Data from the stage of change for physical activity suggests that 57% of the participants were considering (i.e. preparation stage) or already were in the process (i.e. action or maintenance stage) of increasing their physical activity levels. However, at 16th weeks, more than 90 % of those who completed the study, rated themselves in the stage

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of preparation, action or maintenance, in which they considered themselves to be engaging in some of physical activity. This is consistent with the results of this study (found in Chapter 4) that demonstrated a significant increased in steps/day at the end of the study in both FSP and FSFB groups. Meanwhile, almost all of the participants considered themselves to be in the preparation or action stage of dietary behaviour change (for fruits and vegetables, fatty food and fiber intake) at baseline, since they were either actively considering changing their dietary behaviour, or they had recently made an overt dietary behaviour change This suggests that the participants recruited for this research study were ready to change their lifestyle by taking part in a lifestyle modification program to improve their diabetes management. Such behaviours seemed to remain the same throughout the study period.

These characteristics of our sample did not come as a surprise, since as with other clinical trials, volunteer participants tend to be more open to change behaviour than eligible non-volunteers. A random sample of individuals with T2D surveyed showed that majority of them (>50 %) were in the pre-action (i.e. pre-contemplation and contemplation) stages of change with respect to exercise (Plotnikoff, et al, 2000), while participants in our study were generally classified as in the preparation or action or maintenance stages. Meanwhile, Peterson and associates characterized the readiness to improve diabetes management among T2D patients who had A1C values >9.0 %, before taking part in a 3-month diabetes educational intervention (Peterson, et al, 2002). They revealed that 78 % of their T2D patients recruited for their study were either in preparation (39 %) or action stages (39 %). Our findings were similar to Vallis and associates as well in that the majority (>50 %) of the study participants recruited for a

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lifestyle intervention study were in the preparation, action or maintenance stages in terms of healthy, low fat eating behaviours (Vallis, et al, 2003). Again, this showed that T2D individuals who were willing to participate in a diabetes self-care management were either in the state of mind of considering, or in the process of making lifestyle changes. Furthermore, the low dropout rate in our study (14 %) demonstrated that the study participants were motivated and committed to lifestyle changes. However, the applicability and practicality of the FSFB program to the general T2D population might actually be questionable. This is because majority of this population tends to be in the pre-action stage (Plontnikoff, et al, 2000). It is possible that a majority of individuals with T2D might not be interested in participating in any lifestyle modification program, including the FSFB.

The teaching materials, such as the workbook and "GI track", were not formally evaluated. Anecdotally, the teaching materials used in the FSFB, including the CDA education materials, the FSFB workbook and "GI Track", were well received by the FSFB participants. Most participants (>50 %) completed their GI calendar. Furthermore, the evaluation conducted at the end of the group meetings showed that majority of the participants enjoyed the program (Appendix J). Also, close to 70 % of the participants rated the "GI Track" "helpful to very helpful" in achieving their daily intake goals for the number of low GI foods; about 60 % of them were "likely to very likely" to continue using the "GI Track" in the future.

In summary, the media strategy used in recruiting the study participants in this study attracted more subjects than the other methods used. Study volunteers who signed

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up for this research project were considered open to making lifestyle changes. The majority of the study participants found both the FSP and FSFB very helpful.

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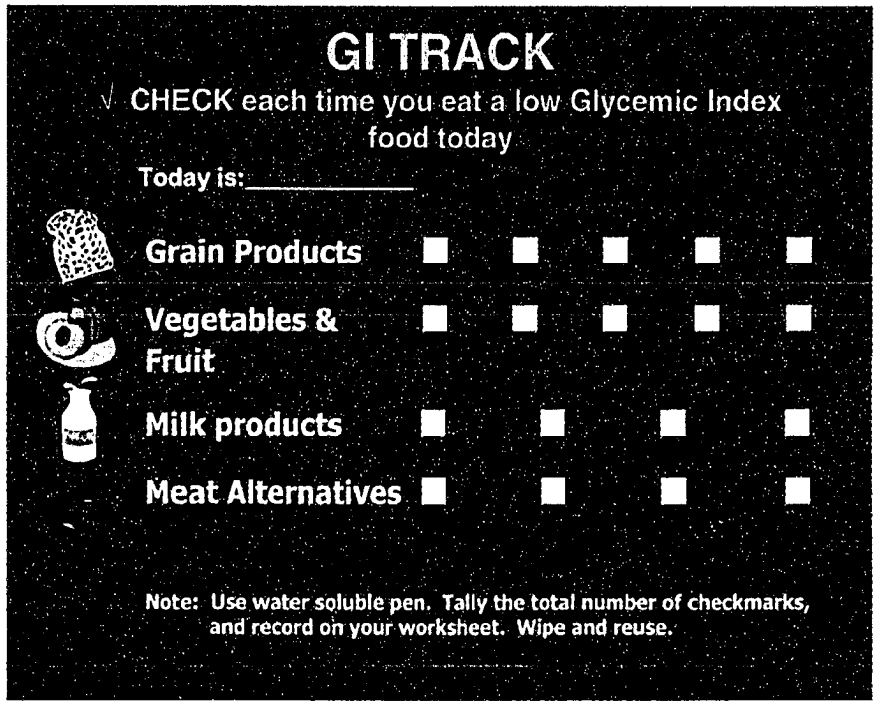
Figure 3.1: The "GI Track": A pocket-size checklist used to help FSFB participants monitor their daily intake of low GI foods



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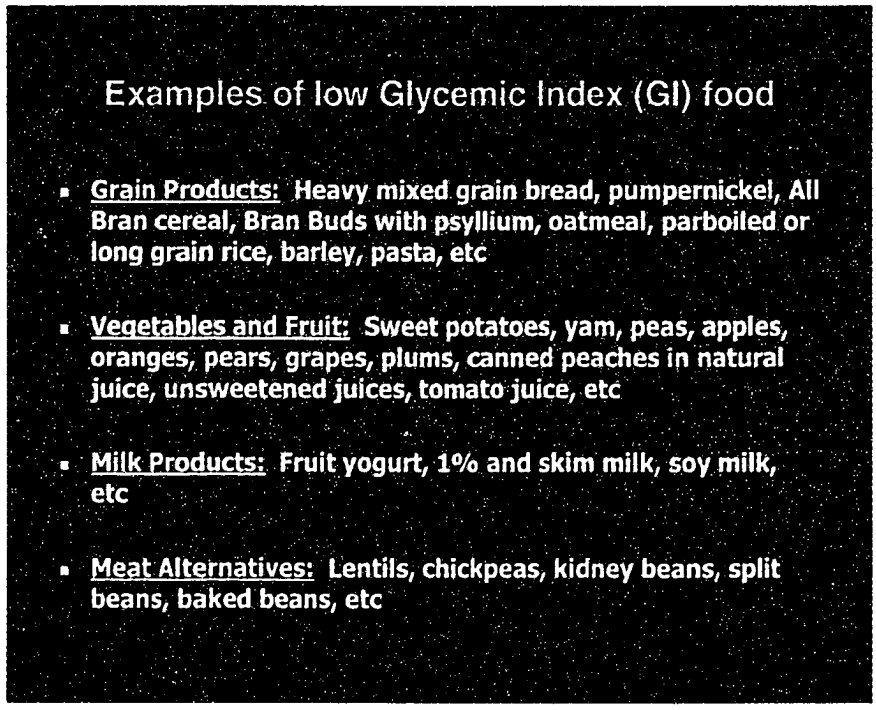

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Table 3.1: List of Edmonton Regional Diabetes Programs and Centres participated in the recruitment of the FSFB research study

Names of diabetes program or centre
• Grey Nuns Community Diabetes Education Centre • Misericordia Community Hospital Diabetes Education Centre • University Hospital Diabetes Education Program • Royal Alexandra Hospital Diabetes Program • Sturgeon Community Hospital Diabetes Education Program • Aboriginal Diabetes Education Program • North East Community Health Centre • Leduc Community Hospital Diabetes Education Program • West Edmonton Diabetes Program

Table 3.2: Summary results of the recruitment strategy

Recruitment strategy	Total of calls received	Total of screenings	Total of completed screening	Total of candidates eligible for and recruited for the study	Total of participants completed the study
Regional Diabetes Program	6	6	4	4	4
Pharmacy Chain	0	0	0	0	0
Diabetes Forum	1	1	1	1	1
TV stations	122	36	31	26	23
Local community newspaper	53	23	20	13	10
Total	182	66	56	44	38

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Table 3.3: Summary of the demographics information of 44 study participants recruited for the FSFB research study

Characteristic	FSP	FSFB
Average Age* (years)	54.1 ± 1.3	55.1 ± 2.1
Gender	11 males, 11 females	12 males, 10 females
Ethnicity (person)	Caucasian: 18 Metis: 4 Chinese: 0	Caucasian: 20 Metis: 1 Chinese: 1
Frequency of physical activity (%)	At least 3 times/week: 27% 1 or 2 times/week: 46% Rarely or never: 27%	At least 3 times/week: 9% 1 or 2 times/week: 36% Rarely or never: 55%
Currently on a diet program (%)	Yes: 9% No: 91%	Yes: 9% No: 91%
Average length of Diabetes* (months)	45.1 ± 7.8	53.0 ± 14.0
Oral hypoglycemic agent (person)	Yes: 21 No: 1	Yes: 18 No: 4
Common Health Problems	Arthritis: 27% Hypertension: 45% High cholesterol: 41%	Arthritis: 23% Hypertension: 45% High cholesterol: 45%
Smoking Status (person)	Current smoker: 1 Former smoker: 9 Non smoker: 12	Current smoker: 3 Former smoker: 6 Non smoker: 13
Education level (person)	Elementary: 0 Some high school: 3 High school diploma: 3 Some college/university: 15 Post graduate degree: 1	Elementary: 1 Some high school: 3 High school diploma: 6 Some college/university: 8 Post graduate degree: 4
Employment status (person)	Full time: 18 Self-employed: 1 Student: 1 Retired: 2	Full time: 13 Part-time: 1 Homemaker/caretaker: 2 Retired: 6
Financial status (person)	Wealthy: 7 Above average: 8 Average: 7 Below average: 0	Wealthy: 8 Above average: 8 Average: 5 Below average: 1
Concerns taking part in the study (person)	Yes: 2 No: 20	Yes: 1 No: 21

*Data are means ± SEM unless otherwise indicated. No statistically significant differences between groups were noted

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Table 3.4: Number of people classified in each stage of change for the physical activity and dietary behaviours at baseline. A: FSP group (n = 22); B: FSFB group (n = 22). The values reflect the number of people. For dietary behaviour, the maintenance and action stages are combined into one stage.

A. FSP Group

	Pre-contemplation	Contemplation	Preparation	Action	Maintenance
Physical Activity	**0**	**10**	**6**	**5**	1
Fruits & Vegetables intake	**0**	**0**	**12**	**10**	-
Fatty food intake	**0**	**0**	**10**	**12**	-
Fiber intake	1	0	10	11	-

B. FSFB Group

	Pre-contemplation	Contemplation	Preparation	Action	Maintenance
Physical Activity	**1**	**8**	**9**	**2**	2
Fruits & Vegetables intake	**1**	**1**	**9**	**11**	-
Fatty food intake	**1**	**0**	**11**	**10**	-
Fiber intake	1	1	11	9	-

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Table 3.5: Number of people classified in each stage of change for the physical activity and dietary behaviours at 16th week. A: FSP group (n = 19); B: FSFB group (n = 19). The values reflect the number of people. For dietary behaviour, the maintenance and action stages are combined into one stage.

A. FSP Group

	Pre-contemplation	Contemplation	Preparation	Action	Maintenance
Physical Activity	1	0	6	10	2
Fruits & Vegetables intake	1	0	10	8	-
Fatty food intake	1	0	9	9	-
Fiber intake	0	1	11	7	-

B. FSFB Group

	Pre-contemplation	Contemplation	Preparation	Action	Maintenance
Physical Activity	0	1	4	11	2
Fruits & Vegetables intake	1	2	10	6	-
Fatty food intake	1	0	14	4	-
Fiber intake	1	1	13	4	-

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Chapter 4: The evaluation of the First Step First Bite Program

4.1 Introduction:

The incidence of T2D is increasing dramatically (Wild, et al, 2004; Mokdad et al, 2001). It is estimated that the number of people with diabetes worldwide will rise from 171 million in 2000 to 366 million in 2030 (Wild, et al, 2004). Some of the contributing factors to such an increase in prevalence include the increasing incidence of obesity and physical inactivity (Boyle, et al, 2001; Wild, et al, 2004).

Numerous studies have demonstrated positive effects of combining both dietary and physical activity interventions (i.e. lifestyle intervention), in a supervised or controlled environment, on glycemic control and other CVD risk factors, such as high cholesterol and blood pressure (Mayer-Davis, et al, 2004; Wolf, et al, 2004; Goldhaber-Fiebert, et al, 2003; Toobert, et al, 2003; Agrus-Collins et al, 1997). Even though these lifestyle interventions are proven effective in reducing the risk of T2D, the resource burden of these lifestyle programs may be too great for the patients, clinicians and health care systems to implement realistically (The DPP Research Group, 2003). Thus, translating these lifestyle treatment trials into lower-intensity, cost-effective interventions is crucial in allowing maximal applicability in practice and long term maintenance of the interventions among individuals with T2D (Glasgow, 2003; Glasgow et al, 2003).

The FSP is a practical physical activity intervention program, which uses a simple physical activity message of "walk more", along with a pedometer as a monitoring and motivational tool, to help individuals with T2D increase their physical activity (Tudor-Locke, et al, 2000). FSP participants typically increase their number of step/day by

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approximately 3000 (vs. baseline), accounting for approximately an extra 30 minutes of walking/day (Tudor-Locke, et al, 2004; Tudor-Locke, et al, 2002). Despite the significant increases in physical activity, the improvements in the physiological health indicators, such as the fasting glucose, insulin and plasma lipids, resting heart rate and blood pressure, body weight, and oral glucose tolerance were small (Tudor-Locke, et al, 2004). It is possible that given the self-directed nature of the FSP, the participants did not increase their physical activity enough to cause changes in these indicators (Tudor-Locke, et al, 2004). In addition, it is likely that positive health benefits could be facilitated if participants were to make changes in dietary intake at the same time as they increase their physical activity (i.e. lifestyle intervention). Currently, the FSP does not provide any information about dietary intake for optimizing glycemic control and reducing the risk of CVD.

In this study, a simple nutrition message of "choose more low GI foods" was incorporated into the FSP, to facilitate lifestyle changes. In the 1980's, Dr. David Jenkins and colleagues outlined the concept of GI for classifying the glycemic response of carbohydrate-containing foods (Jenkins, et al, 1984; Jenkins, et al, 1981). The GI is used to describe the extent of the acute rise in blood glucose concentration after consumption of 50g of available carbohydrates in a test food, relative to the rise evoked following ingestion of the equivalent amount of carbohydrates in a reference food, usually glucose or white bread. Today, extensive listings of GI values for a variety of foods are available for references (Foster-Powell, et al, 2002; Foster-Powell, et al, 1995; Wolever, et al, 1994). There is considerable evidence that demonstrates the salutary effect of a low GI diet on individuals with T2D (Jarvi, et al, 1999; Wolever, et al, 1992a,b; Fontvieille, et al,

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1992; Brand, et al, 1991; Jenkins, et al, 1988). The improvements observed included glycemic control, lipid profiles and fibrinolytic activity. A meta-analysis conducted by Brand-Miller showed that low GI diets can potentially reduce the A1C by 0.43 percent compared to a high GI diet (Brand-Miller, et al, 2003). Recently, the guidelines for the nutritional management of diabetes mellitus released by the CDA recommended replacing high GI foods with low GI foods as part of the nutrition therapy in managing diabetes (CDA, 2003; Wolever, et al, 1999). Stemming from this recommendation, CDA has developed and released its new GI education teaching tools (described below) to help diabetes educators and individuals with diabetes incorporate low GI foods as part of a healthy eating plan in managing diabetes.

Taking this opportunity, we developed a lifestyle intervention program, FSFB, which builds on the FSP. This practical lifestyle intervention program couples the physical activity message of "walk more" with a dietary intake message of "choose more low GI foods" to help improve the management of T2D. We hypothesized that upon the completion of the FSFB, participants in this group would increase their daily intake of low GI food, in addition to increasing in their physical activity. The objectives of this study were to compare changes both in glycemic control and other health indicators in people with T2D who received the FSFB vs. FSP.

4.2 Research Design and methods:

This was a randomized, clinical trial of lifestyle intervention in patients with T2D. Participants were recruited from the general community by local media and advertising. Inclusion criteria were 1) having T2D, 2) not taking insulin treatment, 3) being between

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the ages of 40 and 70, 4) having no known CVD or contraindications to moderate physical activity (i.e. walking), 5) not currently participating in an exercise program, 6) having an average of 3-day pedometer reading of less than 8,800 steps/day (via a 3-day pedometer protocol), 7) having previously received basic diabetes education from a diabetes educator or physician.

Individuals who were taking insulin to manage their T2D diabetes, as this group of individuals, are more likely to have a severe type of T2D (comparing to those where managing with diet and/or oral hypoglycemic agent), and therefore were excluded from this study. The age range of 40 – 70 was chosen because most individuals with T2D are found in this age range. In addition, individuals with T2D over 70 years of age may be associated with other co-morbidities, such as arthritis and CVD, which may prohibit them from taking part in a lifestyle modification program that involves physical activity. The FSP/FSFB is a lifestyle intervention program that helps inactive T2D individuals to initiate physical activity. Therefore, FSP/FSFB might not be beneficial to those who were taking part in any physical activity or exercise program, such as aerobics and cross-country skiing. The rationale of recruiting participants who had previously received basic diabetes education was that participants needed to be aware of basic aspects of self-care diabetes management, such as foot care and medications, but may continue to benefit from a lifestyle approach. An average daily steps of <8,800 has been used previously in the FSP research study as an inclusion criteria (Tudor-Locke, et al, 2004). Evidence exists suggesting that people who take <9,000 steps/day are likely to have an abnormal BMI, thus providing an indication of individuals who may benefit from a physical activity intervention (Tudor-Locke, et al, 2001).

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The study protocol was approved by the ethics committee of the Faculty of Agriculture, Forestry, and Home Economics and the Health Research Ethics Board, University of Alberta. All study participants gave a written informed consent.

4.2.1 Screening:

Potential study participants were interviewed by study coordinators to determine their eligibility for the study. During the screening, participants completed a background questionnaire to solicit demographic information. In addition, they were required to complete a 3-day pedometer protocol, previously described in detail elsewhere (Tudor-Locke, et al, 2005). Briefly, potential participants were instructed to wear a pedometer (Yamax SW-200, Japan) for 3 consecutive days (two weekdays and one weekend day) during waking hours while engaging in their usual activities. They were instructed to record their daily steps/day on the provided log. Participants were considered eligible for the study if their steps/day average was <8,800. No participants reported engaging in activities that could not be detected by the pedometer (e.g. water activities, biking).

4.2.2 Intervention:

FSP: The FSP has been previously developed and evaluated systematically, in collaboration with diabetes educators and people with T2D; it is described in detail elsewhere (Tudor-Locke, et al, 2004; Tudor-Locke, et al, 2002; Tudor-Locke, et al, 2001; Tudor-Locke, et al, 2000). Briefly, it is a facilitated behaviour modification program designed to help people with T2D increase their physical activity. It is based on the principles of self-efficacy and social support, and uses goal setting, self-monitoring and feedback (using a pedometer), as well as the simple premise that walking can be gradually increased over time. The FSP is comprised of four 60-90-minute weekly group

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meetings (i.e. adoption phase), followed by twelve-weeks of adherence phase. During the adoption phase, participants learned how to use a pedometer and established a baseline level of their steps/day. During the sessions, participants also learned to use personal goal-setting, self-monitoring and feedback to increase their physical activity. During the adherence phase, FSP participants monitored their steps/day using a pedometer, and recorded their steps/day in a provided calendar. Follow-up or professional telephone contact was not available to the participants during this period. Instead, motivational postcards, encouraging participants to keep up with their physical activity, were sent to participants at weeks 6 and 10. No nutrition intervention was given to the FSP.

FSFB: The FSFB used the same theoretical basis as the FSP, but in addition to the physical activity message of the FSP, those participants in the FSFB also received the nutrition intervention during the group meetings. Specifically, during the adoption phase (i.e. weeks 1-4), the concept of GI was introduced to FSFB participants and they were taught to use the principles of goal setting and feedback to increase their daily intake of low GI foods. The feedback tool, known as the "GI Track" was designed for this study. The "GI Track" (Figure 3.1) is a pocket-size, laminated checklist designed to help participants monitor their daily intake of low GI foods. It serves as a motivational, self-monitoring and feedback tool. The "GI Track" was developed based on widely available food intake monitoring tools, such as the "FoodTrack, √ Check on Balance" (©BC Dairy Foundation, 1994). It was designed to be easily carried, and thus be accessible for frequent recording. The participants were asked to put a check mark on the "GI Track" whenever they consumed a serving of low GI food. At the end of the day, FSFB participants simply tallied up the total number of check marks and recorded the number

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of check marks on the calendar provided. The "GI Track" could be wiped clean at the start of each day.

The GI education component in the FSFB was accomplished by using the GI teaching materials: the "Glycemic Index Explained" and "The Glycemic Index," both developed by the CDA (CDA, 2003). Sample meal plans, recipes and snacks incorporating low GI foods or ingredients were provided during the group meetings. During the adherence phase (i.e. weeks 5-16), FSFB participants not only monitored and recorded their steps/day, they also monitored and recorded their daily low GI food intake using the "GI Track". Similar to FSP, motivational post cards that emphasized physical activity and the importance of low GI choices were sent to the FSFB participants at weeks 6 and 10.

All group meetings were facilitated by the same RD, who is trained as a FSP facilitator, to ensure consistency in program delivery. All group meetings were held at the University of Alberta, Human Nutrition Research Centre.

4.2.3 Measurements:

Study participants were assessed at baseline and the 16th week (end) of the study. At each assessment point, study participants were instructed by an RD on how to complete a 3-day food record (two weekdays and one weekend day). Body weight and height were measured with subjects wearing a hospital gown and no shoes; weight was measured using a digital scale (Stand-on-Scale, Seca 220) and height was measured using a wall-mounted stadiometer (QuickMedical, Heighttronic^{TM}). BMI was calculated by dividing weight (in kg) by height (in meters) squared. Waist and hip circumferences were measured over a hospital gown using a non-stretch tape measure, and according to the

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standard anthropometric procedures; waist to hip ratio was calculated using these measurements. These anthropometric measurements were determined three times, with the average of these readings included in the statistical analysis. Percentage of body fat, fat mass and lean body mass were measured using dual-energy x-ray absorptiometry (DEXA) (Lunar Prodigy, General Electric, USA.) All scans were administered by a trained x-ray technologist who was blinded to the treatment group of the participants. Resting blood pressure and heart rate were measured using a digital sphyngomanometer according to the manufacturer instructions (Quick Response, LifeSource™, UA-787). These measurements were also taken 3 times and the average of the three readings was recorded. A1C was determined from whole blood obtained from a finger-prick, using an auto-analyzer (DCA 2000+ Analyzer, Bayer, USA). There is evidence demonstrating that A1C values determined by the DCA 2000+ analyzer using capillary blood, shows good accuracy and reliability when compared to A1C values determined by the high-performance liquid chromatography using venous blood (Diem, et al, 2004; Arsie, et al, 2000; DCA 2000+ Hemoglobin A1C Reagent Kit Instruction sheet, Bayer, 2000). However, there is some suggestion that the A1C values may be underestimated by approximately 0.4 % when using the DCA 2000+ analyzers when compared to local laboratories (Paty, 2005, personal communication).

Food records were analyzed using the Food Processor® SQL (ESHA Research, USA). Average daily intake of low GI foods was estimated from the 3-day food record. A food having a GI value of <55, based on glucose as standard food, was considered low GI food (CDA, 2003). GI values were determined using published GI values (Foster-Powell, Holt, Brand-Miller, 2002; Foster-Powell, Holt, Brand-Miller, 1995; Wolever, et al, 1994).

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When GI values of certain foods were not available, GI values based on similar foods were used. One serving of low GI food was determined using the specified serving size for each food group outlined in the Canada's Food Guide to Healthy Eating (Health Canada, 1992). For example, one serving of low GI foods = ½ cup of parboiled rice or 1 medium apple or 1 cup of milk. Average daily intake of vegetables and fruits, and milk products were calculated as well; these 2 food groups have been targeted by other messages designed to promote generally healthy eating (e.g. "5 a day-for better health" campaign) (Foerster, et al, 1995).

4.2.4 Statistics:

Statistical analyses were performed using SPSS (SPSS 12.0, Chicago, USA). All data is presented as mean + SEM, unless otherwise stated. Two-way ANOVA, with a factor being the treatment group, and the other being time, was performed to determine differences between the groups and over time A P value of 0.05 was considered statistically significant.

Correlation analyses were conducted to explore the relationships between steps/day and body weight, anthropometry and A1C concentrations at baseline (for all participants) and at the end (16^{th} week) of the study (for all participants and by treatment group, depending on the analysis). This type of analysis was also used to explore relationships between the intake of low GI foods and body weight, anthropometry and A1C levels.

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4.3 Results

A total of 66 candidates were screened for this study, 44 of whom met the eligibility criteria. These 44 participants were randomized to either the FSP (n=22) or FSFB (n=22). One participant withdrew from the study after the first group meeting; a total of 43 participants completed the intervention (n= 21 for the FSP, n=23 for the FSFB). Of these 43 participants, 41 attended all four group meetings; 2 (both from the FSP group) attended three of the four group meetings. A total of 5 participants (n=2 from the FSP, n=3 from the FSFB) did not return for the measurements at the end of the study. This resulted in a total of 38 participants (n=19 for both FSP and FSFB) completing the study. The findings reported here are based on the 38 participants assessed at both baseline and the 16^{th} week.

4.3.1 Baseline characteristics:

Baseline characteristics of the FSP and FSFB participants are shown in Table 4.1. There were no significant differences between the FSP and the FSFB groups. The baseline characteristics of the 6 participants who did not complete the study were similar to those subjects who completed the study. Generally, participants in this study were in their mid-50s and had BMIs that would be considered obese (Health Canada, 2003). Mean A1C suggested moderately good glycemic control for both groups. The systolic pressure for both groups was considered in the normal range, but the diastolic pressure was considered moderately high for the management of T2D (CDA, 2003). Aside from diabetes, the most commonly reported health problems among participants (N=38) were high cholesterol (45%), hypertension (40%) and arthritis (32%). Seventy-nine percent of the participants were employed, with 3% and 18% considering themselves to be

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homemakers/caretakers and retirees, respectively. Of the total sample, 3% had elementary education, 13% had some high school education, 16% had high school diplomas, 55% had some post-secondary education, and 13% had post graduate degrees.

4.3.2 Outcome measures:

Physical activity and health measurements: One FSFB participant did not return steps/day data at the 16th week. One FSP participant had a weight that exceeded the recommended limit for the DEXA bed (i.e. >300 lbs), and thus did not complete the DEXA scans throughout the study. The resting blood pressure and heart rate of one FSP participant were not successfully measured at the 16th week due to a technical difficulty.

A summary of the outcome measures at the 16th week is shown in Tables 4.2 and 4.3. There were no statistically significant differences between the groups at the 16th week, for all outcome measures. Both the FSP and FSFB groups significantly increased their steps/day at 16 weeks compared to baseline. The FSFB group increased their steps/day by approximately 4000, while those in the FSP group increased their steps/day by approximately 2800 steps (Figure 4.2a.) The difference in the increase between groups did not differ significantly. Body weight and BMI did not change significantly in the FSFB group, but did decrease significantly in the FSP group compared to baseline ($p<0.01$) (Figure 4.2b, 4.2c.) Both groups experienced a significant reduction in waist and hip girth by the end of the study (Figure 4.2d, 4.2e); this resulted in a significant reduction in waist to hip ratio. In addition, the A1C values and fat mass, measured by DEXA, in both groups showed slight improvements from baseline, but the changes did not reach statistical significance (Figure 4.2f, 4.2g). These changes, for the FSFB and FSP respectively, were from 35.1 ± 2.4 to 34.7 ± 2.5 kg and from 39.3 ± 2.8 to 37.4 ± 2.7

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kg for fat mass, and from 7.2 ± 0.3 to 7.0 ± 0.3 % and from 7.2 ± 0.2 to 7.0 ± 0.2 % for A1C values.

Dietary measurements: A total of 36 food records (n=19 and n=17 for FSP and FSFB groups, respectively) were returned at the end of the study. A summary of the intake of major macronutrients and food groups before and after the study is shown in Table 4.3. Neither group changed their intake of macronutrients, vegetables and fruit or milk products significantly compared to the baseline period. Even though both groups reduced their average energy intake by approximately 450 kcal from baseline (-429 ± 264 kcal in the FSFB and –499 ± 311 kcal in the FSP), this reduction did not reach statistical significance. People in the FSFB group increased their daily intake of low GI foods significantly by about 2 servings compared to baseline (Figure 4.3).

4.3.3 Correlational Analyses:

For the total sample, baseline (N = 44) average daily intake of low GI foods was significantly inversely correlated with waist girth (r = -0.30, p=0.045). At the 16th week (N = 37), steps/day were inversely correlated with weight (r = -0.34, p = 0.040), waist (r = -0.38, p=0.021) and A1C (r = -0.37, p=0.026). Daily intake of low GI foods at the 16th week (N = 36) was significantly inversely correlated with the A1C (r = -0.51, p = 0.001) (Figure 4.4a). Specifically, daily intake of low GI foods at the 16th week were significantly inversely correlated with the A1C for both the FSP and FSFB groups (r = -0.495, p = 0.031 and r = -0.58, p = 0.015 respectively) (Figure 4.4b, c).

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4.4 Conclusions:

The results of this study suggest that the FSFB is an effective lifestyle intervention program in increasing physical activity and daily low GI food intake for individuals with T2D. Previous iterations of the FSP in individuals with T2D have focused solely on physical activity, while the FSFB combined two messages and targeted two different lifestyle behaviours. Thus, it is encouraging that both of these behaviours changed when the lifestyle messages were combined and presented in the same general structure as the FSP. Many lifestyle intervention studies have used a structured, supervised and/or intensive approach to bring about behaviour change (Mayer-Davis, et al, 2004; Wolf, et al, 2004; Goldhaber-Fiebert, et al, 2003; Toobert, et al, 2003; Agurs-Collins, et al, 1997). The FSFB and the FSP are designed specifically to be practical and to utilize minimal resources. Thus, the fact that behaviour changes were observed suggests that these programs can be useful, perhaps in place of more structured, resource-intensive programs.

With respect to the impact of the FSFB program on physical activity, our study confirms previous findings that the FSP is effective in helping individuals with T2D increase physical activity (Tudor-Locke, et al, 2004; Tudor-Locke, et al, 2002). Assuming that on average, individuals with T2D take about 110 steps in 1 minute of self-paced walking (Ford, et al, 1995), the average increment of 3468 steps from both study groups represents an extra 31.5 minute of walking/day. This finding is consistent with results observed in a previous study by Tudor-Locke and colleagues of additional 31 minutes of walking per day (Tudor-Locke, et al, 2004). Therefore, combining the

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physical activity message with a second message of dietary advice, the FSFB did not diminish the impact of physical activity in the program.

Despite these similar increments in physical activity, there were small differences between the groups in terms of weight loss and anthropometric measures between the study groups. The improvements observed among the FSFB participants included reductions in waist and hip girths compared with their baseline measures, while the FSP participants had significant reductions in body weight, BMI, and waist and hip girths compared to baseline. It is interesting that the improvements in the FSP slightly exceeded those experienced by participants in the FSFB group. Specifically, compared to FSFB, those in the FSP group lost slightly more body weight (-1.1 ± 0.5 vs. –2.7 ± 0.9 kg, respectively), reduced their waist (-3.8 ± 0.5 vs. -6.0 ± 0.9 cm, respectively) and hip girths (-2.2 ± 0.5 vs. -3.7 ± 0.6 cm, respectively) to a greater degree, and decreased their percent of body fat (-0.04 ± 0.4 vs. -0.8 ± 0.4 %, respectively) and body fat mass (-0.4 ± 0.5 vs. -1.9 ± 0.6 kg, respectively) slightly; however, none of these differences were statistically significant. The participants in the FSP group were slightly more obese (obese Class II) than those in the FSFB group (obese Class I) at baseline (Health Canada, 2003) which coincided with a slightly higher amount of body weight, body fat mass, waist and hip girth at baseline. Therefore, it is possible that individuals with a higher classification of obesity may be more responsive to any form of lifestyle intervention. In Tudor-Locke's study, the baseline BMI, weight, waist and hip girths in the treatment group were similar to our FSFB group (Tudor-Locke, et al, 2004). The improvements observed in the study, such as reductions in weight and waist girth, were of a similar magnitude to those observed in our FSFB group. Moreover, T2D is characterized by

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insulin resistance and progressive beta cell function failure, where oral hypoglycemic agent(s) is often required as the disease progresses (CDA, 2003). Therefore, the history of T2D may influence the impact of the FSFB on the health outcomes, such as weight and BMI, measured in this study. Baseline data demonstrated that the FSFB participants had an average history of T2D about 4.5 years, which was about 1 year more than the FSP participants. This may imply that FSFB participants were more insulin resistance than the FSP participants, where a more intensive lifestyle modification program may be required for the FSFB participants to observe similar reductions in weight, BMI, waist and hip girths.

There were also slight differences between the results of this study and those of Tudor-Locke, et al previous study (Tudor-Locke, et al, 2004). At the end of the present study, the FSP group experienced a significant reduction in body weight, BMI, and waist and hip girths compared to baseline. Over the 16 weeks of this study, the FSP group lost an average of 2.8 kg compared to 0.7 kg in the previous study; BMI decreased from 35.5 to 34.7 kg/m^2; hip and waist girths were reduced by magnitudes of 7 cm and 3.7 cm respectively (vs. 3.0 cm and 1.8 cm, respectively in Tudor-Locke's findings). Again, one reason for this might be due to the higher body mass in our FSP group at baseline than the FSP group in Tudor-Locke's trial. The A1C did not improve in either of our study groups, which is consistent with Tudor-Locke, et al previous findings.

Physical activity and increased consumption of low GI foods are thought to have a positive effect on metabolic control in individuals with T2D (Sigal, et al 2004; Ludwig, 2002). Correlational analyses were used to explore whether such associations existed in our study population. Such analyses revealed some interesting simple associations

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among key variables. First, there was a significant inverse association between steps/day and A1C concentrations at the 16th week for the FSP and FSFB groups combined. Therefore, participants who had a higher number of steps/day at the 16th week had lower A1C values. This is particularly impressive because subjects in this study had relatively low A1C concentrations at the start of the study. There were also significant inverse correlations between the number of steps/day at 16 weeks and body weight, and between the number of steps/day and waist girth. This demonstrates that across the range of physical activity, more activity was associated with better glycemic control and reductions in risk factors for CVD.

The second interesting association observed was between the daily intakes of low GI foods at the 16th week and the A1C levels for the whole sample. A similar correlation also existed for both the FSP and FSFB samples. Thus, participants who had higher intake of low GI foods at the 16th week had lower A1C values. Again, this observation is important because subjects in this study began the study with relatively good glycemic control, and suggests that increased intake of low GI foods is associated with further improvements in glycemia. In addition, there was no significant inverse correlation between the daily intake of low GI food and FSP sample at baseline, but such correlation was significant at 16th week. Even though the FSP participants (on average) did not increase their daily intake of low GI foods significantly over time, 8 out of the 19 FSP participants (compared to 10 out of the 19 FSFB participants) increased their daily intake of low GI foods by at least one serving over time. Canadians were informed by the Dietitians of Canada (via the released of "Glycemic Index: the new buzz word, but what is it really?" newsletter) in June 2004 (i.e. during the study period), to encourage the use

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of low GI over high GI foods. The maximum daily intake of low GI foods for the FSP and FSFB groups were 4.67 and 7.17 servings respectively. This may have contributed to an increased exposure of this particular nutrition message among the FSP participants.

When compared to other lifestyle modification programs for individuals with T2D conducted to-date, physiological changes incurred through the FSP/FSFB can be considered relatively modest. This might be due to several reasons. Both the FSFB and the FSP are of a self-directed nature and are based on the principles of self-efficacy and social support. They use a combination of personal goal setting, self-monitoring and feedback to help lifestyle changes. Therefore, these programs are not heavily structured or intensively supervised. They are, however, practical and easy to implement, and therefore are important from a real-life point of view.

As well, the length and follow-up frequency in this project was shorter and less frequent than in some other trials. In the POWER trial, (Mayer-Davis, et al, 2004), participants with T2D who were assigned to the "intensive-lifestyle" group met weekly with a nutritionist for up to 4 months, and this was followed by regular follow-up visits for up to 8 months. Over time, the participants lost a significant amount of body weight of 2.2 ± 0.4 kg and A1C improved by 1.6 ± 0.3 % over the time of the study (Mayer-Davis, et al, 2004). In the FSP/FSFB, the intervention was only 4 weeks long, followed by a 12-week adherence phase. Also, the intervention was done in a group setting. The fact that the changes achieved by the more intensive program are within the realm of the changes observed in the present study, bodes well for less intense interventions that might be more easily managed and resourced than more intensive programs.

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In the ICAN study, a 12-month lifestyle intervention program led by a RD, participants in the lifestyle case management received both individualized and group counseling, with monthly phone contacts; participants in this study had a goal of 5% weight loss (Wolf, et al, 2004). At the end of the study, these participants had lost 2.4 ± 1.0 kg of weight when compared to baseline, and had a -0.2% reduction in A1C concentrations when compared to the control group. In regards to waist girth, the participants in the ICAN study lost approximately 5.5 ± 1.0 cm at the end of the study. The reduction of 3.8 ± 0.5 cm in waist girth observed in the FSFB group is important when considered in the context of more intensive interventions such as the ICAN study, given the fact that the interventions in our study were shorter and required less frequent contact with study coordinators.

Good glycemic control prior to a lifestyle modification program might have influenced our ability to detect improvements in A1C, as well as other health outcomes, such as body weight, and blood pressure. Subjects in the present study started with relatively good glycemic control, which showed a small, positive change in response to the changes in lifestyle. Participants in the POWER trial improved their A1C by -0.84 percent (with no improvement in other physiological health indicators), but their starting A1C was 9.7 ± 3.1% in the group prior to the intervention.

In our study, the nutrient analysis demonstrates that the FSFB participants altered their dietary behaviour by increasing the number of low GI foods eaten daily. There were no changes in the overall macronutrient composition or in the consumption of servings of vegetables and fruits or milk products. This is consistent with the message given during the FSFB intervention since other aspects of healthy eating in managing T2D, while

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discussed briefly, were not emphasized by this intervention. Participants in the FSFB increased their daily intake of low GI foods by about 2 servings. Nevertheless, this sole dietary change might not be sufficient to have an impact on the measured health outcomes in the time frame of this study.

The simple nutrition message of encouraging the use of low GI foods in the diabetes nutrition education is only a small part of the whole nutritional intake picture in the management of diabetes. The nutrition component in the lifestyle modification programs mentioned above included other major healthy eating principles. These include portion control, weight reducing/maintenance diet and high-fiber/low-fat diet.

This easy-to-deliver, practical, lifestyle intervention study uses simple physical activity and nutrition messages along with basic goal-setting and feedback principles to help people with T2D make behavioural changes that contribute to good metabolic control. The major goal of the FSFB is to encourage individuals to make the "First Step" in getting physically active, and having the "First Bite" in making healthier food choices. For those who walked an additional 30 minutes a day and replaced high GI food with low GI food at meal times, the next step would be to continue to improve and to adopt such lifestyle changes on a long term basis. Despite the limitations and small health improvements observed, the FSFB was effective and successful in achieving the desired behaviour change among the study participants. Translating lifestyle intervention into clinical practice for the T2D population remains a challenge, and the FSP/FSFB approach may be a promising path to achieving this goal.

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Table 4.1: Baseline characteristics of the FSP and FSFB groups

Characteristics	FSP[1]	FSFB
N	19	19
Sex	10M/9F	11M/8F
Age (y)	54.8 ± 1.4	55.4 ± 2.2
Duration of T2D (months)	44.6 ± 8.9	56.3 ± 16.1
Treatment (n):		
Diet only	0	3
Oral medication	19	16
Current Smoker (n)	1	1
Physical activity (steps/day)	5721 ± 512	5251 ± 446
Hemoglobin A1C (%)	7.2 ± 0.2	7.2 ± 0.3
Weight (kg)	102.4 ± 4.5	95.4 ± 4.6
BMI	35.5 ± 1.4	32.6 ± 1.3
Waist (cm)	117.0 ± 3.4	110.2 ± 3.3
Hip (cm)	118.8 ± 3.6	111.5 ± 2.6
Waist : Hip (ratio)	0.99 ± 0.02	0.97 ± 0.02
% body fat	40.0 ± 2.1	38.1 ± 1.8
Fat Mass (kg)	39.3 ± 2.8	35.1 ± 2.4
Lean Mass (kg)	57.6 ± 2.6	57.0 ± 3.3
Heart Rate (per min)	71.7 ± 1.8	72.4 ± 3.1
Systolic (mmHg)	121.5 ± 2.3	120.4 ± 2.7
Diastolic (mmHg)	83.6 ± 1.3	82.9 ± 1.8

[1]FSP data for %body fat, fat mass and lean mass shown here were based on n=18. No statistically significant differences between groups were noted.

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Table 4.2: Physical activity, anthropometric and cardiovascular measures at the 16th week (end) of the study.

Characteristics	FSP (n= 19)	FSFB (n=19)
Physical activity (steps/day)	8527 ± 774*	9381 ± 1190†
Hemoglobin A1C (%)	7.0 ± 0.2	7.0 ± 0.3
Weight (kg)	99.6 ± 4.3†	94.3 ± 4.6
BMI	34.7 ± 1.4†	32.3 ± 1.3
Waist (cm)	111.0 ± 3.3*	106.4 ± 3.4*
Hip (cm)	115.1 ± 3.4*	109.3 ± 2.6*
Waist : Hip (ratio)	0.97 ± 0.02*	0.97 ± 0.02†
Heart Rate (per min)	71.4 ± 1.9	73.7 ± 3.1
Systolic (mmHg)	123.2 ± 3.7	118.1 ± 2.8
Diastolic (mmHg)	82.7 ± 2.0	82.6 ± 2.0
% body fat	39.2 ± 2.1	38.0 ± 1.9
Fat Mass (kg)	37.4 ± 2.7	34.7 ± 2.5
Lean Mass (kg)	57.0 ± 2.7	56.4 ± 3.3

Data are means ± SEM unless otherwise indicated. FSP data for % body fat, fat mass, lean mass, resting blood pressure and heart rate were based on n=17. FSFB data for pedometer was based on n=18. Significantly different from baseline, *P<0.001, †P<0.01. No statistically significant differences between groups

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Figure 4.2a: Steps/day in the FSP and FSFB groups at baseline and 16th week (end) of the study. Data are means ± SEM. Significantly different from baseline, *p<0.001, †p<0.01. No statistically significant difference between groups was noted.

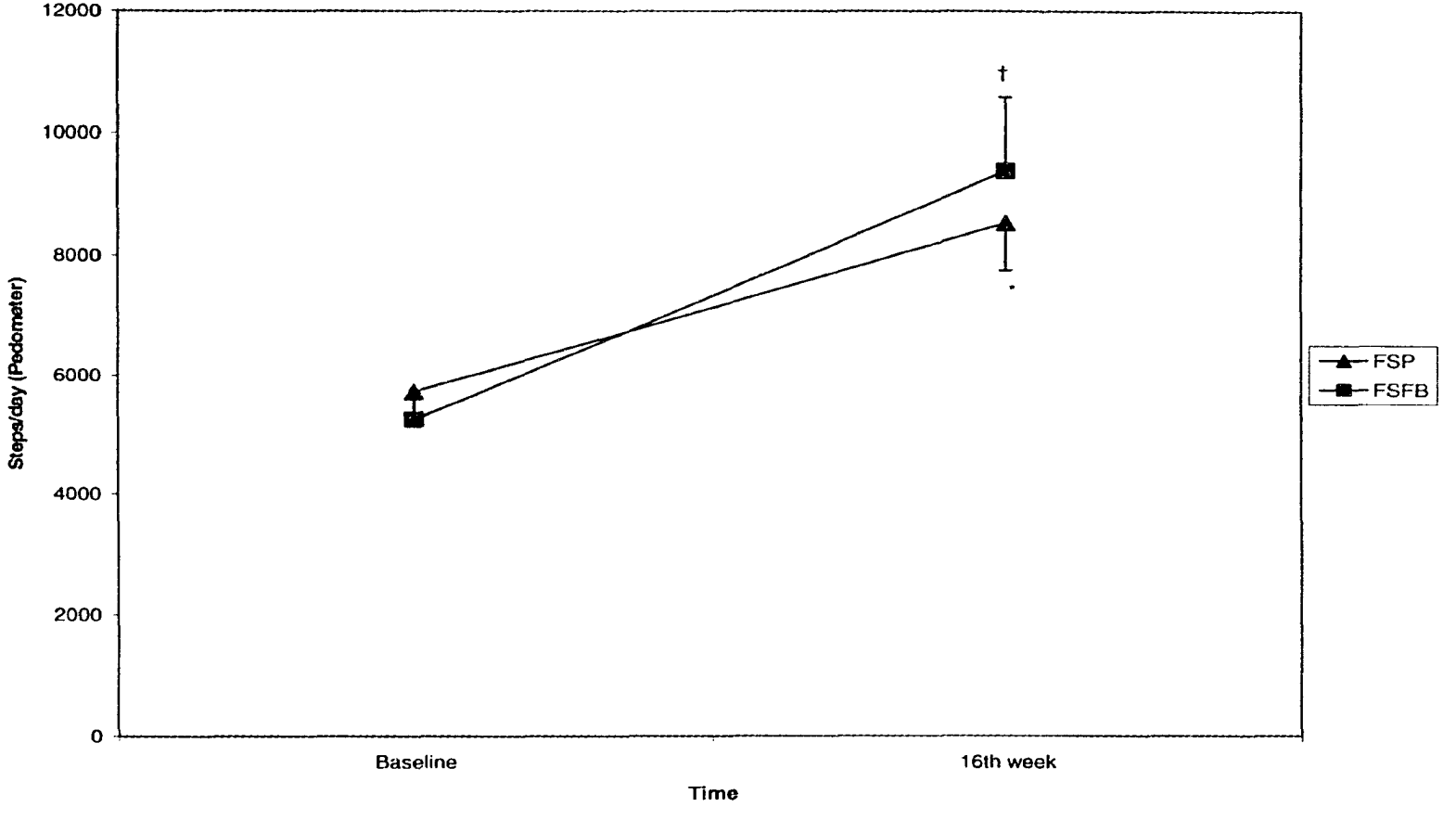

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Figure 4.2b: Body weight in the FSP and FSFB groups at baseline and 16th week (end) of the study. Data are means ± SEM. Significantly different from baseline, †p<0.01. No statistically significant difference between groups was noted.

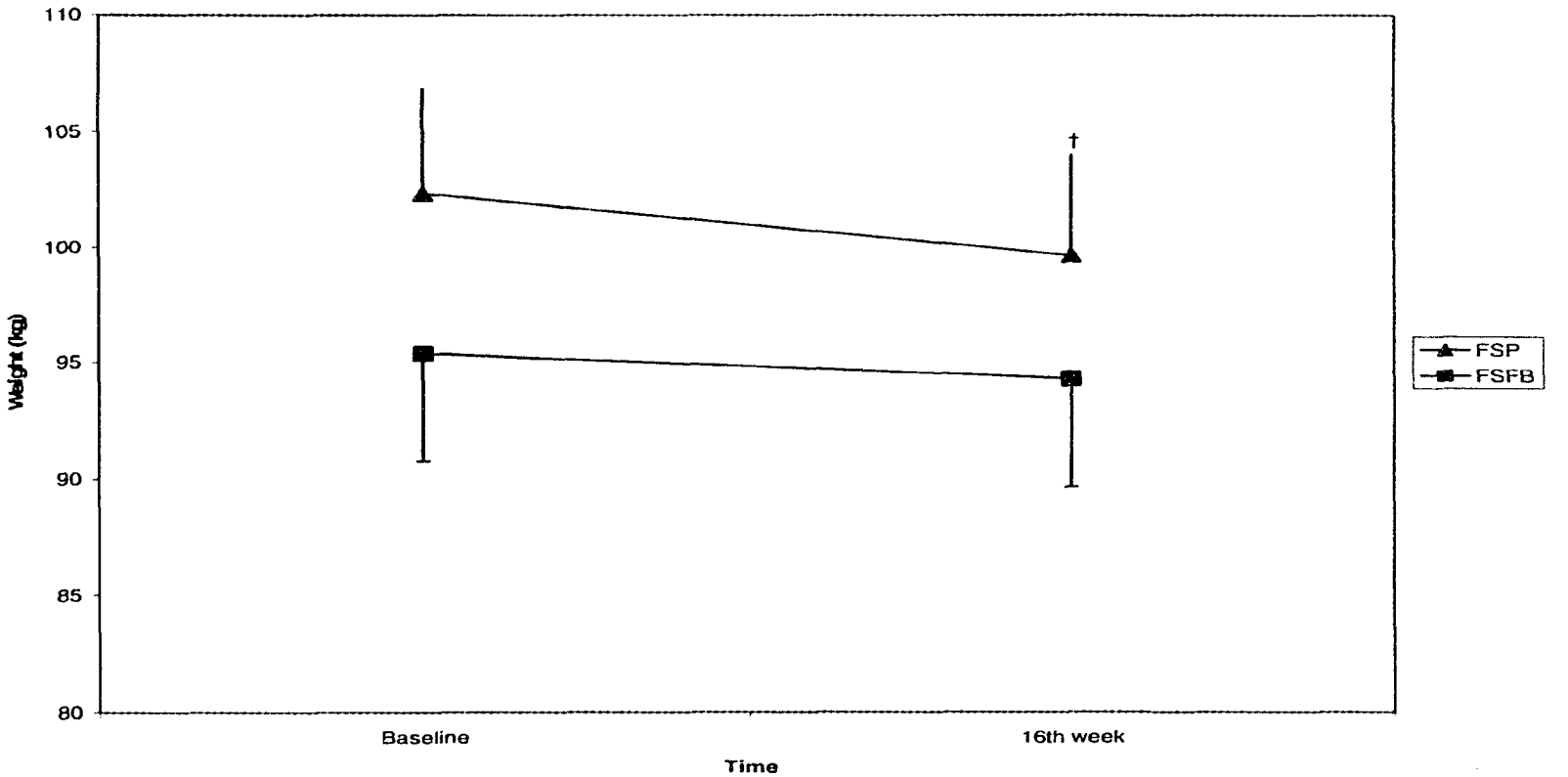

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Figure 4.2c: BMI in the FSP and FSFB groups at baseline and 16th week (end) of the study. Data are means ± SEM. Significantly different from baseline, †p<0.01. No statistically significant difference between groups was noted

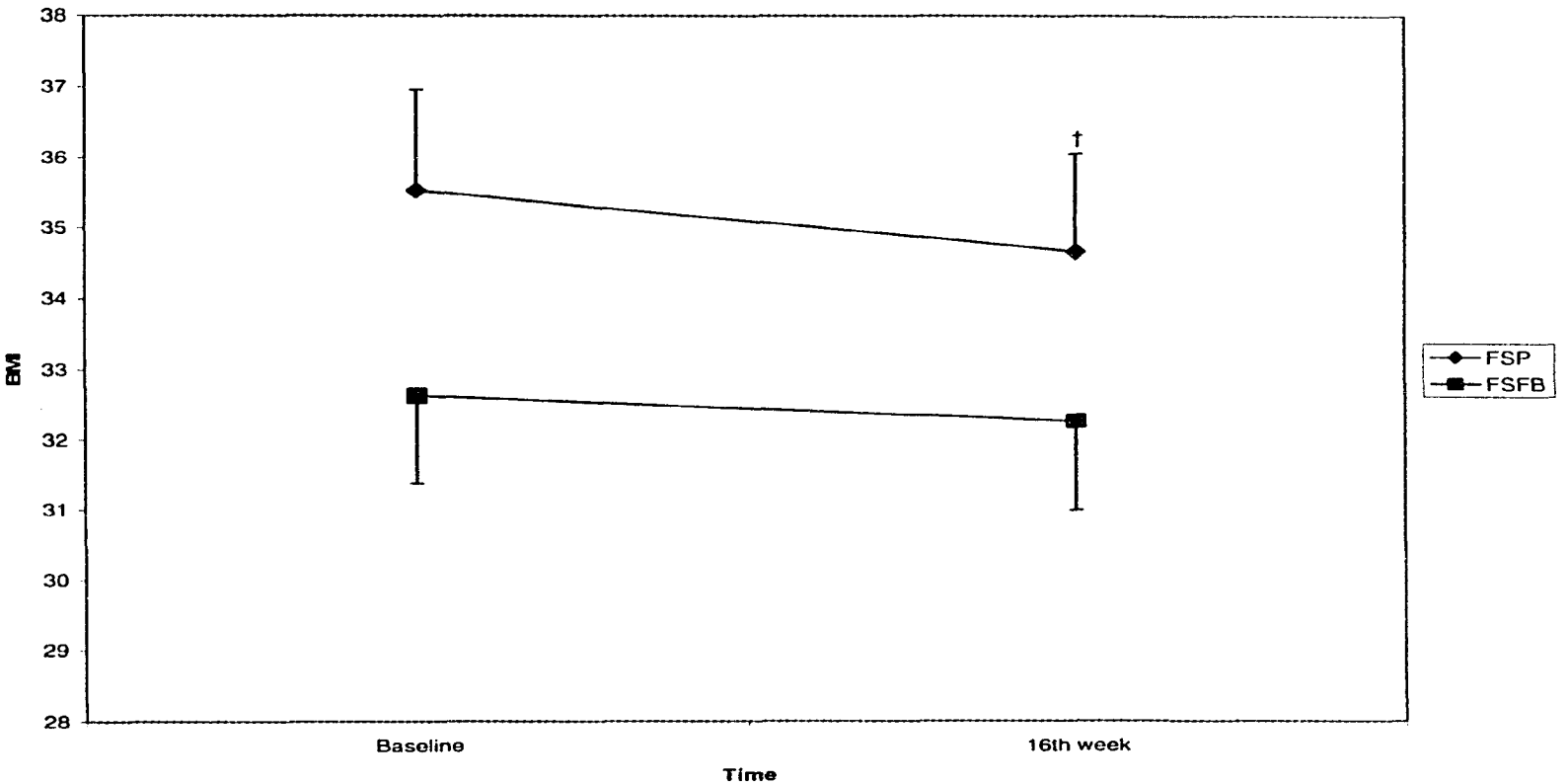

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Figure 4.2d: Waist girth in the FSP and FSFB groups at baseline and 16th week (end) of the study. Data are means ± SEM. Significantly different from baseline, *p<0.001. No statistically significant difference between groups was noted.

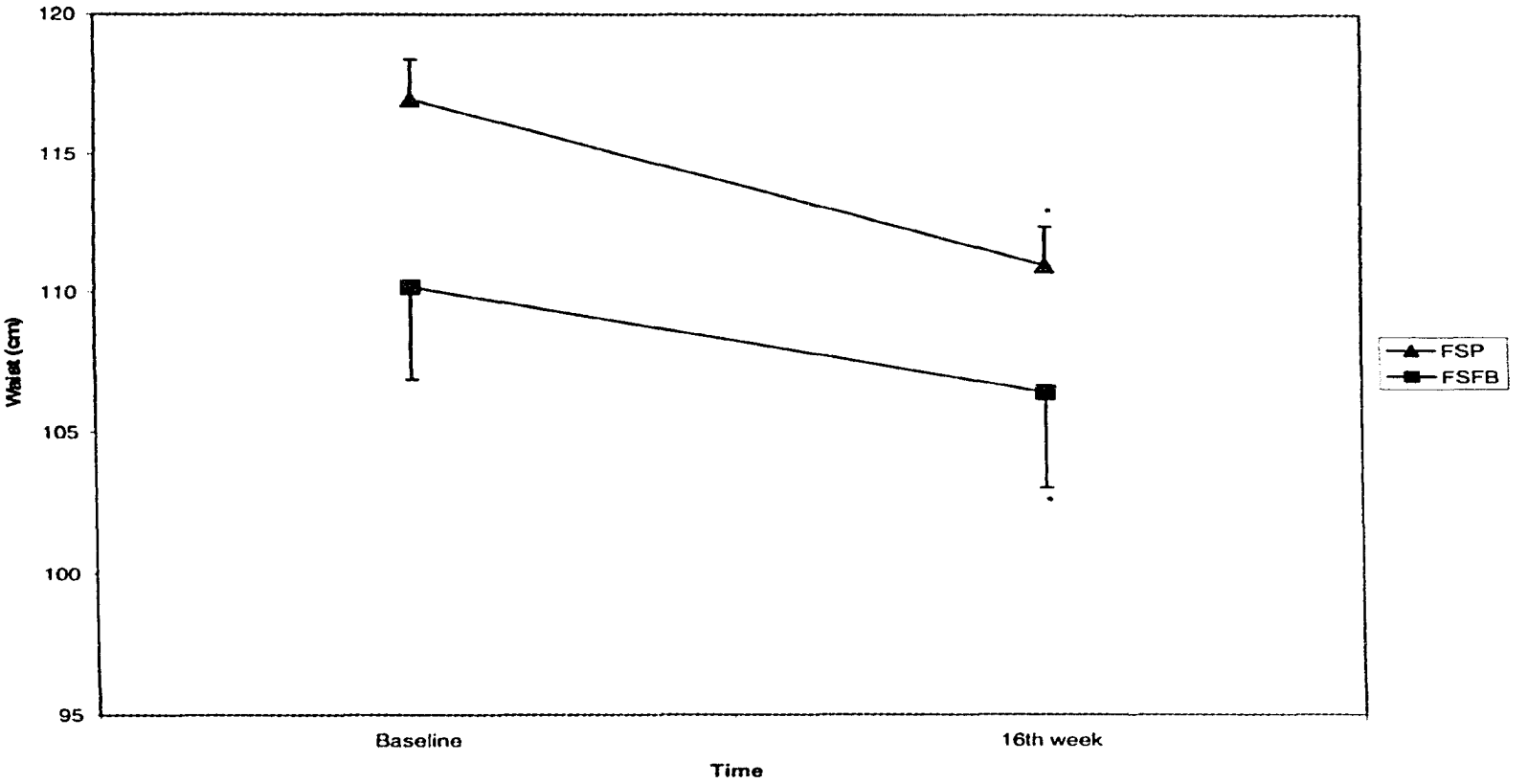

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Figure 4.2e: Hip girth in the FSP and FSFB groups at baseline and 16th week (end) of the study. Data are means ± SEM. Significantly different from baseline, *p<0.001. No statistically significant difference between groups was noted.

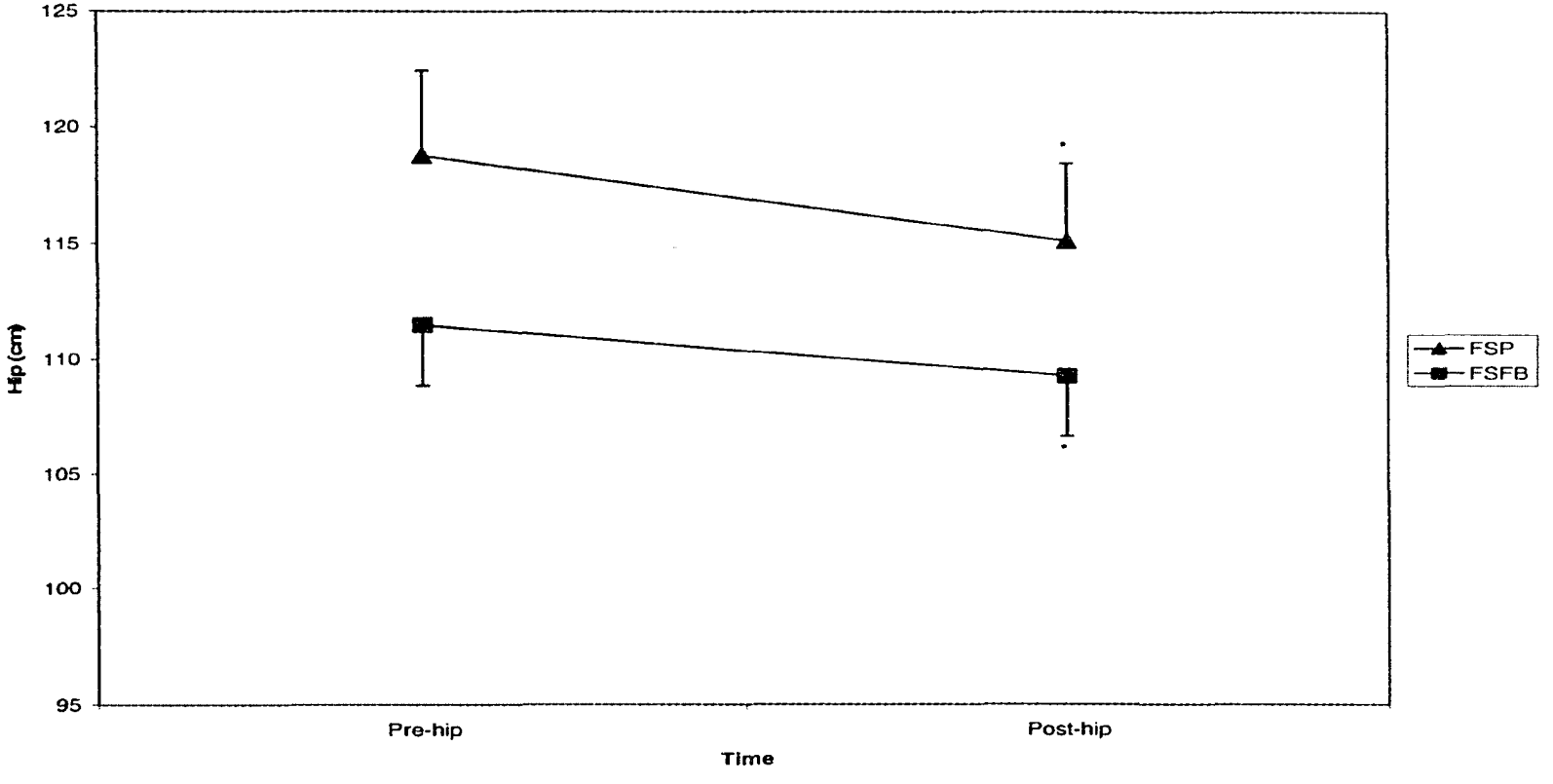

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Figure 4.2f: A1C values in the FSP and FSFB groups at baseline and 16th week (end) of the study. Data are means ± SEM. No statistically significant difference between and within groups were noted.

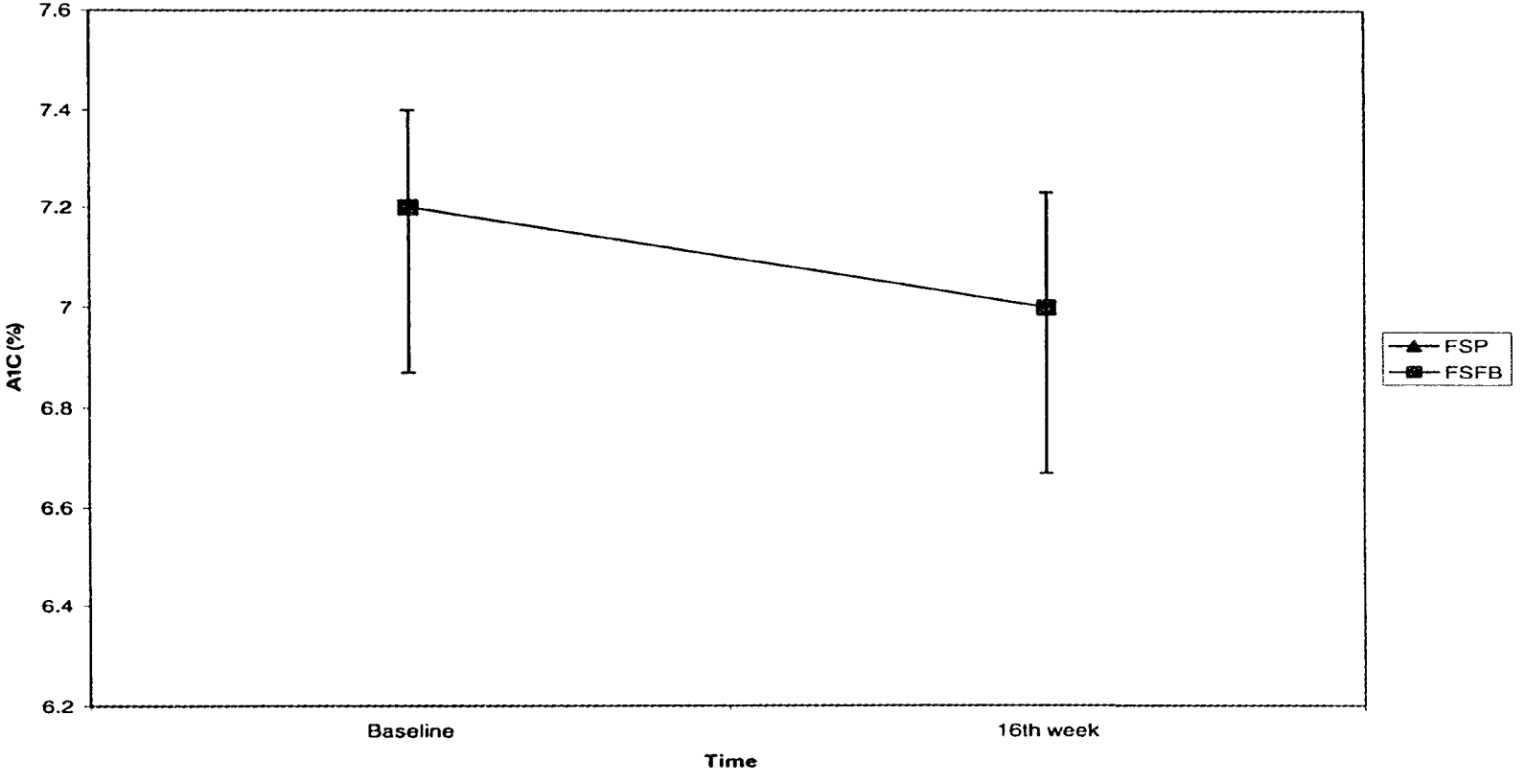

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Figure 4.2g: Total body fat mass in the FSP and FSFB groups at baseline and 16th week (end) of the study. Data are means ± SEM. No statistically significant differences between and within groups were noted.

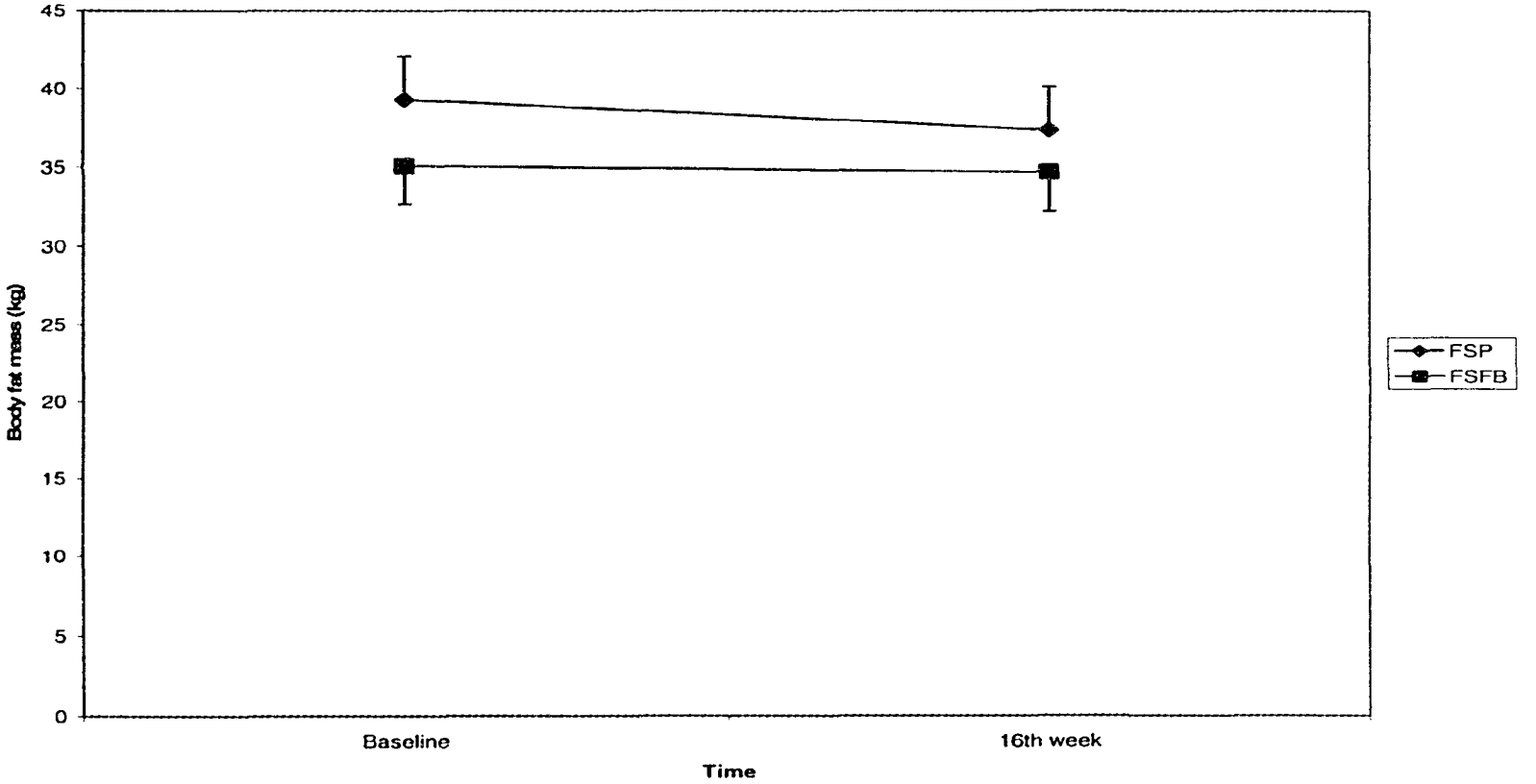

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Figure 4.3: Daily intake of low GI foods in the FSP and FSFB groups at baseline and 16th week (end) of the study. Data are means ± SEM. Significantly different from baseline, †p<0.01. No statistically significant difference between groups was noted.

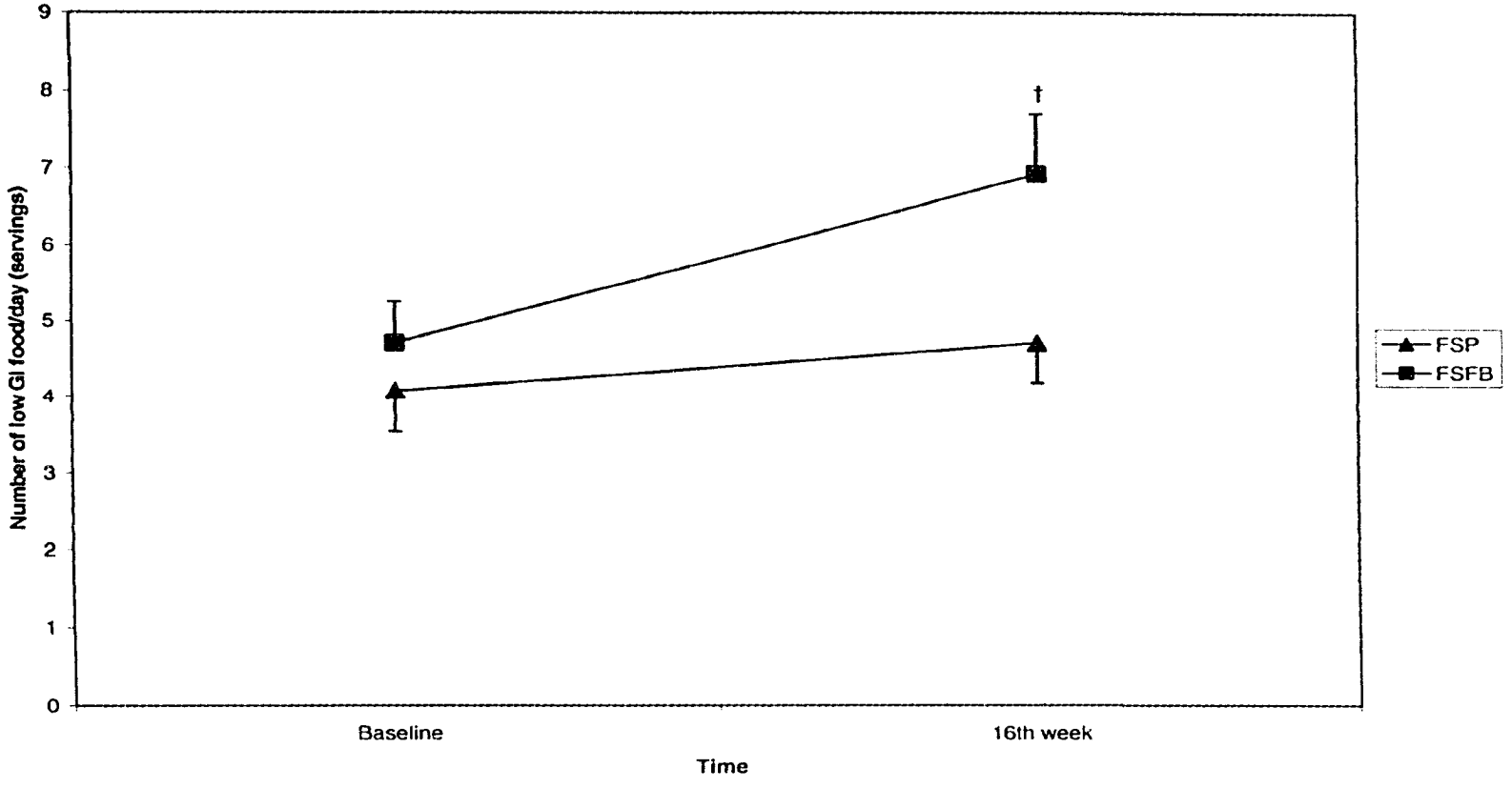

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Figure 4.4a: A significant inverse relationship (r = -0.511, p = 0.001) between daily intake of low GI foods and A1C values at the 16th week for the total sample (n= 36)

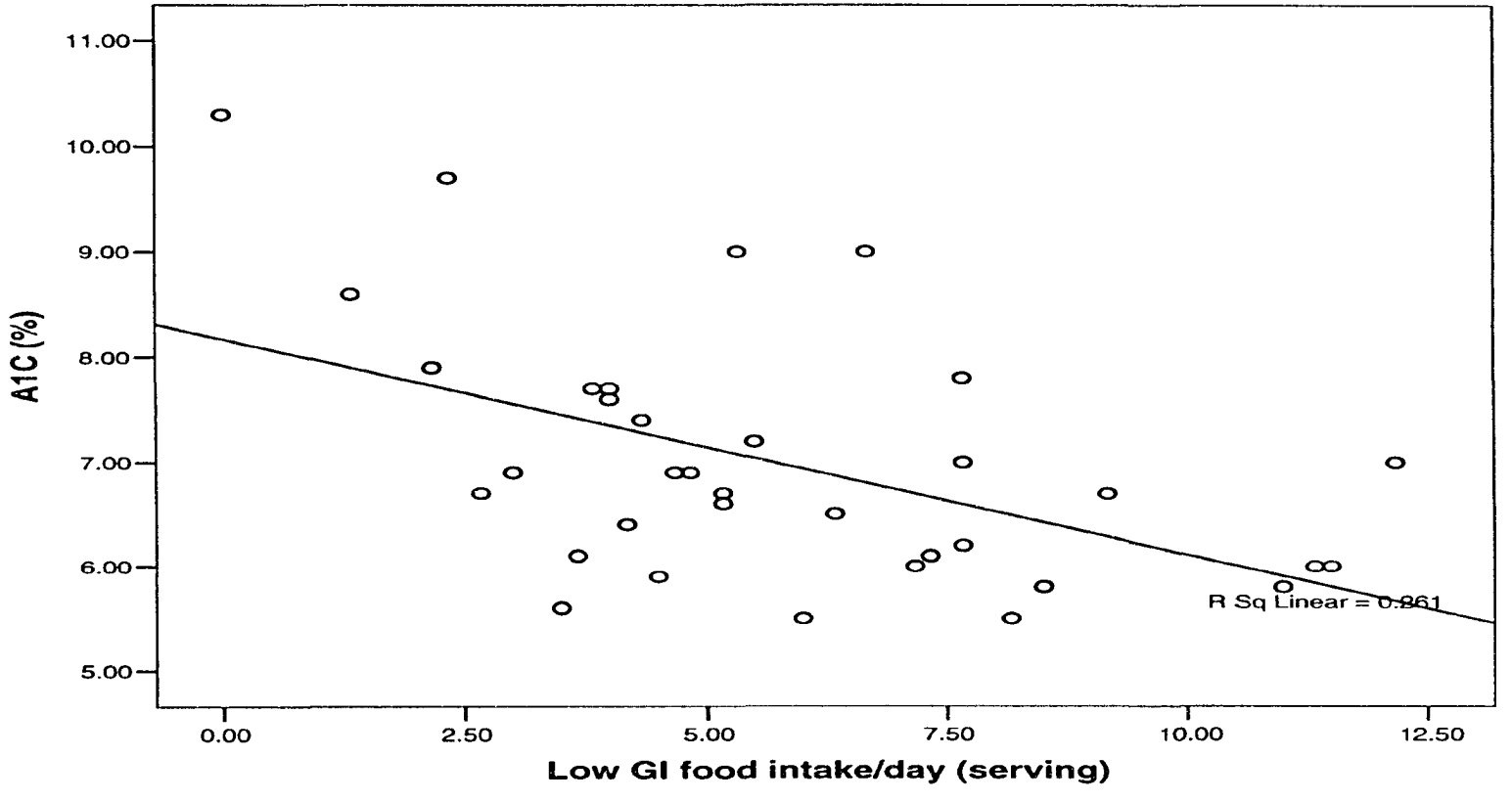

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Figure 4.4b: A significant inverse relationship (r = -0.495, p = 0.031) between daily intake of low GI foods and A1C values at the 16th week for FSP group (n = 19)

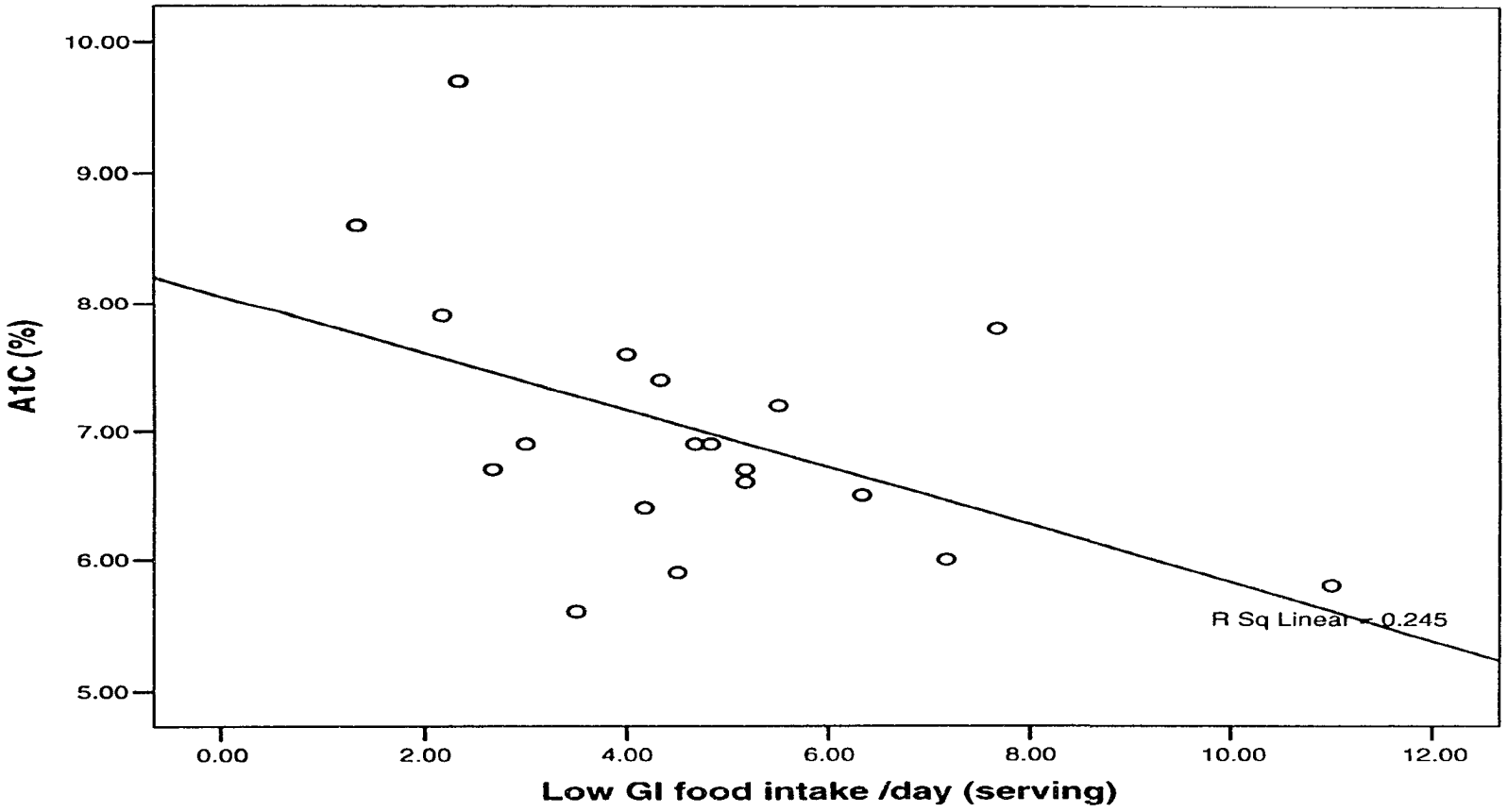

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Figure 4.4c: A significant inverse relationship (r = -0.578, p = 0.015) between daily intake of low GI foods and A1C values at the 16th week for FSFB group (n= 17)

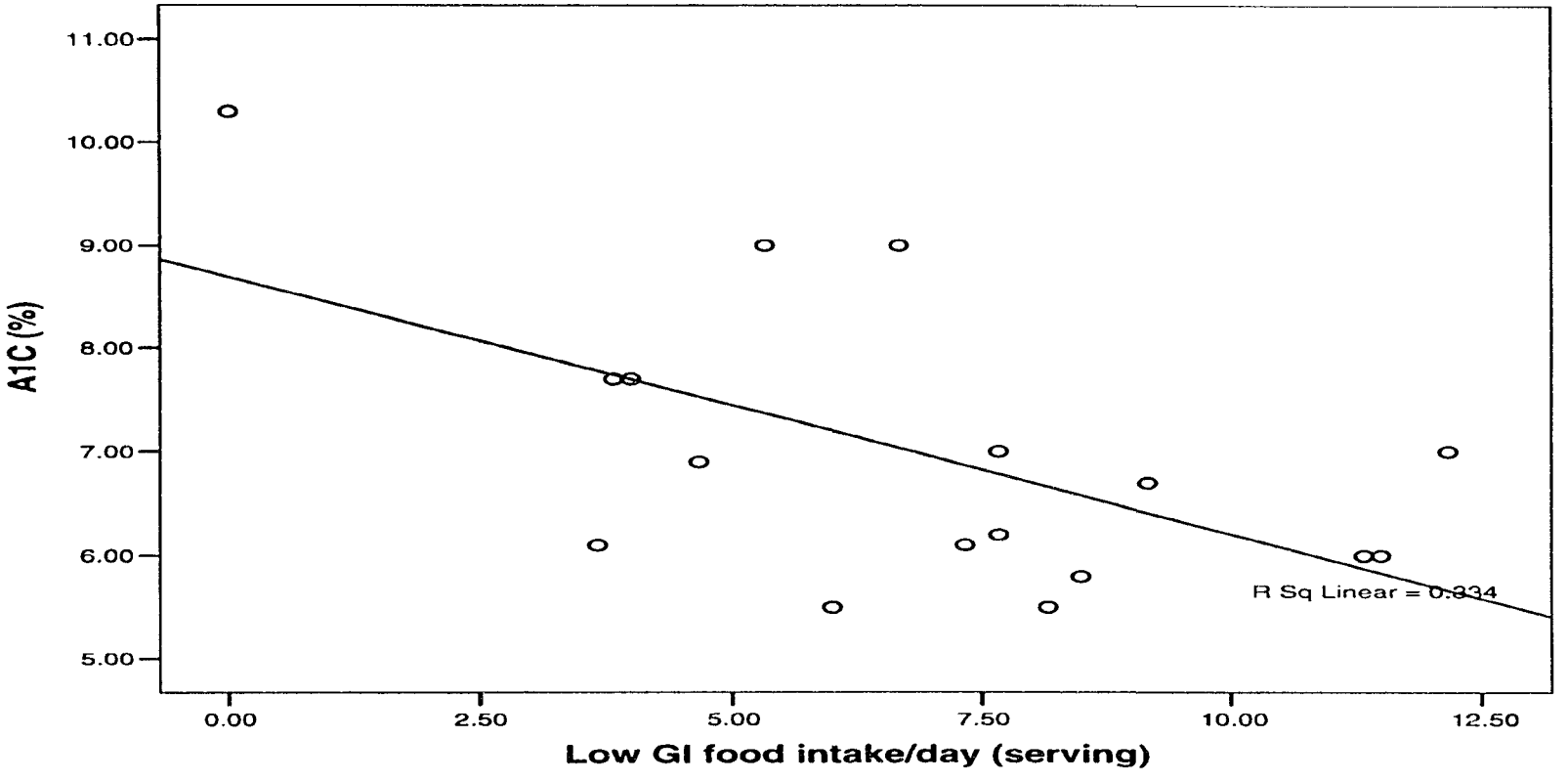

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Table 4.3: Nutrients analysis of the FSP and FSFB groups at baseline and the 16th week. Data are means ± SEM. A total of 17 FSFB participants returned the 3-day food record. Significantly different from baseline, †P<0.01. No statistically significant differences between groups were noted.

Nutrient	FSP (n= 19)		FSFB (n=17)	
	Baseline	Week 16	Baseline	Week 16
Kcal/d	2548 ± 337	2049 ± 129	2506 ± 303	2077 ± 109
Carbohydrate (%)	49.5 ± 6.5	45.8 ± 3.2	50.5 ± 6.1	49.3 ± 2.6
Protein (%)	16.8 ± 1.5	17.2 ± 1.1	16.7 ± 1.4	18.7 ± 1.5
Total Fat (%)	33.7 ± 5.6	37.0 ± 3.4	33.0 ± 4.3	32.0 ± 2.9
Saturated Fat (%)	10.4 ± 1.7	12.0 ± 1.3	10.4 ± 1.4	10.1 ± 0.8
Fiber (g/d)	25.4 ± 2.6	22.0 ± 1.8	28.5 ± 3.2	28.8 ± 2.7
Low GI foods Intake (servings/d)	4.1 ± 0.5	4.7 ± 0.5	4.7 ± 0.6	6.9 ± 0.8†
Fruits & Vegetables Intake (servings/d)	5.8 ± 0.6	4.7 ± 0.5	6.7 ± 0.7	6.3 ± 0.8
Milk products intake (servings/d)	1.9 ± 0.2	1.6 ± 0.2	1.8 ± 0.2	1.8 ± 0.3

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Chapter 5: Conclusions and future research

5.1 Conclusions

The incidence of T2D is increasing at an alarming rate, and lifestyle modification is important in preventing the development and the management of T2D. Most importantly, lifestyle changes involving good nutrition and active living are cornerstones in the management of T2D. A recent statement by the ADA, the North American Association for the Study of Obesity and the ASCN continue to emphasize the importance of lifestyle intervention in T2D management (Klein, et al, 2004).

There are numerous studies that have demonstrated positive effects of using a lifestyle intervention approach in improving the health outcomes, such as glycemic control and weight loss, in individuals with T2D. However, the resource burden of these lifestyle programs may be too great for the patients, clinicians and health care systems to bear, particularly over the longer term. Thus, translating these lifestyle treatment trials into a lower-intensity, cost-effective interventions is crucial in allowing the maximal applicability in practice and long term maintenance of the interventions among individuals with T2D (Glasgow, 2003; Glasgow et al, 2003).

The FSP is a facilitated behaviour modification program designed to help people with T2D increase their physical activity. It is based on the principles of self-efficacy and social support, and uses goal setting, self-monitoring and feedback. The FSFB was developed following the same theoretical basis as the FSP. This research project revealed that the FSFB, where the physical activity message is combined with a second message of dietary advice, did not dampen the impact of physical activity in the program. Moreover, the uniqueness of the FSFB in using simple physical activity and nutrition

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messages along with basic goal-setting and feedback principles helped people with T2D make behavioural changes. Specifically, the study participants increased their physical activity and daily intake of low GI foods, as assessed at the completion of the program. These lifestyle changes contributed to improvements in health indicators, such as the reduction in waist and hip circumferences, observed among the study participants.

This research project also demonstrated that the FSFB is an easy-to-deliver and practical lifestyle intervention program. Most educational resources used in this program were available to the health care professionals and the public. Monitoring and motivational tools, such as the pedometer and "GI Track", used in the program were not considered costly, and have proven themselves helpful in improving the physical activity and eating habits among the study participants. Most importantly, the program was well received and well attended by the study participants. This is evident in the excellent attendance records of study participants at the group meetings, as well as by the low dropout rate in the study. Low dropout rate is an important factor in determining the success of a health promotional program (Glasgow, et al, 2003).

Based on the results of this research project, the FSFB has met its goal in encouraging the T2D individuals to make the "First Step" in getting physically active, and having the "First Bite" in making healthier food choices in the management of T2D. For those who have made these first steps, the next step would be to continue to improve and to adopt such lifestyle changes on a long term basis. Translating lifestyle intervention into a clinical practice for the T2D population remains a challenge, and the FSP/FSFB approach may be a promising path to achieving this goal.

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5.2 Future Research

This research project demonstrated that simple physical activity and nutrition messages used in the FSFB were effective in promoting lifestyle behaviour changes. Future research and lifestyle modification programs using a theoretical basis similar to the FSP/FSFB should be explored to further augment improvements in the physiological health and promote lifelong commitment to a healthier lifestyle in individuals with T2D. Suggestions for future research in this area include:

- Evaluation of the longer-term impact of the FSFB: Lifelong changes to adhere to a healthy lifestyle are pivotal in the management of T2D. Follow-up after the 16th week of the intervention was beyond the scope of the current study. Therefore, it is vital to evaluate the impact of FSFB in a longer-term maintenance, such as at 6 months and 12 months. This may help determine if an easy-to-deliver, practical lifestyle modification program using simple lifestyle messages, such as the FSFB, has a clinical significance in the longer term. This is of particular importance given the fact that the FSFB is not an intensive, structured/supervised lifestyle modification program, otherwise commonly used in the research setting. It is possible that the lifestyle changes observed in the current study may make more of an impact if the participants maintained their lifestyle changes for a longer period. Evaluation of physiological variables, such as glycemic control, body weight, body fat mass and CVD risk factors would help reveal such impact.

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- A1C value as an inclusion criterion: The failure to observe a significant improvement in the A1C values may due to the fact that most participants in the study started with a moderately good control of glycemia. Therefore, these participants may not be as responsive to a less intensive lifestyle modification program such as the FSP/FSFB. Recruitment of study participants with A1C values >8%, which indicates a sub-optimal glycemic control (CDA, 2003), in the future may be necessary to observe a significant improvement in glycemic control among the study participants.

- The impact of booster sessions: Assessment of the FSP at the 24th week in previous study showed a trend of decline in physical activity among the FSP participants (Tudor-Locke, et al, 2004). One of the factors contributing to this decline could be the absence of continuing contact between participants and study leaders between the 16th and the 24th week. Booster sessions have recently been developed into the FSP to continue to facilitate maintenance of physical activity changes among the participants. Such an initiative should be considered in the FSFB. Regular booster sessions may help the participants to continue to choose low GI over high GI food choices over a longer-term period. Assessments at 3 months after the booster sessions may help determine the effectiveness of the booster sessions. Assessments should include physiological health indicators (such as anthropometrics and glycemia) and indicators of behaviour change, with respect to physical activity levels and daily intake of low GI foods.

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- Impact of walking intensity: It is important to determine if the walking intensity and speed are important in mediating the physiological improvements in individuals with T2D, in addition to steps/day alone. The physiological effects of increased walking in previous FSP studies and the current study were considered subtle (Tudor-Locke, et al, 2004; Tudor-Locke, et al, 2002). A more intense or higher speed of walking activity may be required to observe more significant changes in the physiological health outcomes. A feasibility study is currently underway to investigate such relationship.
- Development of a subsequent level of lifestyle modification program: The FSFB is an initial approach to help individuals with T2D in taking the "first step" to get physically active, and the "first bite" to eat healthier. Development of a subsequent level of lifestyle modification program similar to the FSFB may be warranted. The level of this new program should theoretically be of similar nature to the FSP/FSFB: be self-directed (vs. supervised), and be based on the principles of self-efficacy and social support (vs. structured and intensive approach that can be a resource burden). Such new program may incorporate other aspects of physical activity, such as resistance training and flexibility exercises, as well as dietary advice (e.g. portion control and fat consumption) to help these individuals continue to improve their T2D management. As such, it would maintain its characteristics of an easy-to-deliver, practical nature.

  It should be noted that a subsequent level of this program might be too intense for some individuals with T2D. Hence, adherence or dropout rate might be high. Instead, the program could be viewed and offered as an "advanced" module for

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those who are maintaining their lifestyle changes as suggested in the FSFB, and who wish to continue to pursue other aspects of active living and healthy eating to manage their T2D. Individuals who decide to take part in this "advanced" module would likely be highly motivated, and thus may choose to complete the program.

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Appendix A:

Nutrition component in the FSFB workbook

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Week 2

The First Bite Program

Healthy Eating is important in treating and preventing many diseases. But many people say they find it hard to eat healthy or they don't know where to start. You are about to take the FIRST BITE. This program helps you begin to choose more low Glycemic Index (GI) foods as part of healthy eating.

Something to think about

Changing eating habits can be hard to do. Let's begin by thinking about what you can get out of eating healthier, and what you may have to give up.

Gains for me	Losses for me	Plans *(getting the most without giving up too much)*
Gains for people around me	Losses for people around me	Plans

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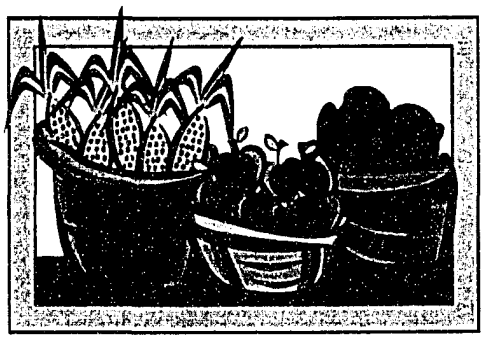
What is the First Bite program about?

This is not a "dieting" class. This program helps you begin to eat healthier by fitting low Glycemic Index (GI) foods into your diet, in your own way.

The First Bite Program and the First Step Program work together to help you control your blood sugars. In the next 3 group meetings, you will learn about the GI, examples of low GI foods, and how to include them in your meal plan. At these meetings, you will also learn how to use the "GI Track" to keep track of the number of low GI foods you eat each day. You will learn how many low GI foods you eat now. You will also get help setting your own goals for eating more low GI foods each day.

The simple message of "choosing more low GI foods" is getting popular among people with Type 2 diabetes and Diabetes Educators and dietitians in different parts of the world, such as Australia, Europe and South Africa. In Canada, the Canadian Diabetes Association recommends that people with Type 2 diabetes to choose more low GI foods as part of their healthy eating plan. At each of the First Step - First Bite meetings, snacks that include low GI choices will be provided, and you will get the chance to try some low GI foods!

Each week you will have homework. You will set your own daily goal for low GI food intake; you can refer to the GI pages in your workbook as well as our class discussions, to help you choose low GI foods. Then, you will use your "GI Track" everyday to monitor the number of low GI foods you eat each day. During the day, refer to it many times to see how close you are to your goals. At the end of each day, write the total number of checked low GI food/day on your activity calendar (next to your pedometer reading, e.g. 5000 steps/6 low GI). If you meet your goal, check off the star drawn on each day (e.g. if you reached your pedometer and low GI food goals that day, you will get two checks/stars).



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So, how many low GI food should I eat each day?

Good question. The answer is different for every person. First you need to know the number of low GI food you normally eat every day. You ate an average of _____ low GI food/day.

Is that good or bad?

The answer is: the more low GI food you eat, the more benefits you get. Studies have shown that people who eat more low GI foods have better blood sugar, lipids and weight control.

Please refer to the attached handout (Green sheet: The Glycemic Index) on examples of low GI foods.

Sample menu using low Glycemic Index (GI) food:

Breakfast: Rolled oats/oatmeal-1 cup
Brown sugar-1 tbsp
1% milk-1 cup
Boiled egg- 1

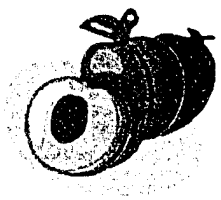
Lunch: Tuna sandwich (on low GI Bread)-1
Beef barley soup-1 cup
Carrots and celery sticks-1 cup
Puffed wheat square-1 small

Supper: Chili (with kidney bean)-1 ½ cup
Multigrain bun- 1
Garden salad-1 cup
Italian dressing-2 tbsp
Orange juice-1 cup
Fruit salad (in pear juice)-1 can

AM Snack: Yogurt-3/4 cup
Apple-1 medium

PM Snack: Pumpernickel- 1 slice
Low fat cheese-1 oz

HS snack: Peanut butter sandwich (on low GI bread)-½
1% milk-1 cup



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So, how do I increase my low GI food/day?

What do you do now that will give you fewer low GI foods/day? Can you do less of this?

What do you do now that will give you more low GI foods/day? Can you do more of this?

What are some other things you could do to get more low GI foods/day?

Who can help you to increase your low GI foods/day? How will they help you?

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Weekly Goal-Setting 2

Date: _____

My average 3-day intake of low GI food was _____ low GI food/day

I will increase this by + _____ low GI food/day

My new daily goal is = _____ low GI food/day

Write down one or two plans you will use to meet your goal.

_____

_____

How sure are you that you can stick to your daily low GI food goal for the next week?

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
Not at all sure				Somewhat sure				Fully sure		

How many days of the week are you sure that you will reach your daily low GI food goal over the next week?

0	1	2	3	4	5	6	7

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Week 3

How did you do?

How many days did you meet your goal? _____

How many total low GI foods did you eat during the week? _____
Divide this number by the number of days you used the "GI track" to get your average low GI foods/day: _____

Let's take a closer look:

On the days when your low GI food/day are the highest, what did you do?

_____

_____

_____

On the days when your low GI food/day are lowest, what did you do?

_____

_____

_____

How often did you look at the "GI track" during the day? Did you change the way you eat when you looked?

_____

_____

_____

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Who helped you?

Who did you show the "GI track" to?

_____

_____

_____

What did they think or say?

_____

_____

_____

How can they help you increase your low GI food/day?

_____

_____

_____

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How about the HIGH RISK situations?

There are times when choosing low GI foods can be difficult. These HIGH RISK situations include weekends, eating-out (especially buffets), luncheon meetings and birthday parties.

What are some of your HIGH RISK situations?

What are some of the things you could do to include low GI foods during a HIGH RISK situation?

Who can help you to include low GI foods in these HIGH RISK situations? How will they help you?

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Weekly Goal-Setting 3

Date: _____

My average 3-day intake of low GI food was _____ low GI food/day

I will increase this by + _____ low GI food/day

My new daily goal is = _____ low GI food/day

Write down one or two plans you will use to meet your goal.

_____

_____

How sure are you that you can stick to your daily low GI food goal for the next week?

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
Not at all sure				Somewhat sure				Fully sure		

How many days of the week are you sure that you will reach your daily low GI food goal over the next week?

0	1	2	3	4	5	6	7

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Week 4

How did you do?

How many days did you meet your goal? _____

How many total low GI food did you eat during the week? _____
Divide this number by the number of days your use the "GI track" to get your average low GI food/day: _____

Let's take a closer look:

On the days when your low GI food/day are the highest, what did you do?

_____

_____

_____

On the days when your low GI food/day are lowest, what did you do?

_____

_____

_____

How often did you look at the "GI track" during the day? Did you change the way you eat when you looked?

_____

_____

_____

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Who helped you?

Who did you show the "GI track" to?

_____

_____

_____

What did they think or say?

_____

_____

_____

How can they help you increase your low GI food/day?

_____

_____

_____

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Weekly Goal-Setting 4

Date: _____

My average 3-day intake of low GI food was	_____ low GI food/day
I will increase this by +	_____ low GI food/day
My new daily goal is =	_____ low GI food/day

Write down one or two plans you will use to meet your goal.

_____

_____

How sure are you that you can stick to your daily low GI food goal for the next week?

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
Not at all sure				Somewhat sure				Fully sure		

How many days of the week are you sure that you will reach your daily low GI food goal over the next week?

0	1	2	3	4	5	6	7

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Relapse

Relapse happens when a person temporarily goes back to their "unhealthy eating" behaviour. Even those with the best healthy eating plans are at risk of relapse due to obstacles or barriers.

How would you feel if you didn't reach your low GI food goal for a few days in a row or even a week?

_____

_____

_____

Relapse is normal, but the key to succeeding is to develop plans to deal with situations that may prevent or discourage you from achieving your low GI food goal. Many people have periods of "unhealthy eating" pattern. Sometimes these breaks can last for just a few days and sometimes a few month or years. Planning ahead for these times may help you to continue with your healthy eating pattern and reach your low GI food goals.

Have you ever had trouble keeping your healthy eating pattern before? If yes, write down the reasons why.

_____

_____

_____

If you had trouble, what has helped you get back on track?

_____

_____

_____

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How to use your calendar

- At the start of each week, write in your steps/day goal (First Step) and low GI foods/day goal (First Bite)
- Each night, write in the number of steps you took and the number of low GI foods you ate that day
- At the end of each week, write these things down:
    - Count up the number of check marks you have checked off on your stars
    - Add up all the steps you took and number of low GI foods you ate during the week
    - Divide the total steps by the number of days you wore the pedometer to get your new average steps/day
    - Also, divide the total number of low GI foods by the number of days you used the "GI track" to get your new average low GI foods/day

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Appendix B:

"The Glycemic Index" (CDA, 2003) handout used in the FSFB

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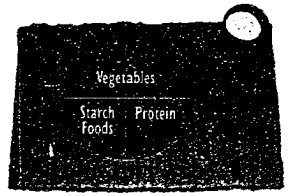
GLYCEMIC INDEX



What is the Glycemic Index of food?

The Glycemic Index (GI) is a scale which ranks carbohydrate-rich foods by **how much** they raise blood glucose levels compared to a standard food. The standard food is glucose or white bread.

Why should I eat foods with a low Glycemic Index?

Eating foods with a low Glycemic Index may help you to:

- Control your blood glucose level
- Control your cholesterol level
- Control your appetite
- Lower your risk of getting heart disease
- Lower your risk of getting type 2 diabetes

Use these meal planning ideas to include the Glycemic Index as part of healthy eating.

- Enjoy vegetables, fruits, and low fat milk products with your meals. These are carbohydrate-rich foods that, in general, have low glycemic index.
- Plan your meals with foods in the **low** and **medium** Glycemic Index starch choices on the list which follows.
- Try foods, such as barley, bulgar, couscous, or lentils that have a low Glycemic Index.
- Consult a registered dietitian for help with choosing low GI foods, adapting recipes, and other ways to incorporate low GI foods in your meal plan.

If I eat foods with a low Glycemic Index can I eat as much as I want?

No. Using the Glycemic Index to choose foods is **only one** part of healthy eating.

Healthy eating also means:

- ✓ Eating at regular times
- ✓ Choosing a variety of foods from all food groups
- ✓ Limiting sugars and sweets
- ✓ Reducing the amount of fat you eat
- ✓ Including foods high in fibre
- ✓ Limiting salt, alcohol and caffeine

Remember that checking your blood glucose before and **1 to 2 hours** after a meal is the best way to know how your body handles the meal.

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Know who to turn to

Check out the Canadian Diabetes Association website, **www.diabetes.ca**, for more information.

CANADIAN DIABETES ASSOCIATION | ASSOCIATION CANADIENNE DU DIABÈTE

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A lot of starchy foods have a high Glycemic Index (GI). Choose medium and low GI foods more often.

Low GI* (55 or less)† choose most often ✓✓✓	Medium GI* (56-69)† choose more often ✓✓	High GI* (70 or more)† choose less often ✓
BREADS:	**BREADS:**	**BREADS:**
100% stone ground whole wheat	Whole wheat	White bread
Heavy mixed grain	Rye	Kaiser roll
Pumpernickel	Pita	Bagel, white
CEREAL:	**CEREAL:**	**CEREAL:**
All Bran™	Grapenuts™	Branflakes
Bran Buds with Psyllium™	Shredded Wheat™	Cornflakes
Oatmeal	Quick oats	Rice Krispies™
Oat Bran™		Cheerios™
GRAINS:	**GRAINS:**	**GRAINS:**
Parboiled or converted rice	Basmati rice	Short grain rice
Barley	Brown rice	
Bulgar	Couscous	
Pasta/Noodles		
OTHER:	**OTHER:**	**OTHER:**
Sweet potato	Potato, New/White	Potato, baking (Russet)
Yam	Sweet corn	French fries
Legumes	Popcorn	Pretzels
Lentils	Stoned Wheat Thins™	Rice cakes
Chickpeas	Ryvita™ (rye crisps)	Soda Crackers
Kidney beans	Black bean soup	
Split peas	Green pea soup	
Soy beans		
Baked beans		

*expressed as a percentage of the value for glucose †Canadian values where available 111018 02-134 08/02 Q-2.5M

Reference: Foster-Powell K., Holt S. H. A., Brand-Miller J. C., International table of glycemic index and glycemic load values: 2002, Am J Clin Nutr. 2002; 76:5 -56

One change I will make **now** is _____

Appendix C:

Snacks, incorporating low GI food or ingredients, provided to all study participants during group meetings

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Snack 1:
Snack of the day: Cheese and crackers, using multi-grain and low GI crackers

Snack 2:
Snack of the day: Hummus and pita bread

Snack 3:
Snack of the day: Sandwiches (on stone-ground and low GI bread)

- Roast Beef + lettuce
- Roast chicken + lettuce
- Ham and cheese
- Vegetarian + cheese

Snack 4:
Snack of the day: Spinach dip and pumpernickel

The following will be provided along with the "snack-of-day" above:
Assorted fruits
Yogurt and beverages (juice, coffee, tea, 1%milk)

Note: Snack ideas above are for both the FSP and FSP-Nutrition Group.
All "snack-of-the-day" above incorporated at least a low-GI food. This might be helpful when teaching low GI food to the FSP-Nutrition group.

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Appendix D:

Recruitment package to the diabetes educators

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Inclusion Criteria Checklist:

	YES	NO
1. Living in Edmonton area.	☐	☐
2. Have completed Diabetes Education Class	☐	☐
3. Told by physician/clinician to increase physical activity	☐	☐
4. Not taking insulin	☐	☐
5. Between 40-70 years of age	☐	☐
6. No known contraindications (e.g. peripheral vascular disease, existing neuropathy, heart conditions) and able to participate in moderate physical activity (walking)	☐	☐
7. Not currently in an exercise program	☐	☐
8. No digestive problems or disease (e.g. Celiac disease, Irritable bowel syndrome, Inflammable Bowel disease)	☐	☐

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Brief Overview of the First Step Program—Nutrition Study

The researchers in this study are trying to determine whether simple messages about physical activity and healthy eating help people with Type 2 diabetes improve their diabetes and risk of heart disease.

The study involves attending 4 group meetings (once a week for four consecutive weeks) and a follow-up session. Each group meeting will be about 60-90 mins long and will include going for a short walk (10-30 mins).

During each meeting, the Study Coordinator will reinforce the simple messages (either focused on physical activity or both physical activity and dietary intake) according to the specific group. People who take part in this study will spend time doing individual goal setting regarding their physical activity and dietary intake, assessing barriers to achieving goals and problem solving.

All meetings and session will be held at the Human Nutrition Research Centre, University of Alberta.

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small tube for further testing. For body composition measurement, you will be asked to stand with either bare feet or nylons on a scale for about 5 seconds, 3 times. Also, you will be asked to put on a hospital gown and lie on an X-ray bed to scan for your body composition. The total time required to complete a total body scan is about 20 minutes. Pregnant women are not able to take part in the scan.

For the whole study, you will be asked to wear a pedometer to help keep track of your regular physical activity. You will be asked to record the number of steps you walk each day in your activity calendar/log book. At the end of this time, you will be asked to return your activity calendar/log book to the Study Coordinator.

At the follow-up session (approximately 16 weeks from now), all of the measurements (weight, height, waist girth, hip girth, body composition, blood pressure, heart rate and Hemoglobin A1C) and questionnaires that you completed during the screening session will be repeated. This will take about 60 minutes. You will also be asked to complete another 3-day food record and to wear a sealed pedometer for 3 days, as you did for the screening.

At the follow-up session, the Study Coordinator will ask you whether we can contact you in the future to ask about how you liked the programs, what changes you think we should make to the programs, your current pedometer use and things like this. This will be a separate study.

Confidentiality:
Only people associated with the research study (Dr. Bell, Dr. McCargar and the Study Coordinator) will have access to your records. Records from the study are confidential and securely stored, in locked filing cabinets. Your records will be listed according to an identification number rather than by name. Published reports resulting from this study will be summarized as group findings. We will not identify you in reports. We will not give your name, phone number, address, or email address to anyone or use them for any other purpose apart from the study.

Other study participants will know that you took part in the study, but they will never see your records.

Benefits:
Physical activity and healthy eating are important in managing diabetes. Physical activity and healthy eating may also help reduce the risk of heart disease. By participating in this study, you may gain health benefits through increased physical activity and/or by being encouraged to eat a healthy diet.

You also may benefit from increased social contact, motivation and support offered through the group meetings.

Risks:
You may experience feelings of fatigue, increased sensation of breathing, and muscle

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Appendix E:

A tear-of recruitment ad placed in the Safeway Pharmacy stores across Edmonton

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Appendix F:

Press release on the FSFB research study

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Appendix G:

FSFB article in the Edmonton Sun newspaper

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Appendix H:

Recruitment ad used in the CDA Edmonton Diabetes Forum
(Actual size: 30.5 X 60cm)

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Appendix I:

Background and stages of change questionnaires

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The First Step Program-Nutrition Study
Background Questionnaire

Participant ID: _____

Date: _____

Questions about your current physical activity level and dietary pattern:

1. In a typical 7-day week, how many times do you engage in physical activity that is long enough and intense enough to cause sweating and/or a rapid heart rate? (Please check one)

- ☐ At least 3 times a week
- ☐ Normally 1 or 2 times a week
- ☐ Rarely or never

2. Are you currently on a diet program (e.g. Weight Watcher, Atkins Diet)? (Please check one)

- ☐ No
- ☐ Yes. Please specify type of program: _____

Questions about your diabetes and your health:

3. About how long has it been since you were first diagnosed with diabetes by a doctor?

If less than 12 months, about how many months? _____ months
If 12 months or more, about how many years? _____ year(s)

4. How do you manage or treat your diabetes? (Please check all that apply)

- ☐ Diet
- ☐ Oral diabetic medication
- ☐ Other. Please explain: _____

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

- ☐ Heart trouble?
- ☐ Chronic asthma, emphysema, or bronchitis?
- ☐ Osteoporosis?
- ☐ Arthritis?
- ☐ High blood pressure?
- ☐ High cholesterol?
- ☐ Back problems?
- ☐ Foot problems?
- ☐ Allergies (including hay fever and sinus problems)
- ☐ Trouble hearing?
- ☐ Trouble seeing?
- ☐ Bladder control difficulties?
- ☐ Balance problems or frequent falls?
- ☐ Other health problems? Please explain:

_____

6. Are you a ... (Please check one)

- ☐ Current, regular smoker
- ☐ Occasional smoker
- ☐ Former smoker
- ☐ Non-smoker

7. What is the highest level of education you have completed? (Please check one)

- ☐ Elementary school
- ☐ Some high school/secondary
- ☐ High school diploma
- ☐ Some college or university/post-secondary school
- ☐ Post-graduate degree

8. How would describe your current employment? (Please check all that apply)

- ☐ Full time
- ☐ Self-employed
- ☐ Student
- ☐ Between jobs
- ☐ Working more than one job
- ☐ Part-time
- ☐ Homemaker or caretaker
- ☐ Retired
- ☐ Unemployed

9. Are you ... Male? Or Female? (Please circle one)

10. What is your age? _____ years

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11. How would you describe your financial situation? (Please check one)

- ☐ I can meet my needs and still have enough money left to do most things I want.
- ☐ I have enough money to meet my needs and to do many of the things I want if I budget carefully.
- ☐ I have enough money to meet my needs but have little left for extras.
- ☐ I can barely meet my needs and have nothing left for extras.

12. Which of the following best describes you... (Please check all that apply)

- ☐ North American Indian
- ☐ Inuit (Eskimo)
- ☐ White
- ☐ Chinese
- ☐ South Asian (e.g. East Indians, Pakistani, Sri Lankan etc)
- ☐ Black
- ☐ Filipino
- ☐ Latin American
- ☐ South East Asian (e.g. Cambodian, Laotian, Vietnamese etc)
- ☐ Arab
- ☐ West Asian (e.g. Afghanistan, Iranian etc)
- ☐ Japanese
- ☐ Korean
- ☐ Other. Please specify: _____

13. Do you have any concern about taking part in this study? (Please check all that apply)

- ☐ No
- ☐ I may not be able to keep up (e.g. physical activity etc)
- ☐ I may not have the skills necessary (e.g. to increase fruits and vegetable intake etc)
- ☐ I may not be able to schedule the time to attend all the class and group meetings
- ☐ I may have transportation problems
- ☐ Other concerns: Please explain:

_____

_____

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Questions assessing readiness for physical activity and dietary change

For the following questions 1-7, please check one that applies to you most.

To answer question 1, please note that "Regular physical activity" is defined as doing activities such as brisk walking, recreation and sporting activities (e.g. jogging, swimming, biking, skiing, housework), and **must add up to a total of 30 minutes or more per day, AND be done at least 4 days per week.**

1. Please check the following that best describes your present physical activity behaviour.

☐ I presently get regular physical activity and have been doing so for longer than 6 months

☐ I presently get regular physical activity, but I have only begun doing so within the past 6 months

☐ I am currently involved in some physical activity, but not on a regular basis

☐ I presently do not get regular physical activity, but I have been thinking about starting to get regular physical activity within the next 6 months

☐ I presently do not do regular physical activity and do not plan to start doing physical activity in the next 6 months

2. Have you seriously thought about eating more fruits and vegetables starting sometime in the next 6 months?

☐ Yes

☐ No (Please skip question 3 and proceed to question 4)

☐ Presently trying (Please skip question 3 and proceed to question 4)

3. Are you planning to eat more fruits and vegetables starting sometime in the next month?

☐ Yes

☐ No

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4. Have you seriously thought about eating less fatty food (e.g. French fries, chicken fingers, etc) starting sometime in the next 6 months?

☐ Yes

☐ No (Please skip question 5 and proceed to question 6)

☐ Presently trying (Please skip question 5 and proceed to question 6)

5. Are you planning to eat less fatty food starting sometime in the next month?

☐ Yes

☐ No

6. Have you seriously thought about eating more fiber-containing food items (e.g. whole wheat crackers, brown rice, oatmeal etc) starting sometime in the next 6 months?

☐ Yes

☐ No (Please skip question 7 below)

☐ Presently trying (Please skip question 7 below)

7. Are you planning to eat more fiber-containing food items starting sometime in the next month?

☐ Yes

☐ No

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Appendix J:

Evaluation results for the FSP and FSFB

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Evaluation results of the First Step Program (n=19). Number of people for each rating is expressed in percentage.

	Rating: 1-2*	Rating:3†	Rating 4-5‡
How helpful have the weekly meetings been for you when setting realistic steps/day goals?	84%	16%	-
How helpful have the weekly meetings been for you in achieving your steps/day goal?	90%	5%	5%
How helpful has using your pedometer been for you when setting realistic steps/day goals?	100%	-	-
How helpful has using your pedometer been for you in achieving your steps/day goal?	95%	5%	-
Do you see yourself continuing to use the pedometer in the future?	100%	-	-
How knowledgeable was your facilitator about the First Step Program?	100%	-	-
To what extent did your facilitator motivate you to increase your steps/day?	95%	5%	-
How would you rate the overall effectiveness of your facilitator during weekly meetings?	95%	5%	-
General overall impression of the First Step Program.	95%	5%	-

*1-**Very** helpful/likely/knowledgeable/motivating/effective/excellent, 2-Helpful/likely/knowledgeable/motivating/effective/good
†3-Neutral/satisfactory
‡4- Not helpful/likely/knowledgeable/motivating/effective/excellent, 5-**Not at all** helpful/likely/knowledgeable/motivating/effective/excellent

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Evaluation results of the First Step First Bite Program (n=22). Number of people for each rating is expressed in percentage.

	Rating: 1-2*	Rating:3†	Rating 4-5‡
How helpful have the weekly meetings been for you when setting realistic steps/day goals?	92%	4%	4%
How helpful have the weekly meetings been for you in achieving your steps/day goal?	96%	4%	-
How helpful have the weekly meetings been for you when setting realistic low glycemic index (GI) foods/day goals?	74%	17%	9%
How helpful have the weekly meetings been for you in achieving your low GI foods/day goal?	70%	26%	4%
How helpful has using your pedometer been for you when setting realistic steps/day goals?	100%	-	-
How helpful has using your pedometer been for you in achieving your steps/day goal?	100%	-	-
Do you see yourself continuing to use the pedometer in the future?	96%	4%	-
How helpful has using your "GI Track" card been for you when setting realistic low GI foods/day goal?	65%	18%	17%
How helpful has using your "GI Track" card been for you in achieving your low GI foods/day goal?	69%	9%	22%
Do you see yourself continuing to use the "GI Track" card in the future?	60%	9%	31%
How knowledgeable was your facilitator about the First Step First Bite Program?	100%	-	-
To what extent did your facilitator motivate you to increase your steps/day?	96%	4%	-
To what extent did your facilitator motivate you to increase your low GI foods/day?	87%	13%	-
How would you rate the overall effectiveness of your facilitator during weekly meetings?	100%	-	-
General overall impression of the First Step First Bite Program.	96%	4%	-

*1-**Very** helpful/likely/knowledgeable/motivating/effective/excellent, 2-Helpful/likely/knowledgeable/motivating/effective/good
†3-Neutral/satisfactory
‡4- Not helpful/likely/knowledgeable/motivating/effective/excellent, 5-**Not at all** helpful/likely/knowledgeable/motivating/effective/excellent

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