THE EFFECT OF GOAL DIFFICULTY ON SELF-EFFICACY, DIETARY INTAKE AND CLINICAL OUTCOMES IN ADULTS WITH TYPE 2 DIABETES

DISSERTATION

Presented in Partial Fulfillment of the Requirements for
the Degree of Doctor of Philosophy in the Graduate
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By

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ABSTRACT

Epidemiologic evidence suggests that low glycemic index (GI) and glycemic load (GL) diets are associated with reduced risk for type 2 diabetes and associated comorbidities. Goal setting theory postulates that increasing goal difficulty should increase self-efficacy and performance. However, there are no studies implementing goal setting theory in a population with type 2 diabetes to help lower the overall GI of the diet. This study randomized adults with type 2 diabetes to two groups; either a diet with an easier goal of consuming 6 low GI food servings/day (the 6 group) or a diet with a more difficult goal of consuming 8 low GI food servings/day (the 8 group). We hypothesized individuals assigned to the 8 group would have greater changes in overall dietary GI/GL, measures of glycemic (HbA1c) and weight control, goal satisfaction, and potential mediating variables (goal commitment and self-efficacy). Adults aged 40-65 with diagnoses of type 2 diabetes ≥ 1 year completed the study (n = 35). Participants met in groups with the study dietitian for 5 weekly lessons about GI and self-monitoring. After the nutrition intervention, participants were randomized to the easier or more difficult goal and entered a period of self-monitoring for approximately 8 weeks. Outcomes of interest were measured at baseline, following nutrition education, following goal assignment and at study end.
At baseline there were no significant differences in any of the outcome measures between groups or between those who did or did not complete the intervention. Within group (mean ± SD) reductions in GI and GL for the 6 group were (GI = -6.78 ± 5.92; GL = -37.38 ± 38.01; p<0.01) and for the 8 group were (GI = -4.56 ± 4.19; GL = -38.52 ± 35.64; p<0.001). Within group changes (all p<0.05) in energy, carbohydrate (% of energy and total grams), total and insoluble fiber, added sugars, calcium, vitamin C, β-carotene and magnesium were noted in the 6 or the 8 group. Within group increases in total low GI food servings for the 6 group were (1.73 ± 3.17 servings; p<0.05) and for the 8 group were (1.85 ± 3.04 servings; p<0.05). Small weight losses were noted for both groups; reductions in HbA1C were 0.38 ± 1.25 % in the 6 group and 0.73 ± 1.28 % (p<0.05) in the 8 group. Self efficacy for making lower GI food choices increased in both groups over the course of the study (all p<0.05); correlation analyses revealed that with increasing goal difficulty, commitment decreased in both treatment groups. When grouped by commitment, greater changes (p≤0.05) in energy, % energy from protein and GL were noted for those with higher commitment. The results from this study illustrate that implementing the components of goal setting theory in combination with a low GI diet can facilitate beneficial dietary change, weight loss and improve glycemic control in individuals with type 2 diabetes. Future research should focus on determining individualized, appropriately difficult goals and building commitment for dietary behavior change.
Dedicated to my husband,
for his love and support.
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CHAPTER 1

Introduction

1.1 Overview

The prevalence of type 2 diabetes has increased substantially in the United States and it is a major contributor to morbidity and mortality. Recent estimates suggest that approximately 17.5 million people in the United States have been diagnosed with diabetes, and this number continues to grow by about 1 million people each year.\(^1\) Individuals with diabetes are at increased risk of complications including neurological, peripheral vascular, cardiovascular, renal and ophthalmic disease. The economic burden of diabetes and the associated complications is great. In 2007, it was estimated that diabetes accounted for approximately $116 billion dollars in direct medical costs and $58 billion from reduced productivity at work and at home, or approximately one of every five health care dollars spent.\(^1\)

Type 2 diabetes accounts for approximately 90 to 95% of diagnosed diabetes in the US. The reduced quality of life and the costs associated with this disease have made it a target for effective medical and behavioral interventions. Current standards of
medical care for the management of type 2 diabetes support the use of dietary therapy as a key component of a patient’s treatment plan.\(^2\) In patients with type 2 diabetes, clinically significant improvements in glycated hemoglobin (HbA\(_{1C}\)) have been noted 3-6 months following diet therapy, with sustained improvements noted when regular follow-up visits were incorporated.\(^3\text{-}^9\) Improvements in blood lipid levels have also been noted following dietary therapy in free-living patients with type 2 diabetes.\(^3\) However, lifestyle change is difficult to maintain, with few achieving long term dietary modifications.\(^10\) Dietary choices are encountered numerous times each day, and people with type 2 diabetes need practical tools to make the best choices for optimal blood glucose control.

Current standards of care for the dietary management of type 2 diabetes suggest monitoring carbohydrate intake is a key strategy for achieving glycemic control and consideration of the glycemic index (GI) of these foods may provide additional benefit.\(^2\) The glycemic index is a scale that categorizes carbohydrate containing foods according to their potential to raise blood glucose, and emphasizes a diet high in dairy products, nuts and seeds, fruits, vegetables, whole grain and high fiber foods.\(^11\) Related to the GI value of foods is the glycemic load (GL), a scale that accounts for the glycemic response of foods while considering both the quality and the quantity of carbohydrate consumed. Blood glucose excursions following a meal emphasizing low GI foods (<56) are attenuated compared to those following a higher GI (≥70) meal, an important characteristic for lowering HbA\(_{1C}\). In fact, a recent meta analysis of 37 epidemiologic studies evaluating the association of GI with chronic disease showed that those consuming diets with the highest GI values were at greater risk for type 2 diabetes,
coronary heart disease, gall bladder disease and various cancers (rate ratio = 1.14 for all
diseases; 95% CI = 1.09, 1.19; p<0.0001) compared to those consuming lower GI diets.12

Though consuming a lower GI diet has been associated with improved outcomes
related to type 2 diabetes,13-15 the knowledge and tools needed to incorporate these foods
on a daily basis can be elusive. Goal setting has been used to help people achieve change
for a variety of tasks, including improving employee performance, increasing exercise
and increasing fiber, fruit and vegetable consumption.16-18 Goal setting theory postulates
that specific, more difficult goals will result in more desirable outcomes than specific,
easier goals.19 As a specific, more difficult goal is accomplished, the mediators of
commitment and self-efficacy for this goal increase, thus increasing satisfaction with the
goal. When satisfaction is felt the goal can be reassessed, and the cycle can begin again
with a slightly more challenging goal.

There are no known studies incorporating goal setting with a low GI diet for
management of type 2 diabetes and thus no evidence exists to support or refute the
combination of these two methods as a potential means of dietary therapy for
management of this disease. Furthermore, it is unknown how many servings of low GI
foods consumed each day constitutes a difficult yet achievable goal. We hypothesize that
individuals randomized to a more difficult dietary goal will have greater changes in
dietary GI and GL, measures of glycemic (HbA1c) and weight control, goal satisfaction,
goal commitment and self efficacy compared to those assigned an easier dietary goal.
The results from this study will provide a basis for the efficacy of using goal setting in
combination with consuming low GI foods for the dietary management of type 2
diabetes. It will also help assess and establish an appropriately difficult, yet achievable
serving goal for low GI foods. The theoretical model for goal setting will help assess potential mediators in the process of behavior change and offer insight on which of these constructs should be modified in future studies regarding glycemic index.

1.2 Aims

Goal setting theory posits that individuals with more difficult, specific goals will have greater behavior change compared to individuals with easier specific goals. Thus, the aims of this research are:

**Aim 1:** To evaluate the effect of goal difficulty on:

- Self-efficacy
- Goal commitment
- Dietary Intake
- HbA\textsubscript{1C} and weight control
- Satisfaction

**Aim 2:** To evaluate the relation among goal difficulty, self efficacy, goal commitment and dietary intake.

We hypothesize that individuals assigned a more difficult, specific goal will have greater changes and greater correlations in the aforementioned outcomes compared to individuals assigned an easier, specific goal.
CHAPTER 2

Literature Review

2.1 Carbohydrate and Glycemic Index

The effect of food on blood glucose has been realized since 1916, when Higgins concluded that not all carbohydrate foods, specifically sugars, are metabolized equally. Carbohydrates, which are ultimately metabolized to glucose, are the preferred fuel of the body with the adult brain using approximately 200 grams each day. Under normal conditions when a meal containing carbohydrate is consumed, blood glucose levels in the body rise and an appropriate amount of insulin is secreted by the pancreas to maintain blood glucose control. In a fasting individual, normal blood glucose levels are usually lower than 100 mg/dL. If blood glucose levels in the body should drop to 50 mg/dL or below, an individual may experience a coma, seizures or even death. On the other hand, if blood glucose levels should rise to 180 mg/dL or greater, an individual may in the short term experience glycosuria and in the long term may experience complications including renal failure, retinopathy or atherosclerosis. Thus, it is normal for the body to maintain blood glucose levels both in the fasted and fed state.
The issue of how carbohydrate containing foods are utilized by the body has been a point of controversy in recent years. In 1981, Jenkins and co-workers developed a scale known as the glycemic index (GI) that categorizes carbohydrate containing foods according to the postprandial glucose excursion following consumption of that food.\(^{11}\)

To determine the GI of a food, at least 10 healthy individuals are fed a portion of a test food that contains 50 grams of available carbohydrate. Over the next 2 hours, blood samples are collected every 15 to 30 minutes, and increases and decreases in blood glucose levels are evaluated to generate an “area under the curve” (AUC). The AUC for the test food is then divided by the AUC for the reference food (glucose or white bread) and multiplied by 100. The average percentage derived from this calculation for the test food in question is the GI for this food.\(^{11}\) A factor of 0.7 can be used to convert GI values as determined by white bread to the glucose scale. Related to the GI value of foods is the glycemic load (GL). The GL was developed by Salmeron and colleagues to account for the glycemic response of foods while considering both the quality and the quantity of carbohydrates consumed.\(^{23}\) To determine the GL of a food, the GI of a food is multiplied by the total amount of carbohydrate from the serving in question, then divided by 100. This value is an indicator of the insulin demand for varying portions of foods.\(^{23}\)

The importance of the type and structure of macronutrients has come to light in recent years. Though all digestible carbohydrate foods are eventually converted to glucose, there are many variables that can increase this rate of digestion. Foods containing fructose and galactose require a longer digestion period as they must be metabolized to glucose, and foods containing a greater amount of amylose have a lower
GI than those higher in amylopectin. Grains in their whole-kernel, minimally milled form have a lower GI than those that have been heavily milled, and foods that have endured less cooking frequently have a lower GI than those that have been fully cooked. Finally, other dietary factors including fat, protein and fiber can also influence the intestinal transit time and act as a barrier to the absorption of glucose from a meal.24

Despite this research, the prevailing message in the United States has reinforced that the amount of carbohydrate consumed is most important for weight control and the management of type 2 diabetes. In fact, the majority of popular diets since the 1960’s have focused on macronutrient composition with less emphasis on the qualities of these macronutrients. Dr. Robert Adkins helped mainstream a low carbohydrate, high protein, high fat diet for weight loss, while Dr. Dean Ornish popularized the low-fat, lower protein, high carbohydrate diet. During the 1980’s, the prevailing thought was that diets high in fat led to weight gain and therefore low fat diets and related products became popular. Individuals following these diets avoided fat and in turn consumed products higher in carbohydrate. Even with the good intentions of individuals attempting to manage their weight and the numerous products manufactured to help in the cause of weight management, as a nation we are much heavier today despite these efforts.

In 1960, an average adult male in the United States weighed about 166 pounds and the average adult woman in the United States weighed about 140 pounds.25 In just a short 42 years, the average weight of an adult male in the US increased to approximately 191 pounds while the average weight of a US adult woman increased to approximately 164 pounds, all while average heights remained approximately the same.25 These
increases in weight since the 1960’s have contributed to a marked increase in the risk of numerous chronic diseases including cancer, cardiovascular disease and diabetes.

Over-nutrition plays an important role in the development of overweight and obesity. To become overweight or obese, an individual must consume more energy than they expend for an extended period of time. When an individual consumes food, much of this fuel is either utilized by the body as mechanical energy or heat, or is stored in the muscle and liver as glycogen or in fat cells as triglycerides. However, when there is excess energy, cells in the liver and muscle become less responsive to insulin and subsequent increases in blood glucose levels are noted. Greater levels of glucose in the blood (hyperglycemia) result in increased insulin production even though the body is resistant to this excess insulin. Hyperinsulinemia is the resulting metabolic state, and many times progresses to the development of type 2 diabetes.26

Recently, mechanisms implicating insulin resistance, type 2 diabetes and dietary carbohydrates in the development of chronic diseases has been examined. Chronic hyperglycemia may result in chronic hyperinsulinemia, with implications in the development of a variety of cancers, primarily through the insulin like growth factor axis. Insulin like growth factors are proteins produced by the liver and by other tissues in the body and have several functions. In children, these proteins are important in normal bone growth and development, and in adults promote cellular growth in many types of tissues.27 In healthy adults, insulin like growth factors are bound to binding proteins and an acid labile subunit, creating a large ternary molecule that sequesters insulin like growth factors. However, several studies have shown that excess insulin can result in lower production of insulin like growth factor binding proteins and even result in their
degradation, leading to an increase in free insulin like growth factors available for growth promotion. Insulin like growth factor receptors have been identified on a variety of cancer cells, and excess free insulin like growth factors have been implicated in their growth and proliferation.

Cardiovascular disease is another comorbidity associated with diabetes, with insulin as one of the primary factors linking diabetes and cardiovascular disease. Insulin resistance occurs when muscle, fat and liver cells in the body become less sensitive to circulating insulin, leading to an increase in blood glucose levels and compensatory higher serum insulin levels. It is also a prominent factor leading to the development of not only type 2 diabetes, but also hypertension and other cardiovascular diseases. In insulin resistance, the body is exposed to a continual state of inflammation, linking the metabolic dysfunction of insulin resistance to the vascular dysfunction seen in cardiovascular diseases.

2.2 Glycemic Index and Cancer

Consuming a low-GI diet has been shown to result in attenuated insulin levels compared to a high-GI diet. Because of the link between increased insulin levels and increased cancer risk, there has been recent interest in the relationship between the GI and GL of the diet and subsequent cancer occurrences. Since 1997, numerous cohort and case control studies have evaluated this association in colorectal, breast, gastric, pancreatic, endometrial, ovarian and prostate cancers.

The association between colorectal cancer and GI or GL is controversial. In 2004, Higginbotham and colleagues evaluated data from the Women's Health Study,
evaluating women (n = 38,451) for incident cases of colorectal cancer and assessing GI and GL through use of a semiquantitative food frequency questionnaire (FFQ). After 7.9 years of follow-up, dietary GL was statistically significantly associated with increased risk of colorectal cancer (adjusted RR = 2.85; 95% CI = 1.40-5.80) as well as dietary GI, though not statistically significant (RR = 1.71; 95% CI = 0.98-2.98). Evaluation of these relationships in the Health Professionals Follow-Up Study and the Iowa Women’s Health Study also noted positive associations in both men and women, though statistically significant only in individuals with BMI values ≥ 25 or 30 kg/m², respectively, perhaps as insulin resistance is more common in individuals with greater BMI values. Several case-control studies have also noted these associations. Slattery and colleagues evaluated the relationship between GI and colon cancer from cases of colon cancer (n=1993) and controls (n = 2410) by developing a GI for individual foods from a diet history questionnaire. In this study, individuals were found to be at highest risk when consuming a high GI diet in combination with a sedentary lifestyle (OR men = 3.46, 95% CI = 1.78-6.70; OR women = 2.00, 95% CI = 0.98-4.07). Franceschi et. al. also noted a statistically significant increased risk for colorectal cancer for individuals that consumed the highest quintiles of GI or GL (OR GI = 1.7, 95% CI = 1.4-2.0; OR GL = 1.8, 95% CI = 1.5-2.2). However, other cohort studies have not noted similar associations between dietary GI or GL and colorectal cancer.  

Recent studies have also evaluated the association between breast cancer and GI and GL with mixed results. Several cohort studies did not note an association between GI or GL and breast cancer. Interestingly, many of the cohort studies that found an association did so only after adjusting for factors such as level of physical activity and
body weight, both which contribute to insulin usage in the body.\textsuperscript{50, 51} Case control studies evaluating GI and GL have consistently found positive associations. In a 2001 study by Augustin et.al., an Italian multi-center study evaluated dietary factors in women with breast cancer (n = 2569) and controls (n = 2588). Dietary habits two years prior to diagnosis were evaluated using an interviewer administered FFQ, and a daily average GI and GL were deduced from these questionnaires. In this study, GI and GL were both associated with increased risk for breast cancer (OR = 1.36, 95% CI = 1.14-1.64 and OR = 1.34, 95% CI = 1.10-1.61, respectively) when compared to individuals consuming a diet in the lowest GI/GL quintiles.\textsuperscript{33} Similar findings also noted associations between GL and breast cancer in Mexican women.\textsuperscript{52}

Endometrial cancer is another hormonally driven cancer that has been associated with GI and GL. Since 2003, several case control and cohort studies have evaluated this relationship, all finding positive associations between diets with higher GI or GL values and increased risk of endometrial cancer, though sometimes modest and sometimes following adjustment for weight, diabetes or physical activity.\textsuperscript{36, 53, 54} The relationship between pancreatic cancer and GI and GL has also been evaluated, though most studies have not found an association.\textsuperscript{35, 55, 56} Other cancers that have only been minimally evaluated for a correlation with GI or GL include gastric, prostate and ovarian cancer. Thus far, these studies have found positive associations between GI or GL and increased risk for these cancers.\textsuperscript{34, 37, 38, 57} Taken together, consuming a lower GI/GL diet has the potential to reduce insulin response and subsequent risk for various cancers.
2.3 Glycemic Index and Cardiovascular Disease

Dietary factors have also been implicated in the development of cardiovascular disease. As an individual gains weight and starts to become insulin resistant, normal levels of several adipokines become higher or lower – one of the first steps in the development of atherosclerosis. Specifically, there are decreased levels of adiponectin, and increased levels of leptin, angiotensinogen, TNF-α and plasminogen activator inhibitor-1 (PAI-1). With a decrease in adiponectin, there is also a decrease in smooth muscle uptake of glucose, a reduction in free fatty acid oxidation and an increase in hepatic glucose production. Increased leptin levels may lead to a further decrease in insulin sensitivity as well as cholesterol accumulation by macrophages. An increase in the precursory molecule angiotensinogen leads to an increase in angiotensin II, stimulating intracellular adhesion molecule-1, vascular cell adhesion molecule-1, monocyte chemoattractant protein-1 and macrophage colony-stimulating factor, leading to arterial macrophage accumulation in blood vessels. Furthermore, an increase in angiotensin II results in a more rapid degradation of nitric oxide, a major vessel dilator. Increased levels of TNF-α result in increased expression of adhesion molecules on endothelial cells and vascular smooth muscle cells. Finally, hyperinsulinemia results in an imbalance in PAI-1 levels, important in the breakdown of fibrin clots and thrombus formation.

The endothelium, vascular smooth muscle cells, inflammatory cells and immune response are also affected by insulin resistance. In the endothelium, impaired blood flow is an outcome of decreased levels of nitric oxide. With less nitric oxide the phosphotidylinositol 3-kinase (PI(3)K) pathway is impaired and the mitogen-activated
protein (MAP) kinase pathway is induced, resulting in cell growth and mitogenesis at the cellular level, vasoconstriction and an increase in endothelin-1 (ET-1). In the vascular smooth muscle cells, excess insulin results in signaling events that result in proliferation and migration of these cells. In obese individuals, a reduced number of insulin receptors have been noted on monocytes, resulting in defective insulin signaling and ultimately the formation of macrophage foam cells. Furthermore, in animal models, insulin-resistance has been noted to up-regulate CD36, the macrophage receptor for oxidized LDL. Insulin resistance also activates an immune response through stimulation of T-lymphocytes through oxidized LDL.29

Hyperglycemia, another characteristic trademark of type 2 diabetes, also influences the progression of cardiovascular disease. This progression is achieved primarily through the production of reactive advance glycation endproducts (AGEs). There are several mechanisms by which AGEs promote cardiovascular disease, including mechanical dysfunction by cross-bridging, then causing other circulating cells to adhere to vessel walls. Furthermore, AGEs can bind to receptors on macrophages, endothelial cells and smooth muscle cell and also promote inflammation through the activation of nuclear factor-κB. Hyperglycemia, independent of AGE production, has also been noted to increase the production of reactive oxygen species and protein kinase C, resulting in vascular inflammation and other vascular complications.29

Relatively few large, epidemiologic studies have examined the relationship between GI, GL and risk for cardiovascular disease. In the Nurses’ Health Study, women without previous cardiovascular diagnoses (n=75,521) were followed to examine this relationship. Dietary intake was determined using a validated FFQ at 3 timepoints during
the study and GI and GL were calculated from these questionnaires. After 10 years, dietary GL was found to be positively associated with coronary heart disease, after adjustment for other cardiovascular risk factors. Individuals in the highest quintile of GL had greater risk (relative risk = 1.98; 95% CI = 1.41, 2.77) for coronary heart disease compared to individuals in the lowest quintile of GL (95% CI = 1.41-2.77).58

In the EURODIAB Complications Study, HDL cholesterol levels were 6% greater for individuals with type 1 diabetes from northern, western and eastern European centers consuming a diet in the lowest quartile of GI.59 Similar relationships between GI, GL and HDL cholesterol levels were also noted amongst US adults (n = 13,907) in the Third National Health and Nutrition Examination Survey.60 Other cross-sectional and cohort studies have noted similar findings between GI and GL and positive associations with triacylglycerol concentrations, yet inverse associations with HDL concentrations.61, 62 In contrast, the Zutphen Elderly Study did not find an association between GI and coronary heart disease, total cholesterol, HDL cholesterol or triacylglycerols.63

One of the first studies to recognize a relationship between GI and cardiovascular risk factors was conducted in 1985 by Jenkins, et.al. In this 3 month study, 12 hyperlipidemic patients consumed their normal diet during the first and third month, but during the second month were instructed to consume a diet high in low GI foods. During the second month, the mean GI value of the diet was 12.7± 1.4 units lower than months 1 and 3, largely due to changes in the types of cereal products consumed. Following consumption of a low GI diet, reductions in mean total cholesterol (9 ± 2%; p<0.005) and triglyceride levels (16 ± 3%; p<0.001) were noted when compared to their levels in
months 1 and 3. Small reductions were seen in mean LDL cholesterol levels, but no changes were noted in HDL cholesterol levels.\textsuperscript{64}

Since this initial study by Jenkins and colleagues, numerous feeding studies have been conducted to assess the relationship between GI or GL of the diet and cardiovascular risk factors. A Swedish study in people with type 2 diabetes evaluated the effect of a high GI test diet compared with a low GI test diet on blood lipids. In this crossover study, participants were randomized to receive a low GI or high GI test diet for 24 days, then consumed the opposite diet for an additional 24 days. All foods except coffee, tea and water were provided and were in general the same for both test diets. The GI of the diets were varied by altering the structure of the food, eliminating the effects of other potential dietary variations. At the conclusion of this study, total cholesterol was reduced in both diet groups, but was much more pronounced following consumption of the low GI diet (-5 \%, p<0.01). LDL cholesterol was also statistically significantly reduced following both diets but greater reductions were noted following the low GI diet (-8 \%, p<0.01).\textsuperscript{65}

People with type 2 diabetes in Australia were evaluated for similar changes in a 2002 study. In this study, participants consumed a high saturated fat, energy-restricted diet for 4 weeks. Following the initial 4 weeks, participants were randomized to a low or high GI diet for an additional 8 weeks. Participants were provided \textasciitilde60\% of foods to aid with compliance and supplemented with additional purchased foods. At the end of the 8 week period, reductions in fasting triglyceride and fasting LDL levels were noted in both the low and high GI groups, but no differences were noted between groups.\textsuperscript{66}
A study in postmenopausal women evaluated the effect of low or high GI diets in combination with soy protein and phytosterols on risk factors for cardiovascular disease. In this study, postmenopausal women with elevated LDL levels and BMI values were randomized to a low GI diet in combination with soy protein and phytosterols or to the standard American Heart Association Step 1 Diet. The study lasted for 12 weeks with the goal of weight loss. At the end of the 12 week period, individuals that consumed the low GI diet had greater reductions in total and LDL cholesterol and triglycerides (p<0.005 or p<0.01) when compared to individuals consuming the American Heart Association Step 1 diet. Increases in HDL cholesterol were also noted for individuals that consumed the low GI diet (p=0.05). Other cardiovascular risk factors that improved in individuals consuming the low GI diet included the total cholesterol to HDL cholesterol ratio and the triglyceride to HDL cholesterol ratio.67 An 18-month study in Brazilian women evaluating the effects of a low or high GI diet on weight change also saw statistically significant (p<0.03) reductions in VLDL cholesterol for individuals consuming the low GI diet.68

2.4 Glycemic Index and Weight Regulation

The influence of carbohydrate quality on weight regulation has been of interest in recent years. An association between consumption of low GI foods and greater satiety has been noted in several studies.69, 70 A review by Ludwig and colleagues closely examined the effects of low GI foods on hunger, satiety or energy intake. In all but one of the 16 studies examined, consumption of a low GI food either increased satiety, decreased hunger or resulted in a lower voluntary energy intake compared to
consumption of a high GI food. Holt conducted a similar study comparing the degree of grain processing on insulin response and satiety. Participants consumed meals of equal macronutrient composition containing wheat that varied in the degree of processing – whole grains, cracked grains, coarse meal flour and fine meal flour. After participants consumed the test meals, the whole grain meal resulted in the greatest satiety.

Several studies in humans have compared the effects of high or low GI diets on weight loss. In one of the first studies to evaluate this association, obese, hyperinsulinemic females were randomly assigned to a diet that either elicited a low insulin response (low GI) or to a conventional diet. After 12 weeks on the assigned diet, about half of the participants from each diet group switched to the alternate diet for 12 additional weeks. At the end of the study period, mean weight loss was greater following consumption of the diet eliciting a lower insulin response (low GI) compared to the conventional diet. In children and adolescents, similar results have been noted. In these studies, obese children and adolescents were randomized to a low GI or a low fat diet. Participants received instruction on how to choose low GI or low fat foods, and then followed the prescribed dietary patterns for several weeks or months. At the conclusion of these studies, significant reductions in BMI were noted in both children and adolescents that consumed a low GI diet compared to a low fat diet. Furthermore, significant reductions in total body fat mass were noted in the adolescent population consuming the low GI diet.

Conversely, other studies have not shown that eating a reduced calorie, low GI diet is more beneficial for weight loss than a reduced calorie, higher GI diet. In a study by Wolever and colleagues, overweight participants with type 2 diabetes were
recruited and randomized to diets of equal macronutrient composition but varying GI values – a low GI diet (GI of 58) vs. a high GI diet (GI of 86) for a period of 6 weeks. At the conclusion of the study, weight loss was observed in both groups, but a greater mean weight loss was noted in the high GI group compared to the low GI group.\textsuperscript{74}

There are no long term studies in humans evaluating the effects of consuming a low GI diet on weight regulation. However, animal studies have provided evidence that long term consumption of high GI diets result in gradual weight gain.\textsuperscript{75} In one study, 4 month old rats were randomized to one of three isocaloric diet groups: a high GI, short chain glucose group, a high GI starch group (amylopectin) or a low GI starch group (amylose). The macronutrient composition of the diets were 45% carbohydrate, 20% protein and 35% fat. Following 32 weeks on this diet, the animals fed the low GI diet were lighter and had 40% less total body fat mass (p<0.05) than those consuming either high GI diet.\textsuperscript{75} This preliminary animal study provides critical evidence of the role and relationship of the GI value of foods and weight regulation – both important factors in the clinical management of type 2 diabetes.

2.5 Glycemic Index and Diabetes

Consistent levels of blood glucose the desired physiological state for the human body. When an individual consumes high GI foods, blood glucose levels respond with high initial blood glucose concentrations, with subsequent low concentrations. With this increase in blood glucose, insulin is secreted by the pancreas promoting the uptake of blood glucose by muscle, liver and adipose cells. Hepatic glucose output is suppressed as well as free fatty acid release from adipose tissue. Two to four hours following
consumption of a high GI food or meal, insulin levels remain high which can result in a drop in blood glucose to a hypoglycemic state. This low blood glucose level triggers the body to release counterregulatory hormones (glucagon, epinephrine, cortisol and growth hormone) stimulating glycogenolysis or gluconeogenesis in the liver, and free fatty acid release from adipose tissue. An increase in these metabolic fuels and counterregulatory hormones mimics a fasted state, and in some studies has been shown to result in an increased appetite. When an individual consumes a low GI food, blood glucose levels are attenuated with smaller variations in blood glucose over time, maintaining blood glucose closer to the body’s desired physiological levels due to the continual absorption of glucose following a meal.76

One of the primary goals of diabetes management is to maintain blood glucose levels within a normal range and research has been conducted to determine if consuming a low GI diet is an effective form of diabetes management. Though the main outcome of many large epidemiologic cohort studies has been risk factors for cancer, some have evaluated the effects of GI on risk of diabetes. The first cohort studies evaluating the relationship between dietary fiber, GL and risk of type 2 diabetes in men and women were published by Salmeron and colleagues in 1997.23, 77 In these studies, the diets of men (n=42,759) from the Health Professionals’ Follow-up Study and women (n=65,173) from the Nurses’ Health Study (free from type 2 diabetes, cardiovascular disease and cancer at the inception of each study) were assessed to evaluate if GI, GL or dietary fiber were associated with the development of type 2 diabetes. Diets were assessed using a validated, semi-quantitative FFQ administered once in the Health Professionals’ Follow-up Study and three times throughout the Nurses’ Health Study. Dietary GI and GL were
calculated from the responses to these questionnaires, and dietary fiber was directly measured from the responses. Incident cases of type 2 diabetes were documented; there were 532 cases in the Health Professionals’ Follow-up Study and 915 cases in the Nurses’ Health Study. In both studies, after adjustment for potentially confounding factors (either age, BMI, smoking, physical activity, family history of diabetes, alcohol consumption, cereal fiber and total energy intake or cereal fiber intake), a statistically significant positive association was noted between dietary GI and risk of type 2 diabetes (RR = 1.37 for both studies; 95% CI for HPFS = 1.02-1.83; 95% CI for NHS = 1.09-1.71). Furthermore, for both studies the combination of a high GL diet and low cereal fiber intake further increased the risk for type 2 diabetes (RR HPFS = 2.17, 95% CI = 1.04-4.54; RR NHS = 2.50, 95% CI = 1.14-5.51). A similar relationship between GI and risk for type 2 diabetes was also noted in the Nurses’ Health Study II (RR = 1.59 for highest quintile; 95% CI = 1.21-2.10). In this study, a significant negative association was also found between cereal fiber intake and risk of diabetes. Barclay et.al. also saw a statistically significant association between dietary GI and risk of type 2 diabetes in a cohort of older Australians (adjusted HR = 1.75, 95% CI = 1.05-2.92). Conversely, the Iowa Women’s Health Study did not find similar associations between GI, GL and risk of type 2 diabetes. In this study, women (n = 35,988) were evaluated over a period of 6 years and after adjustment for potentially confounding factors, no association was noted between risk of type 2 diabetes and GI or GL.

Since the GI was first introduced in 1981, numerous feeding studies have been conducted to evaluate the effects of the GI on metabolic outcomes. Coulston and colleagues were the first group to conduct such a study in individuals with type 2
diabetes, evaluating the effects of various dietary carbohydrates on plasma glucose, insulin and gastric inhibitory peptide following a test meal. Following consumption of the various test meals, they discovered statistically significant (p<0.01) increases in plasma glucose and plasma insulin following a meal containing potato (higher GI) compared to meals containing rice, spaghetti or lentils (lower GI). Following this study, other studies have been conducted evaluating the effects of the GI of specific foods and the glycemic composition of various meals on outcomes important in the management of diabetes. Though the majority of studies conducted evaluating GI and its effects in people with type 2 diabetes have been short term studies, it is important to remember that long term eating patterns and meal composition have the most impact on lifelong management of diabetes. Thus, when evaluating the usefulness of the GI in the management of both type 1 and type 2 diabetes, it is important to consider the long term effects of these diets.

**Type 1 Diabetes**

The medical management of individuals with type 1 diabetes differs primarily from those with type 2 in that insulin is required on a routine basis due to non-functioning \( \beta \)-cells in the pancreas. However, the nutritional management of individuals with type 1 diabetes share many common themes with those that have type 2 diabetes. The primary goal of their nutritional management is to maintain relatively consistent levels of blood glucose throughout the day. Because the GI of foods affects postprandial blood glucose levels, several longer term studies have been conducted to evaluate its effects and usefulness in the management of type 1 diabetes.
One of the earlier studies was conducted in 1992 by Fontvieille and colleagues, evaluating the use of low GI foods in 18 diabetic patients (12 type 1 and 6 type 2). In this study, participants were randomly assigned to consume a low GI diet or a high GI diet for a period of 5 weeks. After the completion of the first 5 week session, the diets were switched and individuals consumed the opposite diet for another 5 weeks. Each diet was similar in macronutrient and soluble fiber content. The high GI diet derived most of its carbohydrate content from bread and potato sources and had a mean GI of 64 ± 2 while the low GI diet derived the majority of its carbohydrate from pasta, rice and legumes and had a mean GI of 38 ± 5. At the conclusion of this study, improvements were noted in fructosamine levels (short term measure of blood glucose control), fasting blood glucose levels, 2-hour postprandial blood glucose levels, mean daily blood glucose levels and serum triglycerides after consuming the low GI diet for 5 weeks. However, no differences were noted in HbA\textsubscript{1c} levels, though a longer diet period is likely warranted for changes in this measure of long term blood glucose control.

Lafrance and colleagues conducted a similar study several years later in individuals with type 1 diabetes randomized to a low GI diet (66.2 ± 1.2), a high GI diet (92.9 ± 3.6) or a high fiber diet (73.5 ± 2.1) for a period of 12 days. At the end of the dietary intervention, pre-breakfast blood glucose and post-breakfast blood glucose in the low GI and high fiber groups, respectively, were significantly lower than the control diet (p<0.05), providing support that dietary modifications in GI and GL affect metabolic outcome measures in type 1 diabetes.

A longer term evaluation of the effect of a low vs. high GI diet on markers of blood glucose control was conducted by Giacco and colleagues. In this study, 63
patients with type 1 diabetes consumed their regular diet for 4 weeks, then were randomized to either a high fiber or low fiber diet for a period of 24 weeks. By nature of the foods consumed in these diets, the high fiber diet was also lower GI than the low fiber diet. Both diets were equivalent in macronutrient content and fatty acid composition. Individuals on the high fiber (low GI) diet were free-living and instructed to consume 1 serving of legumes, 3 servings of high fiber fruit (apples, oranges, pears, tangerines) and 2 servings of high fiber vegetables (artichoke, eggplant, mushrooms, broccoli) each day. Individuals on the low fiber diet were to limit legume consumption to less than one serving per week and to consume low fiber fruits and vegetables. The mean GI of the high fiber (low GI) diet was 70 and the mean GI of the low fiber (high GI) diet was 90. Fifty-four of the initial 63 participants completed the study. However, of those that completed, only 46 patients were compliant to the assigned diet. After 24 weeks, statistically significant (p<0.01 or 0.05) reductions in mean plasma blood glucose concentrations and HbA1c values were observed in participants that were compliant and consumed the high fiber (low GI) diet compared to those that consumed the low fiber (high GI) diet.90

One of the longest studies to address the effects of a low GI diet in a free-living population was conducted by Gilbertson et.al.91 In this study, children with type 1 diabetes and their families were recruited to evaluate the effects of a one time instructional session on either how to choose low GI foods or how to use the carbohydrate exchange system. No further instruction was given apart from the usual clinic visits. Diets were assessed by a 3 day food diary at 1, 3, 6 and 12 months. In the year following the initial dietary instruction, no significant differences were noted in
HbA$_{1C}$ levels between the groups at 3 or 6 months. However, 12 months following the initial instructional session, HbA$_{1C}$ levels for children in the low GI group were statistically significantly lower (p<0.05) compared to those in the exchange group. Furthermore, for both children and parents that had experienced both methods of dietary management of type 1 diabetes, both children and parents expressed an overall preference for the low GI diet over the carbohydrate exchange system.$^{91}$

**Type 2 Diabetes**

The medical management of type 2 diabetes relies heavily on changes in dietary habits. Several longer term intervention and feeding studies have evaluated the effects of GI in patients with type 2 diabetes. Jenkins and colleagues conducted one of the first feeding studies in 8 patients with type 2 diabetes. Participants were provided either a low GI diet (mean of 67.3 ± 0.4) or a high GI diet (mean of 90.5 ± 0.4) for 2 weeks with a 4 to 7 week intermediate period where participants consumed their normal diet. Participants were then provided the opposite diet for a final 2 weeks. Following consumption of the low GI diet, statistically significant (p<0.05) reductions in blood glucose, HbA$_{1C}$ and fructosamine were observed, lending support that a low GI diet has beneficial effects on markers of blood glucose control in type 2 diabetes.$^{14}$

A similar study was conducted by Brand et.al. in a free-living population. In this study, 16 participants with type 2 diabetes were given instructions on foods to consume for either a low or high GI diet. The mean GI value of the low GI diet was 77 (± 3) and the mean GI of the high GI diet was 91 (± 1). At the end of the 2 week period, statistically significant (p<0.05) reductions in HbA$_{1C}$ and 8 hour plasma glucose levels were noted compared to individuals that had consumed the high GI diet.$^{15}$
Two studies similar in nature were conducted by Wolever and colleagues. In these crossover studies, participants with type 2 diabetes were randomized to a high (86 or 87) or low GI (60 or 58) diet and then fed prepared meals for a period of either 2 or 6 weeks, then consumed the opposing meal for an additional 2 or 6 weeks. At the conclusion of both of these studies, statistically significant (p<0.05) reductions in mean serum fructosamine were noted following consumption of the low GI diet compared to the high GI diet.\textsuperscript{74, 92} Other well controlled crossover studies of moderate length evaluating the effects of diets of low and high GI diets on markers of glycemic response in individuals with type 2 diabetes have noted improvements in serum fructosamine, blood glucose and plasma insulin, or HbA\textsubscript{1C}.\textsuperscript{65, 93} Conversely, other studies have not found similar differences in these markers of glycemic control following consumption of diets with varying GI values.\textsuperscript{94} The inconclusive results from these studies could be due to several factors, including the length of the studies, participant compliance or methodological variation for determining the GI of the test diets.

\section*{2.6 Goal Setting Theory}

Goal setting theory is a critical element of behavior change. Aristotle was one of the first individuals to understand this in his theory of final causality, explaining that every action is caused by a purpose. In the 1930’s, Mace examined the effects varying goals on task performance and Ryan conducted further research in this area, recognizing that conscious goals affect action.\textsuperscript{95} Most of the research involving goal setting theory has been done in work settings with the desired outcome of more productive, efficient
employees. Only recently has goal setting theory been applied and tested in nutrition behavior change.

Numerous biological mechanisms have been discovered in recent years to help explain why and how certain physiological processes occur. For these biological mechanisms, one or more factors must change or cause change in order for the desired outcome to occur. Like these biological mechanisms, behavioral mechanisms have also been developed to help begin to explain the factors critical to behavior change.

Goal setting theory is one of many different behavioral mechanisms that has been developed to help explain the process of behavior change. The model used for the current study is noted in Figure 2.1. There are several factors key to goal setting theory. First, an individual must develop discrepancy between their current behavior and their desired behavior. With this, one of the most important features of goal setting theory is the goal itself. Goal setting theory states that if a goal is more difficult and an individual is likely to achieve it, their performance in accomplishing this goal will be better than if trying to achieve an easier goal. In addition to difficulty, the goal at hand must be specific and well defined. Well defined goals help individuals focus on activities related to achieving the goal at hand and away from activities that are not related to the goal. Goal specificity is a critical feature of this theory that has been repeatedly confirmed both in the United States and abroad.19
Figure 2.1. Theoretical Model of Goal Setting Used in Current Study
Mediator variables and moderator variables are both important factors in psychosocial research. Though many times used interchangeably, their meanings are distinct. A 1986 paper by Baron and Kenny best describes these differences. In psychosocial research, a moderator variable can be described as a qualitative or quantitative factor that affects the direction or strength of relationship between a predictor (independent) variable and a criterion (dependent) variable. That is, the causal relationship between two variables changes as a function of the moderator variable. Moderators always function as independent variables and can influence the strength of a relationship between two other variables. Mediator variables can be described as those variables that help explain how external physical events take on internal psychological significance, or the “how and why” these effects occur. A mediator variable is one that explains the relationship between two variables. If the effect of the mediator is removed, the relationship between two variables disappears. The relationship between independent variables, mediators and outcome variables is best described in Figure 2.2 below:

![Figure 2.2. Woodworth’s 1928 formula for mediation hypothesis](image)

During the course of the GOAL study, mediators will be assessed to examine the relationship between goal difficulty and outcomes such as dietary glycemic index values and HbA$_{1C}$ measurements.
Self-efficacy can be described as the level of confidence an individual has to complete a proposed task. Research has shown that individuals with greater self-efficacy will have improved performance when completing tasks than individuals with lower self-efficacy. Factors such as past performance, ability, adaptability and resourcefulness all influence an individual’s self-efficacy. Ability, whether innate or learned, influences performance. An individual with greater ability will most often have better performance. In addition, if an individual is adaptable and resourceful in a given situation, their performance in turn will likely be greater. These intertwined, underlying factors work together to influence an individual’s self-efficacy, either enhancing or diminishing it.

In addition to the aforementioned factors, success, modeling and persuasion also considerably influence self-efficacy. In a study by Mossholder, individuals were randomized to an interesting task or a boring task. Participants were also assigned to a goal group or no goal group. At the end of the study, individuals that were assigned to the goal group and succeeded at achieving their goal rated themselves as significantly more competent than those that did not achieve their goal, which could help build self-efficacy to attempt new tasks. Furthermore, it has been observed that if an individual has an example or role model to help them understand how to complete a task, their self-efficacy will as a result be greater than if they had received instruction alone. Encouragement and persuasion have also been noted to increase self-efficacy. Taken together, greater levels of self-efficacy should result in changes in the outcomes of interest.

Goal commitment is also an important component in the goal setting theory model. If an individual is not committed to a goal, the outcome measure of interest will
likely not change or may even result in the opposite of the desired outcome. Interestingly, it has been shown that an individual does not necessarily need to participate in setting the goal in order to have a high level of goal commitment,\textsuperscript{102} but goals assigned by an authority figure also results in a high levels of goal commitment.\textsuperscript{103} However, the authority figure cannot simply just “tell” an individual to accomplish the set goal – they must give a reasonable explanation why this goal should be achieved and must also support these individuals in their endeavor to accomplish the goal at hand. Peer pressure can affect goal commitment and either result in commitment to lower or higher goals depending on the peers’ standard of performance. Feedback is also a critical component of goal setting theory. Feedback by itself is not sufficient to help an individual improve their performance. But when combined with a specific, difficult goal it can help an individual direct their activities and monitor their performance toward reaching the goal at hand.

Direction of attention is one factor that affects goal outcomes. Specific goals will readily help direct an individual’s attention toward goal related activities where more general goals do not. When a goal is more difficult, an individual will expend more effort attempting to reach this goal compared to an easier goal. Effort toward achieving the goal, therefore, is a second important component of goal setting theory. Persistence, or how long an individual will work for something over an extended period of time, is a factor that can help explain the outcomes of interest. Harder goals generally result in greater persistence compared to easier goals.\textsuperscript{103}

The main objective of goal setting theory is to help individuals change a behavior. Performance, whether objective or behavioral, is one of the primary outcomes that
measures whether the principles of goal setting theory were effective. Depending on the goal, performance can be measured in numerous ways. For the proposed study, physiological measures including the number of low GI food serving consumed, HbA$_{1C}$, weight, waist circumference, and BMI will be objective measures of performance. If an individual achieves their goal, differences in these performance measures should be noted.

Self reaction, expressed as satisfaction or dissatisfaction is the final component of goal setting theory. If an individual has successfully accomplished their goal as noted by desired changes in performance, goal setting theory postulates an individual will feel a sense of achievement, pride in their accomplishment and a feeling of success. These rewards result in goal satisfaction. As in a biological mechanism, if an individual is satisfied with their accomplishments, this satisfaction feeds back to increase self-efficacy and goal commitment. If self-efficacy and goal commitment increase, individuals will be more committed to take on new challenges and set slightly more difficult goals, resulting in additional desired changes in performance.

Goal setting theory has been used for many years in the workplace to improve performance, but only recently has goal setting theory been implemented to help achieve dietary behavior change. Dietary management of type 2 diabetes has repeatedly been noted to improve medical outcomes and overall quality of life. However, there are no known studies utilizing goal setting theory in the dietary management of diabetes.

Several studies have been conducted evaluating the effectiveness of goal setting theory on dietary behavior change. A study conducted in college students to increase dietary fiber randomized participants to 4 groups: short-term goal setting, self-
monitoring, short-term goal setting plus self-monitoring, or no goal setting and no self-monitoring. Participants were in a college nutrition class and received the same instruction. Individuals in the short-term goal setting group set goals of increasing their dietary fiber by 5 grams each week until reaching their long term-goal of 25-35 grams per day. Goals were written daily and submitted twice each week. Those in the self-monitoring group recorded their daily fiber intake and submitted their information twice each week. Individuals in the goal-setting plus self-monitoring group set written goals of increasing their dietary fiber intake by 5 grams each week, and completed daily fiber self-monitoring forms. Goals and self-monitoring sheets were submitted twice each week. Individuals in the no goal-setting and no self-monitoring group monitored daily activity levels and submitted information twice each week to give the appearance of treatment group participation. Students of similar demographic background in a health class served as the control group. At the end of the study, individuals that set goals consumed 91% more fiber and scored 15% higher on a dietary fiber self-efficacy scale than those that did not set goals. Ultimately, goal setting and self-monitoring affected post-intervention dietary fiber intake through increased knowledge and increased self-efficacy.18

Goal setting using newsletters to increasing fruit and vegetable intake was evaluated in a cohort of individuals participating in a health maintenance organization. Consenting individuals completed a baseline fruit and vegetable FFQ and surveys to assess demographic information and behaviors, attitudes and beliefs about fruit and vegetable consumption. Participants were then randomized to 1 of 4 groups: newsletters with non-tailored nutrition information, newsletters with tailored nutrition information
but no goal setting information, newsletters with tailored nutrition information and goal setting information, or no newsletter. Newsletters were mailed at a frequency of 1 each month for a period of 4 months. At the end of the study, 70% of participants that received a newsletter with goal-setting information actually set a goal, compared to 55% in the group receiving tailored nutrition information, 59% receiving non-tailored information and 30% in the control group. Furthermore, those receiving goal setting information also had the greatest increase in fruit and vegetable intake and greatest increase in fruit and vegetable variety compared to the other groups, though these differences were not statistically significant.104

Goal setting theory has also been used to evaluate ways to enhance adherence to exercise programs. Duncan and colleagues evaluated adherence to an exercise program in patients with heart failure. At the beginning of the study, eligible participants were randomized to an exercise only group or to exercise plus adherence facilitation. All patients participated in 12 weeks of supervised exercise at a heart failure clinic and 12 weeks of home based exercise. During the supervised phase of the program, all participants were monitored by appropriate staff that helped them set exercise goals for the supervised phase and the unsupervised phase based on available exercise equipment. Throughout the course of the study, those patients randomized to the adherence facilitation group also received periodic individualized guidance consisting of goal setting, graphic feedback and problem solving strategies. Both groups completed exercise diaries to monitor adherence. At the end of the study, individuals in the exercise adherence group achieved 104.6% (p<0.01) of their exercise frequency goal during the unsupervised phase of the program, compared to the control group which only
achieved 64.1% of their goal. Duration goals were also greater in the exercise adherence group, achieving 108.7% of their duration goal compared to 84.9% in the control group.\textsuperscript{16}

The aforementioned studies evaluated the effects of interventions both with and without goal setting on various health outcomes, providing support that interventions with a goal setting component are more effective than those without a goal-setting component. However, preventative interventions are uncommon in medical care today and most individuals default to “usual care”, which does not incorporate goal setting in any aspect. Several investigators have evaluated the effects of interventions with a goal setting component compared to usual care, and have consistently found that a goal setting component results in more desirable outcomes compared to usual care.\textsuperscript{105, 106} Mayer and colleagues completed a study in older adults that focused on behavior modification to reduce hypertension. Consenting individuals were participants in a health maintenance organization and were randomly assigned to usual care or to a preventative care group. Individuals randomized to the preventative care group completed a health risk appraisal, and lifestyle goals to reduce hypertension were made based on this tool. Increasing physical activity was the most frequently set goal. Following the appraisal, individuals in the preventative care group attended an 8 week health promotion program to aid them in achieving their goals. At the end of the study, statistically significant (p<0.05) increases in exercise and decreases in fat intake and caffeine were noted in the intervention group compared to the control group. Additionally, a statistically significant shift from a sedentary lifestyle to a non-sedentary lifestyle was noted in the intervention group (p<0.0001). A significant (p<0.001) decrease in both systolic and diastolic blood pressure in the intervention group was noted at the conclusion of the study.\textsuperscript{105}
A study targeting couples early in the course of cohabitation was conducted in Australia, as this group of individuals is especially at risk for weight gain resulting from increased food intake and a decrease in exercise usually associated with cohabitation. Couples were recruited and randomized to usual care, or to a low level or high level intervention lasting 16 weeks. Participants in the low level intervention group received 1 initial personal contact and all other health information was received by mail every 2 weeks. Participants in the high level intervention group received their health information at two week intervals through mailings or through personal contact where an interventionist explained the purpose of the information, demonstrated exercise techniques and answered questions and reviewed participant progress. At the conclusion of the study, dietary self-efficacy was increased in both intervention groups and continued at the one year follow-up visit. Self-efficacy for physical activity was increased in the high level intervention group at the conclusion of the study and continued at follow-up. Significant reductions in total and saturated fat intake were noted in both intervention groups, and increased physical activity was noted in all groups at the conclusion of the study. Increased physical activity continued at follow-up for the intervention groups compared to the control group, supporting the role of goal setting interventions for health promotion.106

Goal setting can aid nutritional change in both urban and rural settings. This was demonstrated by the Cooperative Extension Service of Nebraska through their “Eating Today for a Healthier Tomorrow” program to help individuals evaluate their current diet and make appropriate changes to meet current dietary recommendations. Individuals participated in six sessions that incorporated discussion, goal setting, games and food
tasting activities to learn about nutrition and ways to make appropriate dietary changes. Diet and exercise data were collected prior to the intervention and 2 months following the intervention. At the end of the study, individuals selected lower-fat dairy foods, less total protein and red meat, and fewer breads and cereals. Participants also selected fewer foods high in saturated fat and sodium, and also selected fewer desserts following the intervention. Though specific goals were not addressed, use of goal setting theory in this population was successful to accomplish healthy dietary changes. Taken together, these studies demonstrate that goal setting theory can effectively help individuals make substantial dietary changes to positively influence their health.

In conclusion, the role of glycemic index for improved outcomes related to chronic disease is evident. Furthermore, as noted in the aforementioned studies, goal setting theory has specifically been implemented to improve performance in a variety of settings. As goal setting in combination with consuming low GI foods has never been evaluated, this research will assess the effects of a more difficult, specific goal (8 servings of low GI foods/day) and an easier, specific goal (6 servings of low GI foods/day) on dietary, psychosocial and weight control outcomes in individuals with type 2 diabetes.
CHAPTER 3
The Glycemic Index, Opportunities and Lifestyle (GOAL) Study: Dietary, Clinical and Weight Control Outcomes Following Implementation of a Low Glycemic Index Diet

3.1 Introduction

The prevalence of diabetes in the US has increased dramatically since 1980. In 2007 it was estimated that approximately 17.5 million people in the United States were diagnosed with diabetes.\(^1\) Individuals with type 2 diabetes are at increased risk of other health-related issues from this disease including neurologic symptoms, cardiovascular disease and microvascular complications.\(^1\) Though blood glucose control lowers the risk for complications from this disease, there is controversy over optimal macronutrient distribution of the diet.

Current standards of care for the dietary management of type 2 diabetes suggest optimal proportions of fat, carbohydrate and protein vary based on individual circumstances.\(^2\) Monitoring carbohydrate intake is a key strategy for blood glucose control, and the glycemic index (GI) of foods may offer additional benefit. The glycemic index is a scale that categorizes carbohydrate containing foods according to postprandial blood glucose excursions.\(^11\) Related to the GI value of foods is the glycemic load (GL), a scale that accounts for the glycemic response of foods while considering both the quality
and the quantity of carbohydrate consumed. Lower GI diets emphasize increased consumption of fruits, vegetables, dairy products, whole grain and high fiber foods, which have repeatedly shown benefit for weight management and glycemic control.\textsuperscript{71, 108, 109} The utility of GI as a dietary means for improving health has been debated. However, a recent meta analysis of 37 epidemiologic studies evaluating the association of glycemic index with chronic disease showed that those consuming diets with the highest glycemic index values were at greater risk for type 2 diabetes and other chronic diseases compared to those consuming lower GI diets.\textsuperscript{12}

Goal setting has been used as a tool for improving employee performance, increasing exercise and increasing fiber, fruit and vegetable consumption.\textsuperscript{16-18} Goal setting theory postulates that specific, more difficult goals will result in more desirable outcomes than specific, easier goals.\textsuperscript{19} As lower GI diets have shown substantial improvements in metabolic outcomes related to type 2 diabetes,\textsuperscript{108, 109} setting a goal for individuals with type 2 diabetes to consume a specific number of servings of low GI foods each day has the potential to improve glycemic control. Diets with a mean GI value of \textasciitilde{}55 or less have been associated with lower risk of chronic disease,\textsuperscript{12} and we estimate that consuming approximately 6 to 8 servings of low GI foods each day will result in a mean daily GI value of \textasciitilde{}55. As goal setting in combination with consuming low GI foods has never been evaluated, the purpose of this study was to assess the effect of a more difficult, specific goal (8 servings of low GI foods/day) or an easier, specific goal (6 servings of low GI foods/day) on dietary, weight control and clinical outcomes in individuals with type 2 diabetes.
3.2 Research Methods

3.2.1 Recruitment and Subject Selection

The GOAL study was a pretest-posttest randomized controlled trial evaluating the effect of substituting either 6 or 8 servings/day of low GI foods for higher GI foods. Participants recruited to the study were 40-65 years old, diagnosed with type 2 diabetes for \( \geq 1 \) year, had a glycated hemoglobin (HbA1c) value \( \geq 7\% \), and were not on insulin therapy for diabetes management. A score of \( \geq 30 \) on the Mini-Mental Status examination was required for study participation. Participants were recruited from May, 2008 through February, 2009 through newspaper and electronic classified advertisements, employee newsletters, health fairs, medical practices, neighborhood health centers and posted flyers. All study methods were approved by the Institutional Review Board at The Ohio State University (OSU) and participants provided written informed consent.

Following recruitment, participants completed a baseline assessment. Participants then completed a 5-week group nutrition education intervention. After the intervention, participants met with a dietitian from the OSU Clinical Research Center (CRC) for randomization to their assigned treatment group. Following randomization, participants completed approximately 8 weeks of dietary and blood glucose self-monitoring. Midway through the self-monitoring period, participants again met with the CRC dietitian to assess their progress and assist with problem solving followed by final data collection 4 weeks later.
3.2.2 Intervention

The nutrition intervention was conducted by the same dietitian and included five weekly group education sessions. Each group was comprised of approximately 10 participants; friends or family members were also invited to join the education sessions. The weekly sessions addressed current guidelines for optimal blood glucose control, diet and blood glucose self-monitoring, portion control, GI as a means of selecting foods for blood glucose control, factors influencing the GI value of foods, and approaches for maintaining behavior change. A low GI diet can be obtained by choosing lower rather than higher GI foods, by consuming a low carbohydrate diet, or by a combination of approaches. Participants in this study were encouraged to substitute low GI foods for higher GI foods to achieve a lower GI diet. This approach was selected to allow participants to consume a variety of carbohydrate-containing foods. Questions were encouraged throughout the educational sessions and hands-on activities (i.e., weighing and measuring portions, recipe modification) were incorporated for skill building for substituting low for higher GI foods.

Following the educational sessions, participants were randomized to consume either 6 (6 group) or 8 (8 group) servings/day of low GI foods (i.e., foods with a GI value < 56) to evaluate the impact of each serving designation on weight and glycemic control. One serving of a low GI food was defined as the amount of food customarily consumed per eating occasion, commonly noted as “serving size” on the Nutrition Facts Panel. This definition of serving size was selected to concur with serving size as taught during the educational lessons. Randomization assignments were generated for each intervention group by a computerized random number generator program and were
provided to the study participants by a dietitian at the CRC. During this study visit, the CRC dietitian helped participants target changes specific to their diets to meet their low GI serving goal.

Participants implemented their goal for approximately 8 weeks, during which they were requested to self-monitor their dietary intake and blood glucose values. Dietary intake was monitored by completing food records or low GI food checklists; blood glucose readings were recorded on these same monitoring forms. Participants returned these self-monitoring records to the study dietitian who reviewed the records and provided standardized feedback on their progress. The study dietitian remained blinded to treatment group throughout the monitoring period.

### 3.2.3 Measurements

Hemoglobin A\textsubscript{1C} and measures of weight control and dietary intake were assessed at baseline and study end. Measures of weight control were conducted according to methods described in the National Health and Nutrition Examination Survey III anthropometry manual\textsuperscript{112}. Height was measured using a wall-mounted stadiometer (Healthometer Professional Products, Bridgeview, IL) to the nearest 0.1 cm. Body weight was measured using a digital calibrated scale (Healthometer Professional Products, Bridgeview, IL) to the nearest 0.1 kg. Waist circumference was measured using a non-elastic tape to the nearest 0.1 cm. Body mass index (BMI) was calculated from the following formula: \( \text{BMI} = \text{weight (kg)} / \text{height (m}^2) \). A venous blood draw was obtained following an overnight fast to assess HbA\textsubscript{1C} through high pressure liquid chromatography ion-exchange assay. Physical activity was assessed using the Modifiable Physical
Activity Questionnaire. Participants provided a list of current medications at baseline, following goal assignment and at study end.

Participants were instructed to keep a 4-day food record at baseline and study end and were instructed to include 3 weekdays and 1 weekend day. The 4-day food records were entered into Nutrient Data Systems for Research (NDS-R, version 2008, Nutrition Coordinating Center, University of Minnesota, Minneapolis, MN) to assess nutrient intake, GI, GL, and number of low GI food servings consumed. Glycemic index and glycemic load values for the study are expressed relative to glucose (glucose = 100). Whole fruits, non-starchy vegetables, nuts and seeds, whole grain pasta and dairy foods accounted for foods included in the total low GI food serving calculation. These foods were selected as the majority of the foods included in these categories are considered low GI.

3.2.4 Statistical Analyses

Statistical analyses were completed using SAS JMP (version 8.0, 2008, SAS Institute, Cary, NC). All data are presented as mean ± standard deviation unless noted otherwise. Fisher’s exact test and two-sample t-tests were used to compare differences in baseline demographic characteristics, nutrient intake, food group servings, GI and GL. Wilcoxon sign-rank test was used to compare final measures of weight control, clinical and nutrient differences from zero. A $P$ value $< 0.05$ was considered statistically significant.
3.3 Results

Two hundred nine people inquired about the study (Figure 3.1). Of these, 184 were assessed for eligibility, 108 did not meet inclusion criteria, 30 refused to participate, and 46 were enrolled in the study. Eleven participants discontinued during the course of the study; 35 participants completed the intervention. Baseline characteristics of participants that completed the study are presented in Table 3.1. At baseline there were no statistically significant differences in any of the outcome measures between groups or between those who completed or did not complete the intervention. Medication types were similar between groups at baseline. Physical activity and medication changes were similar between groups during the course of the study.
Figure 3.1. Flow of participants
<table>
<thead>
<tr>
<th>Variable</th>
<th>6 Group (n=15)</th>
<th>8 Group (n=20)</th>
<th>P value&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>60.0</td>
<td>70.0</td>
<td>0.72</td>
</tr>
<tr>
<td>White</td>
<td>80.0</td>
<td>95.0</td>
<td>0.29</td>
</tr>
<tr>
<td>Married</td>
<td>53.3</td>
<td>70.0</td>
<td>0.48</td>
</tr>
<tr>
<td>Bachelor's degree or higher</td>
<td>60.0</td>
<td>50.0</td>
<td>0.73</td>
</tr>
<tr>
<td>Employed full-time</td>
<td>80.0</td>
<td>85.0</td>
<td>1.00</td>
</tr>
<tr>
<td>Income ≥ $60,000</td>
<td>60.0</td>
<td>60.0</td>
<td>1.00</td>
</tr>
<tr>
<td>Previous diabetes education</td>
<td>80.0</td>
<td>85.0</td>
<td>1.00</td>
</tr>
<tr>
<td>Self monitoring blood glucose</td>
<td>66.7</td>
<td>75.0</td>
<td>0.71</td>
</tr>
<tr>
<td>Medication Types</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>20.0</td>
<td>15.0</td>
<td>1.00</td>
</tr>
<tr>
<td>Sulfonylureas</td>
<td>40.0</td>
<td>40.0</td>
<td>1.00</td>
</tr>
<tr>
<td>Biguanides</td>
<td>60.0</td>
<td>55.0</td>
<td>1.00</td>
</tr>
<tr>
<td>Thiazolidinediones</td>
<td>20.0</td>
<td>15.0</td>
<td>1.00</td>
</tr>
<tr>
<td>DPP-4 Inhibitors</td>
<td>26.7</td>
<td>35.0</td>
<td>0.72</td>
</tr>
<tr>
<td>Incretin Memetics</td>
<td>13.3</td>
<td>25.0</td>
<td>0.67</td>
</tr>
<tr>
<td>Combination Therapy</td>
<td>6.7</td>
<td>20.0</td>
<td>0.36</td>
</tr>
<tr>
<td>Age (y)</td>
<td>49.6 ± 6.67</td>
<td>52.5 ± 5.94</td>
<td>0.19</td>
</tr>
<tr>
<td>Years diagnosed with diabetes</td>
<td>6.4 ± 5.18</td>
<td>5.8 ± 3.61</td>
<td>0.70</td>
</tr>
</tbody>
</table>

<sup>a</sup> Using Fisher's exact test, two-sample t-test of between group comparisons for age, years diagnosed with diabetes

Table 3.1. Demographic characteristics of adults with type 2 diabetes at baseline

There were no statistically significant differences in the nutrient profiles between groups at baseline or study end (Table 3.2). Participants in the 6 group had greater changes in total fat (p = 0.06), calcium (p = 0.05) and vitamin D (p = 0.02) compared to those in the 8 group. Statistically significant (all p<0.05) changes in energy, and nutrients related to an increase in fruit, vegetable, whole grain intake and an overall lower GI diet (i.e., increased fiber intake, decrease in added sugars) were noted in both groups. Statistically significant decreases for the 6 group (p<0.01) and 8 group (p<0.001) in GI and GL were noted at the end of the study.
Table 3.2. Nutrient profiles at baseline, study end, and change in adults with type 2 diabetes (mean ± standard deviation)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline</th>
<th>Study End</th>
<th>Changea</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>6 Group (n=15)</td>
<td>8 Group (n=20)</td>
<td>P valueb</td>
</tr>
<tr>
<td>Energy (kcal)</td>
<td>2170.7 ± 547.87</td>
<td>2275.5 ± 614.22</td>
<td>0.60</td>
</tr>
<tr>
<td>Carbohydrate (% of energy)</td>
<td>41.3 ± 8.69</td>
<td>42.55 ± 6.26</td>
<td>0.65</td>
</tr>
<tr>
<td>Protein (% of energy)</td>
<td>17.63 ± 5.11</td>
<td>17.64 ± 4.08</td>
<td>0.99</td>
</tr>
<tr>
<td>Total fat (% of energy)</td>
<td>40.85 ± 6.15</td>
<td>39.58 ± 4.74</td>
<td>0.51</td>
</tr>
<tr>
<td>Saturated fat (% of energy)</td>
<td>13.73 ± 1.89</td>
<td>13.41 ± 2.52</td>
<td>0.67</td>
</tr>
<tr>
<td>Cholesterol (mg/1,000 kcal)</td>
<td>170.88 ± 77.98</td>
<td>167.57 ± 83.11</td>
<td>0.90</td>
</tr>
<tr>
<td>Total fiber (g/1,000 kcal)</td>
<td>10.16 ± 4.42</td>
<td>9.65 ± 2.75</td>
<td>0.70</td>
</tr>
<tr>
<td>Insoluble fiber (g/1,000 kcal)</td>
<td>6.92 ± 3.60</td>
<td>6.36 ± 1.75</td>
<td>0.58</td>
</tr>
<tr>
<td>Soluble fiber (g/1,000 kcal)</td>
<td>3.16 ± 1.00</td>
<td>3.20 ± 1.32</td>
<td>0.91</td>
</tr>
<tr>
<td>Total sugars (g/1,000 kcal)</td>
<td>36.95 ± 14.73</td>
<td>40.00 ± 12.53</td>
<td>0.21</td>
</tr>
<tr>
<td>Added sugars (g/1,000 kcal)</td>
<td>19.52 ± 12.46</td>
<td>27.53 ± 12.92</td>
<td>0.07</td>
</tr>
<tr>
<td>Calcium (mg/1,000 kcal)</td>
<td>467.72 ± 263.36</td>
<td>420.41 ± 99.55</td>
<td>0.52</td>
</tr>
<tr>
<td>Vitamin C (mg/1,000 kcal)</td>
<td>48.92 ± 37.30</td>
<td>29.66 ± 16.57</td>
<td>0.08</td>
</tr>
<tr>
<td>Total folate (µg/1,000 kcal)</td>
<td>208.34 ± 77.00</td>
<td>196.99 ± 56.73</td>
<td>0.63</td>
</tr>
<tr>
<td>Vitamin D (calciferol, µg/1,000 kcal)</td>
<td>2.09 ± 1.84</td>
<td>2.23 ± 1.73</td>
<td>0.82</td>
</tr>
<tr>
<td>Beta carotene (µg/1,000 kcal)</td>
<td>2926.40 ± 633.77</td>
<td>1655.23 ± 1660.41</td>
<td>0.46</td>
</tr>
<tr>
<td>Magnesium (mg/1,000 kcal)</td>
<td>150.55 ± 48.82</td>
<td>135.14 ± 22.39</td>
<td>0.27</td>
</tr>
<tr>
<td>Carbohydrate (total grams)</td>
<td>226.70 ± 60.34</td>
<td>250.19 ± 81.57</td>
<td>0.33</td>
</tr>
<tr>
<td>Glycemic indexc</td>
<td>61.66 ± 14.19</td>
<td>61.11 ± 2.98</td>
<td>0.67</td>
</tr>
<tr>
<td>Glycemic loadd</td>
<td>127.82 ± 37.71</td>
<td>139.45 ± 45.89</td>
<td>0.42</td>
</tr>
</tbody>
</table>

a two participants excluded due to personal illness at study end
b two-sample t-test of between group comparisons
c calculated as Σ (ingredient available carbohydrate/total available carbohydrate for food) x ingredient GI; averaged over 4 days of intake
d calculated as Σ (ingredient available carbohydrate X ingredient GI) / 100; averaged over 4 days of intake
Significant change from baseline (* p<0.05; ** p<0.01; *** p<0.001)
There were no statistically significant differences in the number of food group servings consumed between groups at baseline or at the end of the study (Table 3.3). Statistically significant (all p<0.05) increases from baseline were noted in the 6 group or the 8 group for food servings related to a lower GI diet including whole fruit, green and yellow vegetables and reduced fat dairy products. Statistically significant reductions (all p<0.05) from baseline in potato and refined grain bread food servings, both high GI foods, were also noted in both treatment groups. Other notable changes from baseline included reductions in regular fat meat, poultry and fish, whole fat dairy products and animal fat food servings in either the 6 group or the 8 group.

There were no significant differences between groups in measures of weight control or clinical measurements at baseline or study end (Table 3.4). Significant changes from baseline in weight and BMI in females and waist circumference in males were noted in the 6 group (all p<0.05), and a significant change in HbA1C (p<0.05) was noted in the 8 group.
<table>
<thead>
<tr>
<th>Food Group</th>
<th>Baseline Mean ± SD</th>
<th>Study End Mean ± SD</th>
<th>Change Mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Low GI food servings</strong></td>
<td>6.76 ± 4.39  6.53 ± 2.79  0.86</td>
<td>8.31 ± 4.03  8.45 ± 3.56  0.92</td>
<td>1.73 ± 3.17*  1.85 ± 3.04*  0.92</td>
</tr>
<tr>
<td><strong>Fruits</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fruit juice (100% juice and frozen concentrate)</td>
<td>0.29 ± 0.35  0.33 ± 0.64  0.80</td>
<td>0.15 ± 0.36  0.21 ± 0.39  0.64</td>
<td>-0.16 ± 0.40  -0.14 ± 0.67  0.91</td>
</tr>
<tr>
<td>Whole fruit (fresh, frozen, cooked/canned, dried)†</td>
<td>0.77 ± 0.87  0.96 ± 1.11  0.57</td>
<td>1.52 ± 1.34  1.73 ± 0.85  0.62</td>
<td>0.70 ± 1.16*  0.77 ± 1.05**  0.87</td>
</tr>
<tr>
<td><strong>Vegetables</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Green/yellow vegetables (eg, broccoli, carrots, sweet potato)†</td>
<td>0.74 ± 0.79  0.78 ± 0.72  0.87</td>
<td>1.15 ± 0.57  1.20 ± 1.00  0.85</td>
<td>0.50 ± 0.73*  0.47 ± 1.08  0.92</td>
</tr>
<tr>
<td>Tomato (includes raw, sauce, paste, salsa)†</td>
<td>0.66 ± 0.57  0.46 ± 0.40  0.27</td>
<td>0.40 ± 0.54  0.49 ± 0.41  0.98</td>
<td>-0.15 ± 0.77  0.02 ± 0.66  0.51</td>
</tr>
<tr>
<td>Potatoes (all white, including fried)</td>
<td>0.72 ± 0.49  0.45 ± 0.41  0.09</td>
<td>0.18 ± 0.38  0.32 ± 0.45  0.37</td>
<td>-0.54 ± 0.51**  -0.15 ± 0.61  0.05</td>
</tr>
<tr>
<td>Legumes (cooked, dried beans)†</td>
<td>0.17 ± 0.22  0.18 ± 0.28  0.93</td>
<td>0.33 ± 0.41  0.18 ± 0.42  0.32</td>
<td>0.15 ± 0.46  -0.01 ± 0.35  0.31</td>
</tr>
<tr>
<td>Other vegetables (eg corn, sprouts, peas, beets, cabbage, summer squash)†</td>
<td>1.45 ± 1.23  1.23 ± 0.96  0.57</td>
<td>1.19 ± 0.73  1.36 ± 0.70  0.51</td>
<td>-0.20 ± 1.55  0.12 ± 1.11  0.52</td>
</tr>
<tr>
<td>Vegetable juice†</td>
<td>0.22 ± 0.63  0.00 ± 0.00  0.19</td>
<td>0.12 ± 0.40  0.08 ± 0.26  0.78</td>
<td>0.04 ± 0.10  0.08 ± 0.26  0.48</td>
</tr>
<tr>
<td><strong>Meat</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Meat, fish, poultry - regular fat</td>
<td>3.40 ± 1.98  3.75 ± 1.84  0.60</td>
<td>2.51 ± 1.79  2.44 ± 1.78  0.91</td>
<td>-1.06 ± 2.20  -1.34 ± 2.00*  0.72</td>
</tr>
<tr>
<td>Meat, fish, poultry - lean</td>
<td>2.10 ± 1.46  1.88 ± 1.78  0.68</td>
<td>1.97 ± 2.30  1.71 ± 1.75  0.73</td>
<td>-0.26 ± 1.90  -0.17 ± 1.40  0.89</td>
</tr>
<tr>
<td>Eggs</td>
<td>0.63 ± 0.50  0.61 ± 0.54  0.90</td>
<td>0.44 ± 0.76  0.63 ± 0.61  0.46</td>
<td>-0.23 ± 0.61*  0.01 ± 0.53  0.24</td>
</tr>
<tr>
<td>Nuts, seeds and butters†</td>
<td>1.02 ± 3.01  1.12 ± 1.59  0.91</td>
<td>1.24 ± 2.62  1.80 ± 1.85  0.50</td>
<td>0.15 ± 1.27  0.62 ± 1.77  0.38</td>
</tr>
</tbody>
</table>

Table 3.3. Food group servings at baseline, study end and change in adults with type 2 diabetes (mean ± standard deviation)
### Table 3.3 continued

#### Grains

<table>
<thead>
<tr>
<th>Description</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole grains, flour and dry mixes (eg, brown rice, cracked wheat, oatmeal, whole grain meals and flour)</td>
<td>0.19 ± 0.34 0.30 ± 0.58 0.48 0.29 ± 0.41 0.61 ± 0.84 0.15 0.08 ± 0.39 0.30 ± 0.62 0.24</td>
</tr>
<tr>
<td>Partial whole grains, flour and dry mixes (eg, oat bran, rice bran, wheat germ)</td>
<td>0.00 ± 0.00 0.01 ± 0.05 0.37 0.02 ± 0.06 0.03 ± 0.14 0.67 0.02 ± 0.06 0.02 ± 0.86 0.87</td>
</tr>
<tr>
<td>Refined grains, flour and dry mixes (eg, corn meal, pearl barley, flours, white rice)</td>
<td>1.53 ± 1.42 1.49 ± 1.53 0.34 1.14 ± 1.27 1.26 ± 1.69 0.82 -0.39 ± 2.05 -0.26 ± 2.43 0.87</td>
</tr>
<tr>
<td>Whole-grain breads (eg, loaf, rolls, quick breads)</td>
<td>0.29 ± 0.37 0.19 ± 0.35 0.41 0.35 ± 0.65 0.33 ± 0.47 0.94 0.03 ± 0.62 0.13 ± 0.63 0.64</td>
</tr>
<tr>
<td>Partial whole-grain breads (eg, oatmeal, multigrain bread)</td>
<td>0.27 ± 0.64 0.69 ± 1.02 0.14 0.69 ± 0.91 0.94 ± 1.18 0.49 0.41 ± 1.21 0.22 ± 1.37 0.68</td>
</tr>
<tr>
<td>Refined bread (eg, white bread, flour tortilla)</td>
<td>2.67 ± 1.62 2.71 ± 1.51 0.94 1.53 ± 1.52 0.91 ± 0.61 0.17 -1.30 ± 1.59* -1.81 ± 1.53*** 0.35</td>
</tr>
<tr>
<td>Whole-grain cereals</td>
<td>0.16 ± 0.33 0.31 ± 0.32 0.22 0.06 ± 0.14 0.21 ± 0.39 0.13 -0.06 ± 0.22 -0.10 ± 0.36 0.68</td>
</tr>
<tr>
<td>Partial whole-grain cereals</td>
<td>0.00 ± 0.00 0.11 ± 0.35 0.16 0.00 ± 0.00 0.02 ± 0.08 0.33 0.00 ± 0.00 -0.10 ± 0.35 0.22</td>
</tr>
<tr>
<td>Whole grain pasta†</td>
<td>0.40 ± 0.60 0.38 ± 0.51 0.92 0.38 ± 0.51 0.42 ± 0.66 0.87 -0.04 ± 0.67 0.02 ± 0.87 0.82</td>
</tr>
</tbody>
</table>

#### Dairy

<table>
<thead>
<tr>
<th>Description</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milk, cheese, yogurt - whole fat†</td>
<td>0.64 ± 0.59 0.78 ± 0.76 0.55 0.42 ± 0.45 0.43 ± 0.40 0.95 -0.27 ± 0.47 -0.37 ± 0.63* 0.61</td>
</tr>
<tr>
<td>Milk, cheese, yogurt - reduced fat†</td>
<td>0.46 ± 0.43 0.48 ± 0.46 0.89 0.97 ± 1.01 0.69 ± 0.58 0.37 0.58 ± 0.92* 0.21 ± 0.51 0.18</td>
</tr>
<tr>
<td>Milk, cheese, yogurt - non-fat†</td>
<td>0.62 ± 1.76 0.47 ± 0.77 0.78 0.74 ± 1.50 0.38 ± 0.66 0.40 0.09 ± 0.06 -0.11 ± 0.46 0.50</td>
</tr>
<tr>
<td>Frozen dairy desserts</td>
<td>0.09 ± 0.02 0.12 ± 0.31 0.77 0.16 ± 0.27 0.22 ± 0.38 0.60 0.06 ± 0.21 0.09 ± 0.37 0.75</td>
</tr>
<tr>
<td>Artificially-sweetened pudding†</td>
<td>0.00 ± 0.00 0.03 ± 0.09 0.08 0.01 ± 0.02 0.02 ± 0.05 0.45 0.01 ± 0.02 -0.01 ± 0.09 0.36</td>
</tr>
</tbody>
</table>

#### Fat

<table>
<thead>
<tr>
<th>Description</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Animal fat (butter, shortening, cream)</td>
<td>1.45 ± 1.54 1.10 ± 1.07 0.46 0.51 ± 0.57 0.62 ± 1.01 0.68 -0.92 ± 1.39** -0.51 ± 1.16* 0.38</td>
</tr>
<tr>
<td>Vegetable fat (margarine, oil, salad dressing)</td>
<td>3.12 ± 1.98 3.15 ± 1.53 0.79 2.10 ± 1.90 2.63 ± 1.67 0.41 -1.33 ± 2.30 -0.55 ± 1.69 0.29</td>
</tr>
</tbody>
</table>

#### Sweets

<table>
<thead>
<tr>
<th>Description</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sugar</td>
<td>0.09 ± 0.18 0.44 ± 0.73 0.05 0.27 ± 0.35 0.30 ± 0.50 0.86 0.17 ± 0.37 -0.17 ± 0.86 0.14</td>
</tr>
<tr>
<td>Chocolate candy</td>
<td>0.20 ± 0.65 0.28 ± 0.49 0.69 0.02 ± 0.08 0.12 ± 0.26 0.15 -0.19 ± 0.69 -0.16 ± 0.37 0.89</td>
</tr>
</tbody>
</table>

#### Beverages

<table>
<thead>
<tr>
<th>Description</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sugar-sweetened beverages</td>
<td>0.24 ± 0.60 0.52 ± 0.92 0.34 0.12 ± 0.30 0.23 ± 0.48 0.40 -0.14 ± 0.40 -0.32 ± 0.83 0.43</td>
</tr>
<tr>
<td>Artificially-sweetened beverages</td>
<td>0.96 ± 1.27 1.76 ± 1.97 0.15 0.81 ± 1.70 0.42 ± 1.20 0.47 -0.21 ± 1.88 -1.42 ± 1.90** 0.08</td>
</tr>
<tr>
<td>Unsweetened beverages</td>
<td>3.72 ± 4.10 2.9 ± 2.85 0.51 1.08 ± 1.43 1.12 ± 1.81 0.94 -2.11 ± 3.66* -1.56 ± 2.33*** 0.63</td>
</tr>
</tbody>
</table>

#### Miscellaneous

<table>
<thead>
<tr>
<th>Description</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sauces and condiments</td>
<td>0.63 ± 0.48 0.93 ± 1.06 0.26 0.73 ± 1.01 0.44 ± 0.54 0.34 0.06 ± 1.24 -0.51 ± 1.09 0.18</td>
</tr>
</tbody>
</table>

† two people were excluded from final analysis due to personal illness

‡ two sample t-test of between group comparisons

Significant change from baseline (* p<0.05; ** p<0.01; *** p<0.001)

† included in summary of total low GI food servings
Table 3.4. Weight control and clinical measurements at baseline, study end and change in adults with type 2 diabetes (mean ± standard deviation)
3.4 Discussion

This research is unique as it is the first reported in the literature to set a goal for consuming a specific number of low GI foods for improvement of diabetes-related outcomes. Though goal setting theory has been successfully implemented to improve workplace performance and to increase physical activity, it remains underutilized for modifying nutrition-related behaviors, with only a few studies evaluating its effectiveness. This pilot study provides new information for recommending a daily number of low GI food servings for patients with type 2 diabetes.

The impact of GI and its overarching association with chronic disease risk has been demonstrated. In a meta analysis evaluating the association of GI with risk of chronic disease, the median value for those in the highest GI quantile was 58, while those in the lowest GI quantile had a median value of 49. In the GOAL study, mean glycemic index at baseline was approximately 61 – several percentage points higher than those at greatest risk for disease in the aforementioned analysis. From these studies, we estimated that substituting 6 or 8 low GI foods for high GI foods would result in a mean daily GI of approximately 55. Participants in both groups achieved an overall mean daily glycemic index value of approximately 55, a value with lower risk of chronic disease. As blood glucose control plays an essential role in the prevention of chronic disease.

Notable changes in food patterns for these participants included increases in whole fruits, green and yellow vegetables, and reduced fat dairy products, while decreasing intake of potatoes, refined grain breads, regular fat meats, poultry and fish, animal fat and vegetable fat. Similar to the large scale 5-a-day campaign to increase fruit
and vegetable intake in US adults, participants in the GOAL study were able to increase their whole fruit or vegetable intake by approximately 1/3 to 3/4 servings per day. Increasing fruit and vegetable consumption remains a challenge and has been the focus of many public health campaigns. The results from this study lend support not only to the importance of education about the benefits of fruit and vegetable consumption, but also the necessity of setting a specific, achievable goal to provide a means of measuring success.

Changes in the intake of whole grain foods were not included in the overall summary of low GI foods. Though these products are generally lower GI than the refined grain products available today, many whole grain products sold in the US have a GI value >55. While emphasizing a change from refined grain products to whole grain products is critical, manufactures have the continued challenge of producing lower GI, whole grain foods that will help attenuate fluctuations in blood glucose levels.

Weight loss and concomitant reductions in waist circumference were not a primary focus of the GOAL study and varied among participants. However, many that lost weight commented that emphasizing blood glucose control shifted their focus away from a preoccupation with weight loss and more towards making better overall food choices. Calorie and carbohydrate counting in addition to blood glucose and medication monitoring can be overwhelming for individuals with type 2 diabetes. In several studies, lower GI diets have been shown to promote weight loss. Though anecdotal, the comments from these participants suggest that by redirecting diabetes education to focus on consuming a lower GI diet, individuals may feel empowered by the tangible changes in blood glucose levels while less defeated by the challenges of weight loss.
Decreases in HbA_1C were noted in both groups at the end of the study, though greater changes were noted in the 8 group. In a recent review, reductions in HbA_1C by 0.5% were noted for individuals consuming a lower GI or GL diet compared to those consuming a higher GI or GL diet, similar to the results noted in the GOAL study. Though small, these reductions are clinically relevant as complications resulting from type 2 diabetes are reduced approximately 30% for every 1% reduction in HbA_1C.

In this study, goal setting was an effective tool to help participants improve blood glucose control. However, the challenge of consuming 6 or 8 servings of low GI foods each day varied depending on individual energy needs. For a participant with greater energy needs, consuming 6 or 8 servings of low GI foods each day may be easy. Participants with lower energy needs may find that consuming 6 or 8 low GI food servings per day more challenging. Future research should focus on determining appropriate energy intakes and on tailoring a low GI serving goal to reflect individual needs.

This study had several limitations. The demographic makeup of the patient population included primarily white, educated individuals, reducing the generalizability of our results. Food habits vary greatly and are influenced by cultural, social and economic circumstances. Future research should focus on implementing goal setting for type 2 diabetes management in groups with lower socioeconomic status and in minority groups, who are at greater risk of complications from this disease. Secondly, out of 46 participants enrolled, 11 (24%) withdrew during the course of the study, resulting in a smaller sample size. A larger sample size is likely needed to detect a significant difference between groups in outcomes. Notably, participants that withdrew from the
study were in poorer glycemic control (HbA1C 9.5% ± 1.96) compared to those that completed the study (HbA1C 8.8% ± 1.65). Recent reviews of dietary and diabetes self-management interventions have noted similar attrition rates in studies 6 months or longer in duration, which places a higher burden on participants than short-term or feeding studies. The poor glycemic control noted for those that withdrew from the study further emphasizes that dietary management of type 2 diabetes is challenging and continued effort is needed in developing effective programs.

In summary, glycemic control is critical for optimal health in individuals with type 2 diabetes. Consuming a lower GI diet emphasizing fruits, vegetables, reduced fat dairy foods and high fiber whole grain products can contribute to more ideal blood glucose and weight control, and current standards of care for diabetes management suggest that incorporating low GI foods may provide further benefits in addition to reducing overall carbohydrate intake. Providing individuals with type 2 diabetes a concrete goal to consume a specific number of low GI food servings each day may be an alternative, potentially easier method for dietary management of this disease.
CHAPTER 4

Implementation of Goal Setting Theory as a Model for Dietary Behavior Change in Adults with Type 2 Diabetes

4.1 Introduction

The glycemic index (GI) of foods has received attention regarding its role in the dietary management of type 2 diabetes. A recent meta analysis evaluating the association of GI with risk of numerous chronic diseases showed that lower GI diets were associated with decreased risk of type 2 diabetes, cardiovascular disease, stroke and numerous cancer types.\textsuperscript{12} The glycemic index is a scale that categorizes carbohydrate containing foods according to postprandial blood glucose excursions.\textsuperscript{11} Related to the GI value of foods is the glycemic load (GL), a scale that accounts for the glycemic response of foods while considering both the quality and the quantity of carbohydrate consumed. Diets emphasizing foods with low GI values (<56) result in attenuated blood glucose and insulin levels, both important factors for improved outcomes related to type 2 diabetes. Though lower GI diets are associated with improved outcomes related to type 2 diabetes, there are no studies incorporating goal setting theory as a model to help people with this disease implement a lower GI diet.
Goal setting is a strategy frequently used to promote behavior change. However, critical constructs from this model are often not implemented to successfully achieve change. Goal setting theory as a model offers a framework to understand how goals are achieved and which constructs to target for behavior change. Goal setting theory suggests that behavior change occurs when a goal is specific and relatively difficult, when self-efficacy and commitment toward a goal increase, and when achievement of a goal results in increased satisfaction toward behavior change. In the clinical setting, ambiguous goals are often set and exasperation may occur as the goal is not adequately specific or may be too difficult. Goal difficulty is an important characteristic that helps determine how an individual will respond to a goal. According to the model, if a goal is too easy and a person is already achieving the goal, there is no room for improvement and they will abandon the goal. Maximum self-efficacy, commitment and satisfaction with this goal have already been achieved. However, if a goal is too difficult, a person will likewise abandon the goal as they will fail to build self-efficacy and have feelings of defeat. Thus, appropriately difficult, achievable goals are critical to define as they play an important role in moving an individual toward behavior change.

A lower GI diet in combination with goal setting theory offers a new method for improving outcomes related to type 2 diabetes. Thus, the purpose of this study was to evaluate if a specific, more difficult goal to increase consumption of low GI foods would result in a lower GI diet, and greater improvements in self-efficacy, commitment and satisfaction compared to an easier, specific goal.
4.2 Method

4.2.1 Participants

Eligible participants recruited to the study were 40-65 years old, diagnosed with type 2 diabetes for ≥1 year, had an HbA1C value ≥ 7%, and were not on insulin therapy for type 2 diabetes management. A score of 30 or greater on the Mini-Mental Status examination was required to participate in the study. Participants were recruited from May, 2008 through February, 2009 through newspaper and electronic classified advertisements, employee newsletters, health fairs, medical practices, neighborhood health centers and posted flyers. The study was conducted in a Midwestern metropolitan area. All study methods were approved by the Institutional Review Board at The Ohio State University (OSU) and participants provided written informed consent.

4.2.2 Research Design

The GOAL study was a randomized controlled trial where participants were randomized to either a group with a more difficult dietary goal or an easier dietary goal. The study dietitian was blinded to goal assignment.

Following recruitment, participants completed baseline assessment. Participants then completed a 5-week group nutrition education intervention. After the intervention, participants met with a dietitian from the OSU Clinical Research Center (CRC) for randomization to their assigned treatment group. Following randomization, participants completed approximately 8 weeks of dietary and blood glucose self-monitoring. Midway through the self-monitoring period, participants again met with the CRC dietitian to
assess their progress followed by final data collection 4 weeks later. A timeline of study events is depicted in Figure 4.1.

![Figure 4.1. Research study timeline](image)

### 4.2.3 The Nutrition Intervention

The nutrition intervention for the GOAL study implemented principles of goal setting theory to promote behavior change. Dietary behavior change can occur following self-assessment and with the development of a discrepancy between an individual’s current and desired dietary behaviors. Once this discrepancy is developed, a goal can be set to move an individual toward their desired dietary behavior change. Goals can be assigned by a healthcare provider, self-set or set collaboratively and must be specific, measurable and relatively difficult. Goal setting theory postulates that specific, more difficult goals will result in a greater change in behavior than specific, easier goals. Figure 2.1 illustrates the model adapted from goal setting theory implemented in this study.

Once a specific, relatively difficult goal has been set, there are several constructs that offer venues for the promotion of dietary change. In the present study, goal difficulty, goal commitment, self-efficacy and goal satisfaction were targeted as main
constructs for achieving dietary change. The mediating constructs of commitment and self-efficacy are critical for goal setting theory to function effectively. Mediating variables act as a link between the beginning and final constructs in goal setting theory; without these variables the theory is rendered defunct. Commitment measures the level of obligation an individual has toward achieving a goal, and should increase over time. Self-efficacy describes the level of confidence an individual has toward completing a behavior in a specific situation and is built through enactive mastery, vicarious experience, verbal persuasion and change in physiological or affective states. Most importantly, the threshold of goal difficulty is vital as more difficult, yet achievable goals can improve performance. A goal cannot be too difficult or an individual will experience repeated defeat, experience lower efficacy beliefs and reduced commitment to the goal.

The level of goal difficulty and changes in commitment and self-efficacy work in concert to affect behavior change. In the present study, increasing the number of servings of low GI foods consumed each day was the desired behavior. Performance monitoring through food records and low GI food checklists helped individuals recognize if they achieved their goal. Furthermore, increasing the number of servings of low GI foods consumed each day should result in improved weight control, desirable in the management of type 2 diabetes. When an individual monitors their performance related to their goal, they should feel satisfied or dissatisfied with their actions. Overall satisfaction with performance feeds back to the initial constructs of self-assessment and goal setting. Reassessment will occur and if an individual is satisfied with their performance, goal setting theory posits that a slightly more difficult goal will be set and the cycle of changing behavior continues.
The nutrition intervention in this study was conducted by the same dietitian and included five weekly group educational sessions. Each education session was approximately 1.5 hours long and each group was comprised of approximately 10 participants; friends or family members were also invited to join the education sessions for social support. The weekly sessions addressed current guidelines for optimal blood glucose control, diet and blood glucose self-monitoring, portion control, GI as a means of selecting foods for blood glucose control, factors influencing the GI value of foods, and approaches for maintaining behavior change. The association between the amount and type of carbohydrate consumed and resulting blood glucose and health outcomes was addressed to help participants understand the importance of adopting a lower GI diet. Participants were asked to complete food and blood glucose self-monitoring records at least 4 days/week during the course of the educational sessions.

Self-efficacy is an important construct of goal setting theory and can be developed through four primary methods: enactive mastery, vicarious experience, verbal persuasion and physiological or affective states. During the educational sessions, activities were incorporated using the aforementioned methods to build participant self-efficacy for choosing lower GI foods. For example, weighing and measuring food portions and recipe modification activities addressed enactive mastery. Participants sharing life experiences and their strategies for dealing with diabetes addressed vicarious experiences. The study dietitian offered helpful suggestions and words of encouragement to participants to address verbal persuasion. By self-monitoring blood glucose participants could understand how the food choices they made affected overall glycemic control. This activity addressed physiological and affective states.
Following the educational sessions, participants were randomized to either a more difficult goal to consume 8 servings/day of low GI foods (i.e., foods with a GI value < 56), the ‘8’ group, or an easier goal to consume 6 servings/day of low GI foods, the ‘6’ group. These serving goals were chosen as it was estimated that consuming between 6 and 8 servings of low GI foods/day would reduce the overall mean daily GI value to ~55 in an average individual. Based on the results from previous epidemiologic studies, individuals with mean daily GI values of ~55 were at lower risk of chronic disease compared to those with mean daily GI values >55. One serving of a low GI food was defined as the amount of food customarily consumed per eating occasion, commonly noted as “serving size” on the Nutrition Facts Panel. This definition of serving size was selected to concur with serving size as taught during the educational lessons. Randomization assignments were generated for each intervention group by a computerized random number generator program and were provided to the study participants by a dietitian at the OSU Clinical Research Center (CRC). During this study visit, the dietitian helped participants target changes specific to their diets to meet their low GI serving goal.

Participants implemented their goal for approximately 8 weeks, during which they were requested to self-monitor their dietary intake and blood glucose at least 4 days/week and record their weekly satisfaction with their goal. Dietary intake was monitored by completing food records or low GI food checklists; blood glucose readings were recorded on these same monitoring forms. Participants returned these self-monitoring records to the study dietitian who reviewed the records and provided standardized feedback on their progress. Standardized feedback included encouraging statements such as, “Superb!
You met your GI goal every day this week. Keep up the good work for several weeks to make these changes permanent” and “You are working very hard! Diet change is not easy, so keep up the good work. Stay focused on the health benefits that will come from changing the GI of your diet”.

### 4.2.4 Measures

Psychosocial measures were assessed at four timepoints throughout the study: at baseline, following the nutrition intervention, following goal assignment and at the end of the study. Figure 4.1 illustrates when measures of interest were assessed. Self-efficacy for consuming a low GI diet was assessed at all timepoints to evaluate the change that occurred following the intervention, and the change that occurred between receiving their goal and the end of the study. Commitment, difficulty and satisfaction for the goal assigned were assessed following goal assignment and at the end of the study as participants did not know their goal at baseline or immediately following the nutrition intervention. In addition to the assigned goal, participants also recorded a personal goal for behavior change. Commitment level and difficulty regarding their personal goal were assessed at baseline and at the end of the study.

A previously validated questionnaire was used to measure self-efficacy for consuming low-GI foods. This questionnaire was comprised of 17 items and participants were asked to rate their confidence (0 = strongly disagree, 10 = strongly agree) for behaviors related to a low GI diet. This questionnaire was comprised of 3 subscales: the GI efficacy subscale included 6 items evaluating confidence for choosing and preparing low GI foods in specific situations; the goal difficulty subscale included 8 items
evaluating confidence for consuming specific numbers of low GI foods; the negative food selection subscale included 3 items evaluating inability to choose low GI foods in specific situations. Negatively stated items were reverse scored for this scale. Coefficient H values in the previous validation study were $\geq 0.80$, and all coefficient $\alpha$ values were $\geq 0.78$.\textsuperscript{120} Goal satisfaction was measured using a 1-item questionnaire where participants were asked to rank their level of satisfaction with their goal (0 = great deal of dissatisfaction, 8 = great deal of satisfaction). Similar scales have been used to assess goal satisfaction in other goal-setting studies.\textsuperscript{121} Goal commitment was measured using a 7-item questionnaire where participants responded to questions assessing how committed they were to achieving their goal. The questionnaire included both positively and negatively stated items and was scored so that higher scores indicated greater commitment. The items contained in this questionnaire were developed and validated by Hollenbeck and colleagues.\textsuperscript{122} Coefficient $\alpha$ values for this scale were 0.80. Goal difficulty was assessed using a 1-item questionnaire, where participants indicated how easy or difficult (0 = very easy, 8 = very difficult) they believed it would be to reach their goal. Similar scales have been used in other studies to assess goal difficulty.\textsuperscript{121,123}

Participants were instructed to keep a 4-day food record at baseline and study end (3 weekdays and 1 weekend day). These food records were entered into Nutrient Data Systems for Research (NDS-R, version 2008, Nutrition Coordinating Center, University of Minnesota, Minneapolis, MN) to assess nutrient intake, GI, GL, and food servings consumed. Glycemic index and glycemic load values for the study are expressed relative to glucose (glucose = 100). Physical activity was assessed using the Modiﬁable Physical Activity Questionnaire.\textsuperscript{113}
4.3 Statistical Methods

Statistical analyses were completed using SAS JMP (version 8.0, 2008, SAS Institute, Cary, NC). Fisher’s exact test was used to compare differences in baseline demographic characteristics, and two-sample t-tests were used to compare between group differences at baseline, final and changes for age, years diagnosed with diabetes, food group servings and psychosocial data. Wilcoxon sign-rank test was used to compare within group changes for final food group serving and psychosocial data. Repeated measures analysis of variance was used to evaluate between and within group differences in self-efficacy across time. Subjects were nested within groups and were treated as random effects. Correlation analyses were completed to explore the relationship between goal commitment and goal difficulty.

Because commitment can potentially act as a mediator in goal setting theory, participants were also grouped by level of goal commitment. Participants scoring greater than the median commitment score of 4.14 at the end of the study were grouped in the higher commitment group, and participants scoring ≤4.14 were grouped in the lower commitment group. Between group changes in nutrient and food group serving data, assigned goal satisfaction, assigned goal difficulty, and self-efficacy were analyzed by a two sample t-test. Wilcoxon sign-rank test was used to test within group change for the aforementioned outcome measures. A $P$ value $< 0.05$ was considered statistically significant for all analyses.
4.4 Results

Two hundred nine people inquired about the study. Of these, 184 were assessed for eligibility, 108 did not meet inclusion criteria, 30 refused to participate, and 46 were enrolled in the study. Eleven participants discontinued during the course of the study; 35 participants completed the intervention. Baseline characteristics of participants that completed the study are presented in Table 3.1. At baseline there were no statistically significant differences in any of the outcome measures between groups or between those who completed or did not complete the intervention. Medication types were similar between groups at baseline. Physical activity and medication changes were similar between groups during the course of the study.

There were no significant differences between groups for food group servings consumed at baseline or study end (Table 3.3). Significant (all p<0.05) increases were noted in the 6 group and the 8 group for nutrients and food servings related to a lower GI diet, including whole fruit, green and yellow vegetables and reduced fat dairy products. Significant reductions (all p<0.05) from baseline in potato and refined grain bread servings, both high GI foods, were also noted in both treatment groups. Both the 6 and the 8 serving groups achieved a significant reduction in dietary GI and GL (data not shown).

There were no statistically significant differences in self-efficacy and subscales, assigned goal commitment, assigned goal difficulty or assigned goal satisfaction between groups at baseline or following the intervention. (Table 4.1) Repeated measures ANOVA revealed that for both groups, self-efficacy significantly increased following the nutrition intervention and remained high for the remainder of the study (Table 4.2). Following
goal assignment, participants in the 6 group were slightly more satisfied with their goal compared to participants in the 8 group (p = 0.06). At the end of the study, participants in the 6 group were more committed to their assigned and personal goals and thought they were easier compared to participants in the 8 group (p = 0.08 for personal goal; all p<0.05 for assigned goal). Significant within group increases were noted for both groups for self-efficacy (total and all subscales), while a significant decrease in assigned goal commitment was noted within the 8 group (all p<0.05).
<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline</th>
<th>Post-Intervention</th>
<th>Post-Goal Assignment</th>
<th>Study End</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>6 Group</td>
<td>8 Group</td>
<td>6 Group</td>
<td>8 Group</td>
<td>6 Group</td>
</tr>
<tr>
<td></td>
<td>(n = 17)</td>
<td>(n = 20)</td>
<td>(n = 15)</td>
<td>(n = 21)</td>
<td>(n = 15)</td>
</tr>
<tr>
<td>Self Efficacy</td>
<td>6.94 ± 2.02 7.08 ± 1.86 0.83</td>
<td>8.58 ± 1.14 8.38 ± 1.11 0.57</td>
<td>9.31 ± 0.72 9.12 ± 0.80 0.46</td>
<td>9.29 ± 0.99 9.23 ± 0.64 0.98</td>
<td>2.46 ± 2.48** 2.15 ± 1.94*** 0.69</td>
</tr>
<tr>
<td>GI Efficacy Subscale</td>
<td>6.40 ± 2.69 6.70 ± 1.90 0.70</td>
<td>8.54 ± 1.23 8.26 ± 1.13 0.47</td>
<td>8.98 ± 0.96 8.74 ± 1.07 0.48</td>
<td>9.21 ± 0.82 8.97 ± 0.80 0.39</td>
<td>3.01 ± 3.11** 2.27 ± 2.06*** 0.44</td>
</tr>
<tr>
<td>Goal Difficulty Subscale</td>
<td>6.03 ± 2.23 7.00 ± 2.59 0.85</td>
<td>8.54 ± 1.37 8.30 ± 1.50 0.60</td>
<td>9.55 ± 0.69 9.43 ± 0.87 0.65</td>
<td>9.27 ± 0.26 9.46 ± 0.81 0.62</td>
<td>2.45 ± 2.69** 2.30 ± 2.99** 0.88</td>
</tr>
<tr>
<td>Negative Food Selection Subscale</td>
<td>8.04 ± 1.48 7.83 ± 2.14 0.73</td>
<td>8.76 ± 1.58 8.87 ± 1.58 0.82</td>
<td>9.26 ± 1.41 9.08 ± 1.27 0.70</td>
<td>9.51 ± 1.01 9.48 ± 0.76 0.85</td>
<td>1.40 ± 2.08* 1.52 ± 2.18** 0.87</td>
</tr>
<tr>
<td>Assigned Goal Commitmentf</td>
<td>4.64 ± 0.41 4.44 ± 0.58 0.25</td>
<td>4.50 ± 0.46 4.09 ± 0.67 0.04</td>
<td>4.50 ± 0.46 4.09 ± 0.67 0.04</td>
<td>-0.13 ± 0.41 -0.36 ± 0.55* 0.18</td>
<td></td>
</tr>
<tr>
<td>Assigned Goal Difficultyf</td>
<td>2.27 ± 2.02 3.40 ± 2.56 0.15</td>
<td>1.33 ± 1.54 3.80 ± 2.42 0.0009</td>
<td>1.33 ± 1.54 3.80 ± 2.42 0.0009</td>
<td>-0.93 ± 2.63 -0.40 ± 3.33 0.13</td>
<td></td>
</tr>
<tr>
<td>Assigned Goal Satisfactionf</td>
<td>7.53 ± 0.74 6.73 ± 1.55 0.06</td>
<td>6.47 ± 2.36 6.80 ± 1.51 0.63</td>
<td>6.47 ± 2.36 6.80 ± 1.51 0.63</td>
<td>-1.07 ± 2.31 0.05 ± 0.89 0.09</td>
<td></td>
</tr>
<tr>
<td>Personal Goal Commitmentf</td>
<td>4.29 ± 0.52 4.08 ± 0.51 0.23</td>
<td>4.61 ± 0.43 4.33 ± 0.50 0.08</td>
<td>4.61 ± 0.43 4.33 ± 0.50 0.08</td>
<td>0.31 ± 0.67 0.25 ± 0.60 0.78</td>
<td></td>
</tr>
<tr>
<td>Personal Goal Difficultyf</td>
<td>5.20 ± 2.08 5.42 ± 1.58 0.73</td>
<td>3.43 ± 1.78 4.35 ± 1.36* 0.08</td>
<td>3.43 ± 1.78 4.35 ± 1.36* 0.08</td>
<td>-1.57 ± 3.03 -0.48 ± 2.18* 0.47</td>
<td></td>
</tr>
</tbody>
</table>

1 two participants excluded due to extreme values
2 two-sample t-test of between group comparisons
3 one participant excluded due to extreme value
4 one participant did not complete instrument
5 two participants did not complete the study
6 6 Group (n = 15); 8 Group (n = 20)

Significant change from baseline (*p<0.05; **p<0.01; ***p<0.001)

Table 4.1. Outcomes related to goal setting at each assessment (mean ± standard deviation)
Table 4.2. Self-efficacy for GI-related activities across the course of the study (mean ± standard error)

Negative correlations between both personal and assigned goal difficulty and commitment for both groups were noted at baseline, following goal assignment and at study end (Table 4.3). To evaluate if the level of goal commitment may have influenced outcomes, participants were grouped by lower or higher levels of goal commitment.

Table 4.3. Correlations between commitment and difficulty for personal goal and assigned goal
Participants with higher goal commitment levels had greater changes in energy, % energy from protein, and glycemic load (all $p \leq 0.05$) compared to participants with lower goal commitment levels. Significant reductions glycemic index were noted for both groups (Table 4.4).

<table>
<thead>
<tr>
<th>Variable</th>
<th>Change</th>
<th>Lower Commitment (n = 18)$^a$</th>
<th>Higher Commitment (n = 15)</th>
<th>P value$^b$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Energy (kcal)</td>
<td>-345.39 ± 410.01**</td>
<td>-682.31 ± 511.21***</td>
<td>0.05</td>
<td></td>
</tr>
<tr>
<td>Carbohydrate (% of energy)</td>
<td>2.22 ± 7.04</td>
<td>2.40 ± 10.65</td>
<td>0.96</td>
<td></td>
</tr>
<tr>
<td>Protein (% of energy)</td>
<td>0.60 ± 3.68</td>
<td>3.08 ± 3.94*</td>
<td>0.07</td>
<td></td>
</tr>
<tr>
<td>Total fat (% of energy)</td>
<td>-2.78 ± 8.06</td>
<td>-5.27 ± 9.76*</td>
<td>0.44</td>
<td></td>
</tr>
<tr>
<td>Saturated fat (% of energy)</td>
<td>-1.54 ± 2.89*</td>
<td>-1.91 ± 3.04*</td>
<td>0.72</td>
<td></td>
</tr>
<tr>
<td>Total fiber (g/1,000 kcal)</td>
<td>3.24 ± 3.03***</td>
<td>3.52 ± 2.76***</td>
<td>0.78</td>
<td></td>
</tr>
<tr>
<td>Carbohydrate (total grams)</td>
<td>-29.73 ± 63.85</td>
<td>-67.01 ± 58.78***</td>
<td>0.09</td>
<td></td>
</tr>
<tr>
<td>Glycemic index$^c$</td>
<td>-4.36 ± 4.13***</td>
<td>-6.87 ± 5.80***</td>
<td>0.17</td>
<td></td>
</tr>
<tr>
<td>Glycemic load$^d$</td>
<td>-27.00 ± 37.25*</td>
<td>-51.27 ± 30.77***</td>
<td>0.05</td>
<td></td>
</tr>
<tr>
<td>Fruit (servings/1000 kcal)$^e$</td>
<td>0.48 ± 0.56**</td>
<td>0.86 ± 1.02**</td>
<td>0.21</td>
<td></td>
</tr>
<tr>
<td>Vegetables (servings/1000 kcal)$^f$</td>
<td>0.57 ± 1.30**</td>
<td>0.56 ± 1.07*</td>
<td>0.98</td>
<td></td>
</tr>
<tr>
<td>Nuts, seeds and butters (servings/1000 kcal)</td>
<td>0.40 ± 0.72*</td>
<td>0.35 ± 0.68</td>
<td>0.82</td>
<td></td>
</tr>
<tr>
<td>Dairy foods (servings/1000 kcal)$^g$</td>
<td>0.13 ± 0.46</td>
<td>0.40 ± 0.66</td>
<td>0.18</td>
<td></td>
</tr>
<tr>
<td>Whole wheat pasta (servings/1000 kcal)</td>
<td>0.02 ± 0.12</td>
<td>0.09 ± 0.21</td>
<td>0.30</td>
<td></td>
</tr>
<tr>
<td>Total Servings (per 1000 kcal)</td>
<td>1.59 ± 1.52**</td>
<td>2.26 ± 1.83***</td>
<td>0.27</td>
<td></td>
</tr>
</tbody>
</table>

$^a$ two participants excluded due to personal illness and study end

$^b$ two sample t-test of between group comparisons

$^c$ calculated as $\Sigma$ (ingredient available carbohydrate/total available carbohydrate for food) x ingredient GI; averaged over 4 days of intake

$^d$ calculated as $\Sigma$ (ingredient available carbohydrate X ingredient GI) / 100; averaged over 4 days of intake

$^e$ excludes fruit juices

$^f$ includes whole, reduced and non-fat milk, cheese and yogurt

$^g$ includes whole, reduced and non-fat milk, cheese and yogurt

Significant change from baseline (* $p<0.05$; ** $p<0.01$; *** $p<0.001$)

Table 4.4. Change in nutrient and food serving profiles by lower goal commitment or higher goal commitment (mean ± standard deviation)

At the end of the study, participants in the higher commitment group believed their assigned goal was easier ($p = 0.07$) and had greater increases in self-efficacy (all $p < 0.05$) compared to participants in the lower commitment group. Significant improvements in self-efficacy for both the lower and higher commitment groups were noted at the end of the study (Table 4.5).
### Table 4.5. Change in psychosocial variables by lower goal commitment or higher goal commitment (mean ± standard deviation)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lower Commitment (n = 20)</td>
</tr>
<tr>
<td>Assigned (perceived) Goal Satisfaction</td>
<td>-0.35 ± 1.39</td>
</tr>
<tr>
<td>Assigned (perceived) Goal Difficulty</td>
<td>0.50 ± 2.37</td>
</tr>
<tr>
<td><strong>Self Efficacy</strong></td>
<td>1.57 ± 1.59***</td>
</tr>
<tr>
<td>GI Efficacy Subscale**</td>
<td>1.77 ± 1.68***</td>
</tr>
<tr>
<td>Goal Difficulty Subscale**</td>
<td>1.53 ± 2.12**</td>
</tr>
<tr>
<td>Negative Food Selection Subscale**</td>
<td>1.27 ± 2.38*</td>
</tr>
</tbody>
</table>

* Two sample t-test of between group comparisons

This scale included response options ranging from 0 = strongly disagree to 10 = strongly agree.

Excludes two participants due to extreme scores

The mean score of 6 items.

The mean score of 8 items.

These items were reverse scored so a higher score represents greater efficacy beliefs.

The mean score of 3 items

Significant change from baseline (* p<0.05; ** p<0.01; *** p<0.001)

---

### 4.5 Discussion

This research is one of the first reported in the literature to implement goal setting theory as a model for improvement of diabetes-related outcomes. Dietary behavior change is multi-faceted with many factors influencing the degree and success of change. Individuals engage in dietary behaviors multiple times during the day, and many individuals with type 2 diabetes desire to make appropriate food choices. However, the confidence and the skills to make these choices often elude individuals with this disease and offers many opportunities for improvement.

In general, the findings from this study support the relationships between the components in the model for goal setting theory. Over the course of the study, participants in both groups were able to implement the tools related to making lower GI food choices. Self-efficacy increased following the intervention, suggesting that
education and training which incorporate enactive mastery, verbal persuasion, vicarious experiences, and physiological and affective states facilitates improvements in self efficacy. Helping participants build self-efficacy for choosing low GI foods resulted in significant increases in the total number of low GI food servings consumed, regardless of the goal assigned. These findings lend support that setting specific goals and building self-efficacy can result in desirable dietary change.

Though both groups in the GOAL study were able to increase self-efficacy and the total number of low GI food servings they consumed each day, commitment to the assigned goal decreased over the course of the study for both groups. Goal setting theory posits that commitment to a goal, whether assigned or self-set, is essential to successfully achieve a goal. Some argue that individuals are less committed to an assigned rather than a self-set goal. This was not the case in the present study. Furthermore, though the participants in this study were assigned a goal, they were given the freedom to implement this goal as appropriate for their lifestyle.

In the present study, the findings suggested a relationship between the level of goal difficulty and the level of commitment to the goal. As previously stated, goal difficulty is a key component of goal setting theory. Goals that are too easy provide no incentive for change, but goals that are too difficult can result in feelings of defeat and decreased self-efficacy. In this study, the negative correlation between difficulty and commitment suggests the goal was too difficult for some. This may be in part due to the fact the level of difficulty of the goal assigned was perceived differently based on overall energy consumption. For an individual with greater energy intake, consuming 6 low GI food servings would likely be perceived as an easier goal compared to someone with
lower energy intake. The decrease in commitment for both groups over the course of the GOAL study was a curious finding and led us to believe that commitment may be acting as a potential mediator. The small sample size prohibited a formal evaluation of this hypothesis. However, grouping participants by lower or higher commitment to the assigned goal revealed that individuals with greater commitment had more substantial changes in several variables of interest (Table 4.4 and Table 4.5).

The changes noted when participants were grouped by level of goal commitment illustrates the need to incorporate tactics for building commitment into future studies. Early studies by Lewin showed that simply asking individuals to make a public commitment to an activity resulted in greater implementation of that activity.124 Other studies suggest verbal commitment results in greater theft prevention and improved fulfillment of blood donation pledges.125-127 However, none of these studies evaluated commitment to changing a nutrition-related behavior. Future studies that help participants develop discrepancy between their current behavior and their future goal and that implement a component of verbal commitment may result in individuals that are more compelled to change their dietary behavior for improved diabetes outcomes.

Type 2 diabetes is a complex disease and requires an increased level of personal organization for medication, dietary and blood glucose management. In the present study, hands-on nutrition-related activities including weighing and measuring portions, recipe modification and smart choices for dining out were included to help build skills for choosing lower GI foods. Other skills including time management, grocery shopping for low GI foods on a budget and recipe preparation were not addressed. Though some of the aforementioned activities could be addressed in a group setting, time management
and organizational skills are highly variable and are better addressed on an individual level. Problem solving therapy (PST) is a strategy that has been used to teach skills for adaptive coping and has successfully been used to help patients manage depression and obesity.\textsuperscript{128, 129} PST formally involves eight steps, including identifying, defining and understanding a problem, setting goals and alternative solutions, and evaluating, choosing and implementing the best alternatives. Implementing PST to help participants develop additional skills needed for diabetes management, with concurrent goal setting, may increase commitment and build additional self-efficacy for achieving a goal. Only one intervention has implemented PST in individuals with type 2 diabetes.\textsuperscript{130} Furthermore, the main outcome of this study was not related to dietary change. The successful use of PST to build skills for depression and obesity management warrants further investigation for its use in the management of type 2 diabetes.

This study had several limitations. The demographic makeup of the patient population was primarily Caucasian, reducing the generalizability of our results. Food choices, methods of food preparation and other food-related dynamics vary among races and socioeconomic levels. Furthermore, incidence of type 2 diabetes is greater in minority groups.\textsuperscript{1} Future research in minority groups and groups with lower socioeconomic levels that implement goal setting combined with a lower GI diet is warranted.

The attrition rate for the current study was relatively high. Out of 46 participants enrolled, 11 (24%) withdrew during the course of the study, resulting in a smaller sample size. Recent reviews of dietary and diabetes self-management interventions have noted similar attrition rates in studies 6 months or longer in duration, which places a higher
burden on participants than short-term or feeding studies. The small sample size limited our ability to conduct mediator analyses. Furthermore, the wide variation noted in this group for all outcomes of interest resulted in large standard deviations and few statistically significant results. A larger, more diverse sample is needed to determine the efficacy of a goal setting approach to achieve dietary change.

4.6 Implications for Practice and Research

The GOAL study is the first reported evaluating the feasibility of implementing goal setting theory as a model in conjunction with consuming lower GI foods. Setting specific, achievable goals and building self-efficacy for achieving these goals was shown to increase daily consumption of low GI foods, but ambivalence toward dietary change may remain. Strategies from motivational interviewing including recognizing and rolling with resistance, building self-efficacy for change and helping develop discrepancy may aid in increasing commitment toward achieving a lower GI diet. Verbally committing to a goal, whether individually or in a group setting may also prove useful for increasing obligation. Finally, implementing principles from problem solving therapy should be employed to help individuals recognize the additional daily challenges encountered with type 2 diabetes and develop the skills needed to effectively manage these challenges. Further research formally incorporating these concepts into a model for behavior change is needed.

4.7 Conclusion

In summary, the GOAL study successfully implemented goal setting theory to aid individuals with type 2 diabetes build self-efficacy for consuming low GI foods and
adopt an overall lower GI diet. Goal setting theory helped establish the initial easier and more difficult goals of consuming 6 or 8 low GI food servings each day, and helped focus the intervention toward building self-efficacy for achieving these goals through enactive mastery, vicarious experience, verbal persuasion and change in physiological and affective states. Though more research in the area of increasing goal commitment needs to be conducted, this study demonstrates that individuals with type 2 diabetes benefit from setting goals for achieving a lower GI diet.
CHAPTER 5

Conclusions

5.1 Summary of Findings

This study examined the effectiveness of using goal setting theory to set a specific low GI food serving goal to increase self-efficacy for choosing low GI foods, and to improve weight control and glycemic control in adults with type 2 diabetes. The significant increase in the prevalence of type 2 diabetes in the United States and the comorbidities associated with this disease illustrate the importance of effective nutrition interventions.

Appropriate food choices are a critical part in the management of type 2 diabetes. Food choices are made multiple times throughout the day, and in general individuals have substantial control over the foods they choose to eat. Carbohydrate foods generally constitute the largest percentage of daily energy intake and are a major factor in glycemic control. Larger portions of carbohydrate result in greater increases in blood glucose compared to smaller portions, thus the quantity of carbohydrate consumed is a key factor for dietary management of type 2 diabetes.
Though carbohydrate quantity is important, carbohydrate quality is also critical for optimal blood glucose control. The glycemic index offers a means for evaluating carbohydrate quality, but is not frequently used as a tool for the management of type 2 diabetes. This is in part due to the fact that dietitians may not have the appropriate knowledge or skills needed to teach concepts about the glycemic index. The appropriate number of low GI food servings needed for optimal blood glucose control in people with diabetes is unknown.

Goal setting is frequently used as a strategy to modify behavior. In order to successfully achieve a goal, the goal needs to be specific and relatively difficult, yet achievable, according to the theory. Often, set goals are vague, and there are no concrete measures to determine if the goal has been achieved. This, in combination with inadequate skills can lead an individual to abandon their goal to change a behavior. Taken together, goal setting in combination with a specific, achievable low GI food serving goal offers a new means of nutrition education for the dietary management of type 2 diabetes.

The results from this study demonstrate that individuals with type 2 diabetes can implement the goal setting and nutritional concepts related to choosing foods for a lower GI diet. Both easier and more difficult goals helped participants achieve a lower GI diet. This lends support to the idea that goal setting theory can be implemented to promote low GI dietary change. The theoretical constructs that constitute goal setting theory helped participants move through the process of behavior change to achieve their goals. Notably, we focused much of the educational portion of the study on building self-efficacy for incorporating lower GI foods into daily food choices. Through
encouragement from the study dietitian, understanding how others with type 2 diabetes coped with similar dietary situations, practicing making appropriate choices in difficult situations, learning how to modify recipes and understanding how these actions affected blood glucose levels, participants were able to build self-efficacy for choosing low GI foods. In turn, significant increases in self-efficacy were seen for both groups between baseline and the end of the study. Significant increases in the total number of low GI food serving consumed each day were also noted for both groups, with concomitant improvements in HbA1C values and improvements in weight and waist circumference. Though lower GI foods were a key factor, we recognize that the changes in weight and in HbA1C may also have been related to reduced carbohydrate intake. Replacing higher GI foods with lower GI foods was the main emphasis of this study, but carbohydrate quantity was also addressed in the educational lessons. Activities such as label reading and comparing actual portions consumed to serving sizes indicated on the nutrition facts panel emphasized the importance of portion control. Taken together, carbohydrate quantity and carbohydrate quality both have an important role for improved health.

These results are encouraging as participants in this study were in poor glycemic control and stood to benefit most from dietary change. The changes demonstrate that with appropriate education, building self-efficacy for choosing lower GI foods is feasible and choosing these foods results in clinically relevant changes in glycemic and weight control outcomes.

Although participants were able to build self-efficacy for choosing low GI foods through the course of the study, commitment to the goal assigned decreased over the course of the self-monitoring period. This may be due in part that participants had built
self-efficacy for choosing low GI foods through the educational sessions and felt commitment to the goal when it was assigned, but had not yet tried to implement it on a daily basis. Furthermore, though the goals assigned to participants in this study were objective and based on epidemiological data, their difficulty was perceived differently depending on individual energy intake. For those with greater energy needs, the goal was likely perceived as easier compared to those with lower energy needs as the serving goal constituted a lower proportion of foods in their total dietary intake. Other stressors, including job, family and economic factors may also influence the perceived level of goal difficulty. Notably, negative correlations were observed between the level of goal difficulty and commitment to the goal both after receiving their goal and at the end of the study. These correlations may indicate that some reached a threshold of goal difficulty, which has been corroborated by other studies. Additionally, strategies to build commitment were not addressed in this study. Dietary needs and personal preferences vary greatly. Because of these differences, it is important to assess current intake before setting a goal for behavior change. By evaluating energy intake and the current level of low GI food servings consumed, appropriate recommendations for energy intake can be made and a challenging yet achievable low GI serving goal can be set. Further research on setting specific, appropriately difficult individualized goals in combination with strategies to increase commitment are needed.

Goal setting theory posits that satisfaction should increase with goal attainment. Self-efficacy and commitment should help an individual move toward achieving their goal, and satisfaction should increase with this achievement. In this study, satisfaction was measured using a 1-item scale, where 0 = a great deal of dissatisfaction with their
goal and 8 = a great deal of satisfaction with their goal. Satisfaction is an important construct to measure because it helps evaluate if the other constructs are working appropriately according to the theoretical model. In the current study, most participants reported they were greatly satisfied with their goal when they received it, leaving little room for improvement. At the end of the study, participants were similarly satisfied. In the future, a multiple item tool incorporating more facets of satisfaction should be used to better evaluate this construct.

More frequent contact with a health care professional has been reported to improve desired health outcomes compared to less frequent contact. Furthermore, one of the most common comments from participants at their final study visit was that they missed meeting weekly as a group, both for social support and for accountability. The ability to maintain behavior change long term is difficult, and there are few studies that have evaluated strategies for behavior change maintenance. In the future, a combination of more frequent group meetings and more one-on-one support may be beneficial to help participants meet their goals and to maintain this change in the long run.

In the current study, approximately ¼ of the participants initially enrolled were not able to complete the study. Similar attrition rates have been seen in other studies 6 months or longer in duration, as longer term, behavior change studies place more burden on participants than shorter term or feeding studies. It is important to note that although attrition was 24%, many of these participants did not continue due to major life events including the death of a spouse, the death of a parent, and the recurrence of cancer or other personal illness. Another group of participants may have had fewer life events,
however, these events illustrate the need for practical tools for managing diabetes during all stages of life.

5.2 Implications for Future Research

The main focus of traditional dietary management of type 2 diabetes has emphasized that monitoring the amount of carbohydrate consumed is most important for optimal glycemic control. Implementing information about GI has in part been largely avoided as controversy over its utility still exists. Though the quantity of carbohydrate consumed is most certainly an important aspect of diabetes education, numerous studies now provide evidence that the quality of the carbohydrate consumed is equally important for attenuation of blood glucose levels following a meal. This study supports that education about the glycemic index in individuals with type 2 diabetes is both feasible and results in improved metabolic outcomes. Furthermore, education about the glycemic index may present an easier alternative to traditional carbohydrate monitoring. At the end of the current study, several participants commented they thought that using the glycemic index to help them make appropriate food choices was much easier than any of the other methods attempted previously. Using the tools provided to determine the GI value of a food and eating a smaller portion avoided the numeracy involved with carbohydrate counting and diabetic exchanges. Though anecdotal, these comments suggest that emphasizing appropriate portion size in combination with choosing low GI foods may help patients feel less frustrated about the food choices they need to make and promote greater adherence to dietary change.
Implementing goals for participants also proved to be effective in helping achieve a lower GI diet. Though goal setting is frequently used to help promote behavior change, feedback and other necessary follow-up is often lacking in the clinical setting. There are many reasons for this, including the costs associated with more frequent follow-up, lack of time and lack of staff that can bridge the many aspects encountered when counseling for behavior change. In this study, participants had frequent contact with the study dietitian and had a follow-up visit with the CRC dietitian midway through the self-monitoring period. Although there were no significant differences noted between the goals, implementing the model and including appropriate follow-up helped participants achieve their goal. In clinical practice, setting goals with patients is important, and this study lends evidence to the great necessity of adequate follow-up toward achieving these goals.

During the course of this research, it was evident that goal setting was beneficial for achieving behavior change. Six or 8 servings of low GI foods/day were chosen as the target goals as epidemiological evidence suggests that incorporating low GI foods at these levels should result in an overall dietary GI of ~55. Moreover, a mean daily low GI goal was not provided to participants as calculating a daily GI value is relatively difficult, even for those well versed in the field. As the study progressed it became apparent that some individuals believed their goal was more difficult while others thought the same goal was easy. This was due largely in part to the fact that some participants had to replace a greater proportion of their energy intake with low GI foods compared to others. Because an absolute low GI serving goal may not suit the needs of all individuals with type 2 diabetes, it is now imperative to understand how to determine individual goals that
are specific, yet appropriately difficult in the clinical setting. The level of goal difficulty is important, as goals that are too difficult result in reduced self-efficacy and feelings of defeat.

Food choices vary greatly, and it is important to assess individual needs when making dietary change. When setting individual low GI serving goals, one suggestion is to assess the number of servings consumed prior to attempting change. For example, one individual may be consuming 4 low GI food servings each day, while someone else may already be consuming 8 low GI food servings each day. For the person consuming 4 low GI food servings each day, asking them to increase their intake to 8 servings each day may be too difficult, while it will be too easy for the person already consuming 8 servings/day. By assessing individual intake prior to attempting change, a goal can be set relative to current intake. In this case, it may be appropriate to set a goal of 2 additional low GI food servings/day, making the individual goals 6 and 10 servings/day, respectively. Though individualized, the serving goal is still absolute (2 servings/day). Clinically, it will be important to work with patients individually to help determine what are effective and appropriately difficult goals.

In conclusion, this study has effectively shown that education about glycemic index in combination with goal setting can be used to promote dietary change and improve glycemic control outcomes in individuals with type 2 diabetes. Building self-efficacy is critical to behavior change, but future research is needed in the area of building commitment and setting appropriately difficult goals. Dietary habits also vary greatly across different races and ethnicities, and more research regarding glycemic index education and goal setting is needed in an ethnically diverse population. Finally, social
support through more frequent group meetings may be needed to maintain long-term dietary change.
REFERENCE LIST


69. Ludwig DS. Dietary glycemic index and obesity. J Nutr 2000;130(2S Suppl):280S-3S.


APPENDIX A

Recruitment Materials
Diabetes?

Do you ever feel like there is always more to learn?

Would you like to receive more information to help you manage your blood sugar?

Join the GOAL study!!

A nutrition education program for diabetes management

Participate in an education program and provide information that will help us develop more effective programs for people with diabetes.

You may be eligible if you:

✓ are 40-65 years of age;
✓ have had adult-onset diabetes (type 2 diabetes) for at least 1 year
✓ do not use insulin therapy.

For more information, please call (614) 292-4772

This research study is being conducted by Dr. Carla Miller, PhD, RD and has been approved by the Institutional Review Boards at The Ohio State University.
APPENDIX B

Telephone Screening Questionnaire
Telephone Screening Questionnaire

Did participant provide waiver of signed consent (per response on screening script?)  □ Yes  □ No  (If no, do NOT continue)  Date__________________

ID#___________

Name_____________________________________________________

Preferred Name or nickname_________________________________

Phone Number (H)____________________ (W)__________________
(C)_________________________________________________________________

Best time to call ____________________________________________

May we call you at work??____________________________________

Email address:_____________________________________________

Ok to email?_______________________________________________

Call Log  __________________________________________________

1. How did you learn of this study?

2. Why would you like to participate in this study?

3. When is your birthday? _________________________________
4. How old are you? ____________ If <40 or > 65 years old, ineligible.

Give brief explanation of type 2 diabetes:

Type 2 diabetes is the kind of diabetes that people usually get when they are older. People with type 2 diabetes either don’t make enough insulin to control their blood sugar, or the cells in their body can’t use the insulin it does make very well.

5. Has your MD ever told you that you have type 2 diabetes? _____ yes _____no If no, ineligible.

6. How long have you known you have diabetes? ___________________ If < 1 year, ineligible.

7. Do you remember the season/month and year that the MD told you that you had diabetes? Season/Month_______________________Year____________

8. How old were you when you first learned you have diabetes? _________________

9. Do you take insulin? _____yes _____no If yes, ineligible.

10. Do you take any oral medication for your diabetes? _____ yes _____ no
    If yes, type of medication(s) _________________________________
    __________________________________________________________

11. Have you had your HbA1c measured in the last 3 months? ____yes ____no
    If yes, date and value? ______________________________________
    __________________________________________________________

    If you qualify for the study, could you please bring a written record of this measurement to your next appointment?

12. Do you have any other medical conditions? _____ yes _____ no
    If yes, please describe ________________________________________
    __________________________________________________________

    (medical conditions affecting hemoglobin levels are ineligible – Anemias, acute blood loss, frequent blood transfusions, dialysis)
a. Do you follow a special diet for any of these conditions?
   _____yes _____no
   If yes, please describe________________________________________
   (If on a special diet other than diabetic diet, low cholesterol, low fat,
   low sodium or high fiber, ineligible)

b. If renal disease, do you receive kidney dialysis treatments?
   _____yes _____no (if yes, ineligible)

c. Do you take any other medications (prescription or non-prescription) or
   any vitamin/mineral/herbal
   supplements??_________________________________________________
   __________________________________________________________________
   (Steroid medications, vitamins C, E or aspirin affect HbA1c levels)

13. Do you follow a weight reduction or other type of popular fad diet?
    _____yes _____no
    If yes, please describe ____________________________
    (If following a commercial weight reduction diet, e.g. Weight Watchers,
    ineligible)

14. If a female of child-bearing age, are you pregnant, planning to become
    pregnant, or breastfeeding at this time? _____yes _____no
    (If yes, ineligible)

15. Have you received education about the glycemic index? _____yes _____no
    (If formal training other than familiarity with the term or trying the South
    Beach diet, etc, ineligible.)

16. Do you plan to live in the greater Columbus area for the next 6 months?
    _____yes _____no  (If no, ineligible)

17. Do you have reliable transportation for study visits?_____________________
18. Race:

______American Indian or Alaska Native
______Asian
______Black or African American
______Native Hawaiian or other Pacific Islander
______White

19. Ethnicity:

______Hispanic or Latino
______Not Hispanic or Latino

20. Gender

______Male
______Female

21. Education level

__________Less than 12th grade
__________High school diploma or GED
__________Vocational/Trade school
__________Some college
__________Bachelor’s degree
__________Advanced degree (MS, PhD, JD, MD, etc.)
22. Employment

__________Full time (32+ hours/week)

__________Part time (<32 hours/week)

__________Full time homemaker

__________Full time student

__________Retired

__________Disabled/not able to work

23. If working, please tell me about your work schedule. Do you travel a lot? Will your employer be flexible with study appointments?

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________

24. Marital Status

_______Never married

_______Married

_______Separated/Divorced

_______Widowed

Subject is _______ ineligible _________ potentially eligible

Recorder ______________________  Date ____________________

If ineligible, reason _________________________________________
If ineligible, thank person for their inquiry.
If eligible, review the purpose of the study. Ask if they want to participate. If they wish to participate, indicate availability for individual interview session and education sessions below. Tell them they will be contacted with a scheduled date and time within the next week.
Preferred day and time for individual session:

_____Monday _____Tuesday _____Wednesday _____Thursday _____Friday

____Morning _____Afternoon _____Evening

Comments ____________________________

Appointment Date _______________ Time _______________

Preferred day and time for education sessions:

_____Monday _____Tuesday _____Wednesday _____Thursday

_____Morning _____Afternoon _____Evening

Comments (is participant cognitively impaired?)

_____________________________________________________________

_____________________________________________________________
APPENDIX C

Participant Contact Letter
Dear Participant:

Thank you for agreeing to participate in the GOAL study. Many people with diabetes know they can help control their diabetes with diet, but want more information on how to make the best food choices. To help people with type 2 diabetes learn how to make the best food choices, we have developed an education program about low glycemic index food choices for diabetes management. During these group education sessions, we will help people learn how to achieve their diet goals. Your participation in this study helps other people like you who are trying to manage their disease.

You are of assured complete confidentiality throughout the study. All the information collected during the course of the program will be tracked with an identification number rather than your name. The Informed Consent form for the study is included in this packet. This form describes the purpose of the study and how we will protect the confidentiality of the information you give us. Please read the form and bring it to your first visit for the study. You will need to sign it at the first visit to continue in the study. For your first visit, please come to the General Clinical Research Center at Ohio State for your visit and park in the visitor parking garage (see enclosed directions). A parking permit will be provided at your visit.

I will be happy to answer any questions you may have about the study or the questionnaires. If you would like to speak with me, please call (614) 292-4772. Thank you for being an important part of this project!!

Sincerely,

Amy Headings, RD, LD
Project Coordinator
APPENDIX D

Informed Consent Form
The Ohio State University Consent to Participate in Research

Study Title: Evaluation of a Glycemic Index, Goal Setting Pilot Intervention in the Management of Type 2 Diabetes: The Glycemic Index, Opportunities And Lifestyle (GOAL) Study

Principal Investigator: Dr. Carla Miller, PhD, RD

Sponsor: None

• This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.

• Your participation is voluntary. You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.

• You may or may not benefit as a result of participating in this study. Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.

• You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate. If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

1. Why is this study being done?

This study is being conducted to understand how setting goals for eating different servings of low-glycemic index foods can help people with diabetes better manage their disease.

2. How many people will take part in this study?

We anticipate that 50 people will take part in this study.
3. What will happen if I take part in this study?

The GOAL study is being conducted to help us better understand how low glycemic index (GI) foods in combination with different goals can help people with type 2 diabetes better control their blood glucose (sugar). The glycemic index is a scale that describes how certain foods that contain carbohydrates affect your blood glucose after you eat them.

There are several components to the GOAL study. During the course of the GOAL study you will be asked to come to The Ohio State University General Clinical Research Center (GCRC) for several clinical visits. During the first visit, we will ask you to sign this consent form, then provide a fasting fingerstick blood sample (1 drop of blood) so we can determine your HbA1c value. HbA1c is a way to measure your blood glucose level over approximately the previous 3 months. We are attempting to recruit individuals with HbA1c values ≥7.0%. If your HbA1c value is ≥7.0%, we will ask you to provide a venous blood sample to further confirm this value. The blood drawn during this sample will amount to 5 mL, or approximately 1 tsp. Following this blood draw, we will ask you to complete several questionnaires that ask you about your experience with diabetes and blood glucose (sugar) control, as well as a few questions about you and your household. We will also take some common measurements like height and weight, as well as your waist and hip circumferences. To accurately measure your waist and hip circumferences, we will ask that you go to a private room with the GCRC dietitian. To measure your waist, we will ask that you slightly lower your pants so the GCRC dietitian can feel the top of your hip bone. They will then wrap a measuring tape around you at this level for your waist measurement. To measure your hips, you will be asked to either lower your pants a little further, or you may wear a thin pair of exam pants. The GCRC dietitian will look at you from the side, then place the measuring tape around you at the widest point for your hip measurement. At this visit, you will also be provided a small meal and a parking pass. This visit will take approximately 1-1.5 hours.

Following your first visit, you will return to the GCRC in a few weeks to meet with the study dietitian. This visit will take approximately 1 hour. At this visit, we will meet to talk more about your experience with diabetes, what your personal goals are for the GOAL study, and blood glucose control. During this visit, we will ask you to complete 2 questionnaires that relate to your personal goals. We will also go through an instructional session on how to complete a 4 day diet record. During the course of the GOAL study, we will ask you to complete several 4 day diet records. During the first 5 weeks, we will ask you to complete 1, 4 day diet record each week (3 weekdays and 1 weekend day). During weeks 6-10, we will ask you to complete a diet record on 2 days each week (1 weekday and 1 weekend day). During weeks 10-13, the diet record will be optional. We will ask you to complete 1 more very detailed 4 day diet
record during the last week of the study (week 14). In addition to the diet record, we will ask you to complete a low-GI foods checklist on 4 days each week (3 weekdays and 1 weekend day) to help you monitor the number of low-GI foods you consume throughout the day.

Following your individual visit with the study dietitian, you will be asked to schedule your educational sessions. The educational sessions, or classes, will be held with a group of approximately 5 to 7 other participants in the GOAL study. One class will be held per week over a period of 5 weeks, and each class will last approximately 2-2.5 hours. These classes will take place at one of several branches of the Columbus Public Libraries most convenient to individuals attending that class. During these educational sessions you will learn about self monitoring, keeping a food record, carbohydrates and the glycemic index, things that affect the glycemic index, and how to maintain behavior change. These sessions will be interactive, with several activities to help you best understand the information discussed, as well as a question/answer session at the end of each session to make sure all questions are answered. At the end of these 5 weeks, you will be asked to complete a questionnaire that asks you about your confidence relating to the glycemic index.

Following these educational sessions, you will be asked to return to the GCRC to meet with one of the GCRC dietitians (study week 6). During this session, you will be randomly assigned 1 of 2 goals for consuming a certain number of low-GI foods each day. One goal will be an easier goal; the other goal will be a little more difficult. The study coordinators have no control over which goal you are assigned – your group will be assigned randomly, somewhat like your chances of flipping a coin and getting a heads or tails. During this session, you will also be able to troubleshoot any remaining questions you may have about the glycemic index, and you will also be able to work with the GCRC dietitian to develop some strategies to help you incorporate lower GI foods into your daily diet. We will also ask you to complete 4 questionnaires that relate to your new goal. This visit will take approximately 1 hour.

Following this visit with the GCRC dietitian, you will enter the self-monitoring period of the study. During study weeks 6-10, you will be asked to complete food records as described above, as well as a low-GI foods checklist. You will also be asked to complete a short questionnaire each week that relates to your goal. At the end of each week, you will be asked to mail your food records, your low GI foods checklist, and your questionnaire to the study dietitian. The study dietitian will review your food records and your low GI foods checklist. If there are any questions, you will be contacted by the study dietitian to clarify the questions. Then, based on the number of low GI foods you consumed during the week, you will receive feedback that relates to your goal. Each day, please plan to spend about 1 hour for food records and study questionnaires.
At study week 10, you will return to the GCRC to meet with the study dietitian. During this visit, you will be able to ask questions you may have encountered during weeks 6-10 of the self-monitoring period. You will be able to work further with the study dietitian to learn tactics for incorporating low GI foods into your diet. Please do NOT share your assigned goal with the study dietitian during this visit or during any other part of the GOAL study. This visit should take approximately 1 hour.

At the conclusion of this visit, you will enter another 4 weeks of self-monitoring (weeks 10-14) similar to study weeks 6-10. During weeks 10-14, you will be asked to complete 4 low-GI food checklists throughout the week (3 weekdays and 1 weekend day) and the short questionnaire relating to your goal at the end of each week. You will be asked to return your low-GI foods checklist and the questionnaire to the study dietitian for review, and will receive feedback in a similar manner as you did during study weeks 6-10. During weeks 10-13, food records will be optional. However, you will be asked to complete 1 final 4 day food record during the last week of the study (week 14) and bring it to your final visit to the GCRC. Please plan to spend approximately 1 hour completing the low GI foods checklist and related questionnaires each day.

At the conclusion of the self-monitoring period, you will be asked to return to the GCRC for one last clinical visit. At this visit, you will be asked to give one more fasting blood draw to determine your HbA$_{1c}$ value. Following this blood draw, you will be offered a small meal. During this visit, we will also measure your height, weight and waist and hip circumferences the same way we measured them during your first visit. You will also be asked to complete several questionnaires. This visit should take about 1.5 hours.

4. How long will I be in the study?

You will be in the study for approximately 20 weeks.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.
6. What risks, side effects or discomforts can I expect from being in the study?

Two blood draws will be conducted during the course of the study, one at the beginning of the study and one at week 14. Blood draws are a common procedure, though they can cause pain in some individuals. Pain at the blood draw site and some bruising may occur with this procedure.

7. What benefits can I expect from being in the study?

By participating in this study, you will learn how eating low-glycemic index foods can help you better manage your diabetes. By participating in this study, you will also help researchers understand if different goals can help people better manage their diabetes. The results from this study will help researchers develop more effective programs to help people best manage their diabetes.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law. Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;

If the study involves the use of your protected health information, you may also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form.

10. What are the costs of taking part in this study?

There are no costs to you for participating in this study. However, you will need to have reliable transportation to attend the required study visits.
11. Will I be paid for taking part in this study?

You will not be paid money for taking part in this study. All parking fees will be paid for study-related visits to Ohio State. However, you will have access to weekly visits with a registered dietitian, a benefit sometimes not covered by insurance.

12. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

13. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

14. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact Dr. Carla Miller at 614-292-1391.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.
If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Dr. Carla Miller at 614-292-1391.
Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form.

<table>
<thead>
<tr>
<th>Printed name of subject</th>
<th>Signature of subject</th>
<th>AM/PN</th>
</tr>
</thead>
<tbody>
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<td></td>
<td>Date and time</td>
</tr>
</tbody>
</table>

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

<table>
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<tr>
<th>Printed name of person obtaining consent</th>
<th>Signature of person obtaining consent</th>
<th>AM/PN</th>
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<td>Date and time</td>
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</table>

Witness(es) - May be left blank if not required by the IRB

<table>
<thead>
<tr>
<th>Printed name of witness</th>
<th>Signature of witness</th>
<th>AM/PN</th>
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<tr>
<th>Printed name of witness</th>
<th>Signature of witness</th>
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<td>Date and time</td>
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</table>
APPENDIX E

HIPPA Form
THE OHIO STATE UNIVERSITY
AUTHORIZATION TO USE
PERSONAL HEALTH INFORMATION IN RESEARCH

Title of the Study: Evaluation of a Glycemic Index, Goal Setting Pilot Intervention in the Management of Type 2 Diabetes: The Glycemic Index, Opportunities and Lifestyle (GOAL) Study

OSU Protocol Number: 2008H0057

Principal Investigator: Dr. Carla Miller

Subject Name__________________________________________________________

Before researchers use or share any health information about you as part of this study, The Ohio State University is required to obtain your authorization. This helps explain to you how this information will be used or shared with others involved in the study.

- The Ohio State University and its hospitals, clinics, health-care providers and researchers are required to protect the privacy of your health information.
- You should have received a Notice of Privacy Practices when you received health care services here. If not, let us know and a copy will be given to you. Please carefully review this information. Ask if you have any questions or do not understand any parts of this notice.
- If you agree to take part in this study your health information will be used and shared with others involved in this study. Also, any new health information about you that comes from tests or other parts of this study will be shared with those involved in this study.
- Health information about you that will be used or shared with others involved in this study will include your research record and your HbA1c results obtained at the Ohio State University.

Please read the information carefully before signing this form. Please ask if you have any questions about this authorization, the University’s Notice of Privacy Practices or the study before signing this form.

Initials/Date: _______________

Page 1 of 3
Those Who May Use, Share And Receive Your Information As Part Of This Study

- Researchers and staff at The Ohio State University will use, share and receive your personal health information for this research study. Other Ohio State University staff not involved in the study but who may become involved in your care for study-related treatment will have access to your information.

- Those who oversee the study will have access to your information, including:
  - Members and staff of the Ohio State University’s Institutional Review Boards, including the Western Institutional Review Board
  - The Office for Responsible Research Practices
  - University data safety monitoring committees
  - The Ohio State University Research Foundation

- Your health information may also be shared with agencies that have oversight of the study or to whom access is required under the law. These may include:
  - The Office for Human Research Protections

These researchers, companies and/or organization(s) outside of The Ohio State University may also use, share and receive your health information in connection with this study:

- None

The information that is shared with those listed above may no longer be protected by federal privacy rules.

Authorization Period

This authorization will not expire unless you change your mind and revoke it in writing. There is no set date at which your information will be destroyed or no longer used. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

Signing the Authorization

- You have the right to refuse to sign this authorization. Your health care outside of the study, payment for your health care, and your health care benefits will not be affected if you choose not to sign this form.
- You will not be able to take part in this study and will not receive any study treatments if you do not sign this form.
- If you sign this authorization, you may change your mind at any time. Researchers may continue to use information collected up until the time that you formally changed your mind. If you change your mind, your authorization must be revoked in writing. To revoke your authorization, please write to:
  
  Dr. Carla Miller, Ph.D.
  331A Campbell Hall
  1787 Neil Avenue
  Columbus, Ohio 43210

  Initials/Date: ___________________
• Signing this authorization also means that you will not be able to see or copy your study-related information until the study is completed. This includes any portion of your medical records that describes study treatment.

Contacts for Questions

• If you have any questions relating to your privacy rights, please contact:
  HIPPA Privacy Manager
  The Ohio State University Medical Center
  140 Doan Hall
  410 W. Tenth Avenue
  Columbus, Ohio 43210

• If you have any questions relating to the research, please contact:
  Dr. Carla Miller, Ph.D.
  331A Campbell Hall
  1787 Neil Avenue
  Columbus, Ohio 43210
  614-292-1391
cmiller@ehe.osu.edu

Signature

I have read (or someone has read to me) this form and have been able to ask questions. All of my questions about this form have been answered to my satisfaction. By signing below, I permit Dr. Carla Miller and the others listed on this form to use and share my personal health information for this study. I will be given a copy of this signed form.

Signature ______________________________________________________
(Subject or Legally Authorized Representative)

Name __________________________________________________________
(Print name above)
(If legal representative, also print relationship to subject.)

Date___________ Time _________ AM / PM

Initials/Date: ____________________
APPENDIX F

Mini-Mental State
### Mini-Mental State

<table>
<thead>
<tr>
<th>Max Score</th>
<th>Score</th>
<th>Orientation</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td></td>
<td><strong>Administrator:</strong> Ask for the date. Then specifically ask for the parts omitted, e.g., “Can you tell me what season it is?” One point for each correct.</td>
</tr>
<tr>
<td>5</td>
<td></td>
<td>1. Year? (1 point)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Season? (1 point)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Date? (1 point)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4. Day? (1 point)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5. Month? (1 point)</td>
</tr>
</tbody>
</table>

| 5         |       | **Administrator:** Ask in turn, “Can you tell me the name of this hospital?” (town, county, etc.) One point for each correct. |
| 5         |       | 1. State? (1 point) |
|           |       | 2. County? (1 point) |
|           |       | 3. Town? (1 point) |
|           |       | 4. Hospital? (1 point) |
|           |       | 5. Floor? (1 point) |

| 3         |       | **Registration** |
|           |       | **Administrator:** Name 3 objects; 1 second to say each. Then ask the patient all 3 after you have said them. The first repetition determines his score (0-3). Give 1 point for each correct answer. Then repeat them until he learns all 3. Count trials and record, up to 6 trials. If he does not eventually learn all 3, recall cannot be meaningfully tested. |
|           |       | 1. Chair (1 point) |
|           |       | 2. Ball (1 point) |
|           |       | 3. Horse (1 point) |
|           |       | Trials? ______________ |

| 5         |       | **Attention and Calculation** |
|           |       | **Administrator:** Ask the patient to begin with 100 and count backwards by 7. Stop after 5 subtractions. Score the total number of correct answers. |
|           |       | 1. 93 (1 point) |
|           |       | 2. 86 (1 point) |
|           |       | 3. 79 (1 point) |
|           |       | 4. 72 (1 point) |
|           |       | 5. 65 (1 point) |
OR

5

Administrator: If the patient cannot or will not perform this task, ask him to spell the word “world” backwards. Score = number of letters in correct order. E.g., dlrow = 5; dlorw = 3

Correct answer = DLROW (5 points)

1. Record participant’s spelling _________________________

Recall

3

Administrator: Ask for the three objects repeated above; 1 point for each correct.

1. Chair (1 point)
2. Ball (1 point)
3. Horse (1 point)

Language

2

Naming

Administrator: Show the patient a wrist watch and ask him what it is. Repeat for pencil.

1. Wrist watch (1 point)
2. Pencil (1 point)

1

Repetition

Administrator: Ask the patient to repeat the sentence after you. Allow only one trial.

1. “No ifs, ands or buts.” (1 point)

3

3-stage command

Administrator: Give the patient a piece of plain blank paper and repeat the command. 1 point for each part correctly executed.

1. “Take a paper in your right hand, fold it in half, and put it on the floor.”
   1. Right hand (1 point)
   2. Fold in half (1 point)
   3. Put on floor (1 point)
<table>
<thead>
<tr>
<th>1</th>
<th><strong>Reading</strong></th>
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<tbody>
<tr>
<td>Administrator. On a blank piece of paper print the sentence, “Close your eyes” in letters large enough for the patient to see clearly. Ask him to read it and do what it says. Score 1 point only if he actually closes his eyes.</td>
<td></td>
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<tr>
<td>1. Close eyes? (1 point)</td>
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<tr>
<th>1</th>
<th><strong>Writing</strong></th>
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<tr>
<td>Administrator: Give the patient a blank piece of paper and ask him to write a sentence for you. Do not dictate a sentence, it is to be written spontaneously. It must contain a subject and verb and be sensible. Correct grammar and punctuation are not necessary.</td>
<td></td>
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<tr>
<td>1. Sentence? (1 point)</td>
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<th><strong>Copying</strong></th>
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<tr>
<td>Administrator: On a clean piece of paper, draw intersecting pentagons, each about 1 inch, and ask him to copy it exactly as it is. All 10 angles must be present, and 2 must intersect to score 1 point. Tremor and rotation are ignored.</td>
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<tr>
<td><img src="image.png" alt="Intersecting Pentagons" /></td>
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<tr>
<th><strong>Total Score?</strong></th>
<th>Administrator: If total score is less than 20, participant does not qualify for the intervention.</th>
</tr>
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</table>

| **ASSESS level of consciousness along a continuum (Mark X appropriately)** |
| --- | --- | --- | --- |
| Alert | Drowsy | Stupor | Coma |
APPENDIX G

Medication Tracking Form
# Medication Tracking Sheet

<table>
<thead>
<tr>
<th>Medication Name</th>
<th>Dosage How much? How often?</th>
<th>Taken for what reason?</th>
<th>Taken for how long?</th>
<th>Any changes?</th>
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</table>

Aside from medication changes, have you had any new medical conditions diagnosed? _____ yes _____ no

If yes, please explain ____________________________________

Have you received any diagnostic or treatment procedures in the last 2 months? _____ yes _____ no

If yes, please explain ____________________________________
APPENDIX H

Diabetes and Demographic Questionnaire
Diabetes Questionnaire

Directions: This questionnaire covers a variety of topics about your diabetes. We value your opinions. You do not have to answer any questions you do not wish to answer, although we would like you to answer as many questions as possible. Your answers are very important for our evaluation. Your answers will be kept completely confidential. All your comments will be read and taken into account. Thank you!

1. In general, would you say your health is:
   _____ Excellent
   _____ Very good
   _____ Good
   _____ Fair
   _____ Poor

2. Do you test your blood sugar at home?
   _____ No (please skip to question 6)
   _____ Yes (please continue with question 3)

3. How many days a week do you test your blood sugar?
   _____ 0-1 days/week
   _____ 2-3 days/week
   _____ 4-5 days/week
   _____ 5-7 days/week

4. On the days that you test, how many times do you test your blood sugar?
   _____ 1-2 times/day
   _____ 3-4 times/day
   _____ 5-6 times/day
   _____ >6 times/day

5. Do you keep a record of your blood sugar test results?
   _____ No
   _____ Yes
   _____ Only unusual values
6. Do you change the foods you eat on the basis of your home blood sugar tests?
   ____No
   ____Yes
   ____Don’t test at home

7. How often do you follow a meal plan or diet?
   ____Never
   ____Rarely
   ____Sometimes
   ____Usually
   ____Always

8. Which methods have you used to control your blood glucose? Please check all that apply.
   ____Exchange Lists
   ____Carbohydrate Counting
   ____Glycemic Index
   ____Smaller Portions
   ____Routine meal plan
   ____Popular or fad diets (please list ________________________________)
   ____Exercise
   ____Other (please describe ________________________________)

9. How often are you preoccupied with your blood sugar?
   ____Never
   ____Rarely
   ____Sometimes
   ____Usually
   ____Always

10. How often are you preoccupied with food?
    ____Never
     ____Rarely
     ____Sometimes
     ____Usually
     ____Always

128
11. How important would you say it is for you to control your blood sugar? On a scale from 0-10, where 0 is not at all important and 10 is extremely important, where would you say you are? Please circle the appropriate number.

0       1       2       3       4       5       6       7       8       9       10
Not at all important                                            Extremely important

12. How confident would you say you are with controlling your blood sugar? On the same scale from 0 to 10, where 0 is not at all confident and 10 is extremely confident, where would you say you are? Please circle the appropriate number.

0       1       2       3       4       5       6       7       8       9       10
Not at all confident                                            Extremely confident

13. In the past year, has your health care provider made changes in your medications on the basis of your home blood sugar tests? Please check one.

   _____ No
   _____ Yes
   _____ Not using medications
   _____ Don’t test
   _____ Not sure

14. How often do you take your diabetes medication correctly as it was prescribed to you?

   _____ Always
   _____ Usually
   _____ Sometimes
   _____ Rarely
   _____ Never
   _____ Do not take diabetes medications
15. What are the three most difficult problems you face when trying to control your blood sugar? (Try to be as specific as possible. If you cannot think of three problems, list as many as you can think of).

1. ______________________________________________________________
2. ______________________________________________________________
3. ____________________________________________________________

16. Have you ever received diabetes education?
   ____No (please skip to question 18)
   ____Yes
   ____Not Sure

17. Please check all of the sources where you received instruction in diabetes from the options below.
   ____Physician in physician’s office
   ____Nurse in physician’s office
   ____Dietitian or nutritionist
   ____Physician or nurse in a hospital
   ____Diabetes education class
   ____Diabetes support group
   ____Health department
   ____Other, please describe ____________________________

18. How many times have you seen a dietitian about a meal plan or diet?
   ____1-2 times
   ____3-5 times
   ____More than 5 times
   ____Never had a visit with a dietitian

19. My last visit with a dietitian was: (please check one)
   ____Within the last 12 months
   ____1-2 years ago
   ____2-3 years ago
   ____More than 3 years ago
   ____Never had a visit with a dietitian
20. Has any health care provider told you to follow a meal plan or diet?
   ____No
   ____Yes
   ____Not sure

21. Have you been told to weigh or measure your food?
   ____No
   ____Yes
   ____Not sure

22. Have you been told to use exchange lists or food group lists to plan
    your meals?
   ____No
   ____Yes
   ____Not sure

23. Have you been told to use carbohydrate counting to plan your meals?
   ____No
   ____Yes
   ____Not sure

24. Currently, would you like more information about the following? (Please
    check all that apply).
    ____Overall diabetes care
    ____Meal planning for blood sugar control
    ____Eating out and blood sugar control
    ____Managing my weight
    ____Exercise and diabetes care
    ____Medications you are taking
    ____How to use the results of blood sugar monitoring
    ____Treatment of high blood sugar
    ____Treatment of low blood sugar
    ____Benefits of improving blood sugar control

25. What is the best way for you to learn new information about diabetes?

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
26. How do you rate your understanding of diet and blood sugar control? (Please circle one number).

<table>
<thead>
<tr>
<th>Poor</th>
<th>Good</th>
<th>Excellent</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4</td>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

27. Which of the following best describes your household income in 2007?

- [ ] Less than $10,000
- [ ] $10,000 to $19,999
- [ ] $20,000 to $29,999
- [ ] $30,000 to $39,999
- [ ] $40,000 to $49,999
- [ ] $50,000 to $59,999
- [ ] $60,000 or more


- [ ] I live alone
- [ ] 1 person
- [ ] 2 people
- [ ] 3 people
- [ ] 4 people
- [ ] 5 or more people

Please rate the following 8 statements using the scale provided:

**In general, I believe that I:**

1. . . .know what part(s) of taking care of my diabetes that I am dissatisfied with.

- [ ] Strongly disagree
- [ ] Somewhat disagree
- [ ] Neutral
- [ ] Somewhat agree
- [ ] Strongly agree

2. . . .am able to turn my diabetes goals into a workable plan.

- [ ] Strongly disagree
- [ ] Somewhat disagree
- [ ] Neutral
- [ ] Somewhat agree
- [ ] Strongly agree
3. . . .can try out different ways of overcoming barriers to my diabetes goals.

<table>
<thead>
<tr>
<th>Strongly disagree</th>
<th>Somewhat disagree</th>
<th>Neutral</th>
<th>Somewhat agree</th>
<th>Strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

4. . . .can find ways to feel better about having diabetes.

<table>
<thead>
<tr>
<th>Strongly disagree</th>
<th>Somewhat disagree</th>
<th>Neutral</th>
<th>Somewhat agree</th>
<th>Strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

5. . . .know the positive ways I cope with diabetes-related stress.

<table>
<thead>
<tr>
<th>Strongly disagree</th>
<th>Somewhat disagree</th>
<th>Neutral</th>
<th>Somewhat agree</th>
<th>Strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

6. . . .can ask for support for having and caring for my diabetes when I need it.

<table>
<thead>
<tr>
<th>Strongly disagree</th>
<th>Somewhat disagree</th>
<th>Neutral</th>
<th>Somewhat agree</th>
<th>Strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

7. . . .know what helps me stay motivated to care for my diabetes.

<table>
<thead>
<tr>
<th>Strongly disagree</th>
<th>Somewhat disagree</th>
<th>Neutral</th>
<th>Somewhat agree</th>
<th>Strongly agree</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>
8. . . . know enough about myself as a person to make diabetes care choices that are right for me.

[ ] Strongly disagree
[ ] Somewhat disagree
[ ] Neutral
[ ] Somewhat agree
[ ] Strongly agree
APPENDIX I

Self-Efficacy Questionnaire
**Confidence Inventory**

**Directions**: Several statements are listed below. After considering the difficulty of each statement, please rate how confident you feel about performing the activity now. We are not asking if you actually perform the behavior but how confident you feel about each statement. Place an X in the column that indicates how strongly you agree or disagree with each statement.

Several questions include statements about the glycemic index. The glycemic index is a measure of how high blood glucose (blood sugar) increases after eating.

**Example:**

<table>
<thead>
<tr>
<th></th>
<th>Strongly disagree</th>
<th>Moderately disagree</th>
<th>Neither agree nor disagree</th>
<th>Moderately agree</th>
<th>Strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. I can eat 3 different vegetables a week.</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

An X has been placed under the number 2. This means you do not feel confident about eating 3 vegetables per week and moderately disagree with the statement.
<table>
<thead>
<tr>
<th></th>
<th>Strongly disagree</th>
<th>Moderately disagree</th>
<th>Neither agree nor disagree</th>
<th>Moderately agree</th>
<th>Strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>I can make healthful food choices based on the glycemic index value of foods.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>I can substitute one low glycemic index food for one high glycemic index food at each meal.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>I can select low glycemic index foods at the supermarket.</td>
<td></td>
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<tr>
<td>4.</td>
<td>I can prepare foods in ways that lower the glycemic index value.</td>
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<tr>
<td>5.</td>
<td>I can prepare recipes using foods with a low glycemic index.</td>
<td></td>
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</tr>
<tr>
<td>6.</td>
<td>I can choose low glycemic index foods when I eat out.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Strongly disagree</td>
<td>Moderately disagree</td>
<td>Neither agree nor disagree</td>
<td>Moderately agree</td>
<td>Strongly agree</td>
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</tr>
<tr>
<td>7.</td>
<td>I can eat 1 low glycemic index food per day.</td>
<td></td>
<td></td>
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<tr>
<td>8.</td>
<td>I can eat 2 low glycemic index foods per day.</td>
<td></td>
<td></td>
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<tr>
<td>9.</td>
<td>I can eat 3 low glycemic index foods per day.</td>
<td></td>
<td></td>
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<tr>
<td>10.</td>
<td>I can eat 4 low glycemic index foods per day.</td>
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<tr>
<td>11.</td>
<td>I can eat 5 low glycemic index foods per day.</td>
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<tr>
<td>12.</td>
<td>I can eat 6 low glycemic index foods per day.</td>
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<tr>
<td>13.</td>
<td>I can eat 7 low glycemic index foods per day.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Strongly disagree</td>
<td>Moderately disagree</td>
<td>Neither agree nor disagree</td>
<td>Moderately agree</td>
<td>Strongly agree</td>
</tr>
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<td>0</td>
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<td>1</td>
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<td>2</td>
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<td>4</td>
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<td>8</td>
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<tr>
<td>9</td>
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<td></td>
</tr>
<tr>
<td>10</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

14. I can eat 8 low glycemic index foods per day.

15. I cannot prepare foods that are low in glycemic index.

16. I have to make too many changes in the way I eat to follow a low glycemic index diet.

17. I cannot lower the glycemic index of my diet.
APPENDIX J

Individual Session Interview
Individual Session Interview

1. What do you hope to gain by participating in this program?

*In order for me to help you achieve these goals, I need to learn more about your medical history and diabetes management.*

2. What physician do you see for your diabetes management? ____________________

_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________

3. How often do you see him/her? _________________________________________

**Medical History:**

1. Please describe any weight reduction methods you have tried in the past.

_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________

2. Were your efforts at weight loss successful? Yes _______ Amount lost __________

No ______ Why not? ____________________________________________________

3. Do you have a history of high blood pressure? Yes _______ No _______

4. Do you have a history of high blood cholesterol or triglycerides? Yes _____ No _____

If known:

TC = _______ Date __________ 
LDL = _______ Date __________ 
HDL = _______ Date __________ 
Tg = _______ Date __________

5. Do you self-monitor your blood glucose at home?

If yes, what are your usual blood glucose values?
Fasting = ____________________ Nonfasting = ____________________

6. How often do you experience low blood sugars? ________________________
Medications
What medications, including diabetes medications, are you currently taking? (Record on medication tracking sheet)

Physical Activity
Administer Modified Physical Activity Questionnaire

Diet History
Please describe your usual dietary intake in a typical day.

Does anyone in your household, other than yourself, have any special dietary needs?
Yes _______ No _______
If yes, please describe
_____________________________________________________________________
_____________________________________________________________________

Diabetes History
1. What's the hardest thing about managing your diabetes?

2. Can you give me an example?

3. What is YOUR goal for changing your self-care behaviors?
4. Is that goal realistic?

5. How strong is your commitment to pursuing this goal?

6. What would keep you from reaching your goal?

7. Have you successfully dealt with that issue before? Would your solution work now?

8. Who do you turn to for “moral” support in managing your diabetes?

_____________________________________________________________________

9. Thinking only of yourself, what is YOUR personal goal for diabetes management?

What questions do you have about your diet or nutrition? _________________
_____________________________________________________________________
_____________________________________________________________________

What questions or concerns do you have about participating in this program? ______
_____________________________________________________________________
_____________________________________________________________________
APPENDIX K

Personal Goal Difficulty Questionnaire
**Personal Goal Difficulty Questionnaire**

**Directions:** Please indicate how easy or difficult it will be for you to reach your **PERSONAL** health goal. Your personal health goal was the goal you filled out on the Personal Goal Commitment Questionnaire. The choices range from zero which represents very easy to 8 which represents very difficult. Place an X in the column that best represents your level of feeling about the goal.

<table>
<thead>
<tr>
<th>Very easy</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>Not easy or difficult</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>Very difficult</th>
<th>8</th>
</tr>
</thead>
</table>

ID No. __________
Date __________
APPENDIX L

Personal Goal Commitment Questionnaire
**Personal Goal Commitment Questionnaire**

**Directions:** A **personal health goal** is something you want to do to improve or maintain your health. Several statements are listed below about your **PERSONAL** health goal. Place an X in the column that indicates how strongly you agree or disagree with each statement.

My **personal health goal** is: ______________________________________________________________

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly disagree</th>
<th>Disagree</th>
<th>Neither agree nor disagree</th>
<th>Agree</th>
<th>Strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. It is hard to take this goal seriously.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. It is unrealistic for me to expect to reach this goal.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. It is quite likely that this goal may need to be revised, depending on how things go.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Quite frankly, I don't care if I achieve this goal or not.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. I am strongly committed to pursuing this goal.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. It would not take much to make me abandon this goal.</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>7. I think this goal is a good goal to shoot for.</td>
<td></td>
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</tbody>
</table>

ID No. ____________________________________________ Date: ________________________________
APPENDIX M

Food Record and Blood Glucose Monitoring Form
<table>
<thead>
<tr>
<th>TIME</th>
<th>PLACE</th>
<th>FOODS AND BEVERAGES</th>
<th>COMPLETE DESCRIPTION</th>
<th>GI Value</th>
<th>Blood Glucose Level</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>A.m.</td>
<td>7 0 0</td>
<td>Home Cereal</td>
<td>Quaker instant oatmeal, cooked and prepared</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>with water</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A.m.</td>
<td>7 0 0</td>
<td>Home Orange Juice</td>
<td>Tropicana Pure Premium Extra Pulp</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Medication**

**Number of Tablets**

**Dose**
For each food or beverage listed, how much did you eat or drink?

<table>
<thead>
<tr>
<th>FOODS AND BEVERAGES</th>
<th>PLACE</th>
<th>TIME</th>
<th>VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TIME</th>
<th>PLACE</th>
<th>VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>HR</td>
<td>MIN</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>OZ</th>
<th>TB</th>
<th>tsp</th>
<th>Grams</th>
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<td></td>
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<table>
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</table>

<table>
<thead>
<tr>
<th>BLOOD GLUCOSE LEVEL</th>
<th>GI VALUE</th>
</tr>
</thead>
<tbody>
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<td></td>
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<table>
<thead>
<tr>
<th>CREATION</th>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>COMPLETE DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>
APPENDIX N

Attendance Record
APPENDIX O

Assigned Goal Difficulty Questionnaire
**Goal Difficulty Questionnaire**

**Directions:** Please indicate how easy or difficult it will be for you to reach the goal you were given. The choices range from zero which represents very easy to 8 which represents very difficult. Place an X in the column that best represents your level of feeling about the goal.

<table>
<thead>
<tr>
<th>Very easy</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>Not easy or difficult</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>Very difficult</th>
<th>8</th>
</tr>
</thead>
</table>
APPENDIX P

Assigned Goal Commitment Questionnaire
Goal Commitment Questionnaire

Directions: Several statements are listed below about your goal. Place an X in the column that indicates how strongly you agree or disagree with each statement.

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly disagree</th>
<th>Disagree</th>
<th>Neither agree nor disagree</th>
<th>Agree</th>
<th>Strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. It is hard to take this goal seriously.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. It is unrealistic for me to expect to reach this goal.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. It is quite likely that this goal may need to be revised, depending on how things go.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Quite frankly, I don't care if I achieve this goal or not.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. I am strongly committed to pursuing this goal.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. It would not take much to make me abandon this goal.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. I think this goal is a good goal to shoot for.</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
APPENDIX Q

Assigned Goal Satisfaction Questionnaire
**Goal Satisfaction Questionnaire**

**Directions:** Please indicate your level of satisfaction or dissatisfaction with the goal you were given on a scale of 0 to 8. The choices range from zero which represents a great deal of dissatisfaction to 8 which represents a great deal of satisfaction. Place an X in the column that best represents your level of feeling about the goal.

<table>
<thead>
<tr>
<th>A great deal of dissatisfaction</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>No satisfaction, No dissatisfaction</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>A great deal of satisfaction</th>
<th>8</th>
</tr>
</thead>
</table>
APPENDIX R

Weekly Goal Satisfaction Questionnaire
Weekly Goal Satisfaction Questionnaire

**Directions:** Please indicate your level of satisfaction or dissatisfaction in meeting your goal last week on a scale of 0 to 8. The choices range from zero which represents a great deal of dissatisfaction to 8 which represents a great deal of satisfaction. Place an X in the column that best represents your level of feeling about how well you met the goal.

<table>
<thead>
<tr>
<th>A great deal of dissatisfaction</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>No satisfaction, No dissatisfaction</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>A great deal of satisfaction</th>
<th>8</th>
</tr>
</thead>
</table>
APPENDIX S

End of Study Evaluation
GOAL Program Evaluation

Directions: Please answer each of the following questions. Your input will help us improve the program for people with diabetes. For the first set of statements, please place a check in the column that best represents your satisfaction with the program using the scale below. Thank you!

1= poor  2 = fair  3=good  4=very good  5=excellent

<table>
<thead>
<tr>
<th>Statement</th>
<th>1</th>
<th>2</th>
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<tbody>
<tr>
<td>1. Comfort of facility</td>
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<td>2. Comfort with staff</td>
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<td>3. Competence and knowledge of person working with you</td>
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<td>4. Quality of staff</td>
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<td>5. Satisfaction with amount of help received</td>
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<td>6. Appropriateness of program for your needs</td>
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<td>7. Ability of program to help you deal more effectively with diabetes</td>
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<td>8. Program organization</td>
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<td>9. Information provided in workbook</td>
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<td>10. Ability of workbook to reinforce the information presented during group meetings</td>
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<td>11. Length of group sessions</td>
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<td>12. Usefulness of feedback received on monitoring records</td>
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<td>13. Likelihood that you will use this information in the next 1 month</td>
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<td>14. Likelihood that you will use this information in the next 6 months</td>
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<td>15. Likelihood that you would recommend this program to someone else with diabetes</td>
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Please rate the following items on a scale of 1 - 5 regarding the helpfulness of the program by checking the appropriate column.

1 = Not at all helpful  2 = Somewhat helpful  3 = Unsure if helpful or not  4 = Helpful  5 = Very helpful

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<tr>
<th>Statement:</th>
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<tbody>
<tr>
<td>1. Learning that others face a similar situation and experiences</td>
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<td>2. Seeing how others cope with diabetes</td>
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<td>3. Learning different ways to approach similar problems</td>
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<td>4. Receiving advice and practical suggestions</td>
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<td>5. Getting honest and individualized feedback</td>
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<td>6. Specific practice activities during the group sessions</td>
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<td>7. Recognizing that I can take responsibility for my own decisions and actions</td>
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<td>8. Learning more about my own positive strengths</td>
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<td>9. Learning more about personal areas for improvement</td>
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Please complete the following questions about the GOAL program.

1. What was your overall impression of the program?

2. Has the program helped you meet your needs for managing your diabetes? Why or why not?

3. What strategy presented during the program helped you make changes in your food c

4. What changes would you recommend to the program?