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A High Fiber Diet Versus a Low-Carbohydrate Diet for Weight Loss in Obese Individuals With or Without Type 2 Diabetes

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A HIGH FIBER DIET VERSUS A LOW-CARBOHYDRATE DIET FOR WEIGHT LOSS IN OBESE INDIVIDUALS WITH OR WITHOUT TYPE 2 DIABETES

By

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Each person whose signature appears below certifies that this dissertation, in his/her opinion, is adequate in the scope and quality as a dissertation for the degree of Doctor of Public Health.

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ABSTRACT OF THE DISSERTATION

A High Fiber Diet versus a Low-Carbohydrate Diet for Weight Loss in Obese Individuals With or Without Type 2 Diabetes

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In the United States, obesity rates have climbed steadily over the years. Many different diets for weight loss have been proposed and studied, yet no one diet seems to clearly be more beneficial. Among diets that have been promoted are those high in fiber and low in carbohydrates, yet thus far, results of these studies have been mixed.

Using a 2x2 complete factorial design, 173 obese men and women with or without type 2 diabetes were randomized to one of two conditions: (a) a high fiber diet ($\geq$ 40 grams of fiber per day for women, $\geq$ 50 grams of fiber per day for men), or (b) a low-carbohydrate diet (< 120 grams carbohydrate per day for both men and women). The two diets were not matched on any macronutrient nor were there any calorie restrictions. Individuals were followed for 16 weeks, upon which participants' BMI, waist circumference, blood lipids (total, HDL, and LDL cholesterol, and triglycerides), fasting blood sugar levels, and HbA_{1c} were measured. Additionally, lipid profiles, fasting blood sugar and HbA_{1c} among those with and those without type 2 diabetes were compared.

While both groups experienced weight loss, decreases in BMI, waist and hip circumferences and blood pressure, independent *t* tests revealed no significant differences between diets after 16 weeks with regards to these factors. Total cholesterol (mean difference between groups=9 mg/dL, p= 0.038) and LDL-C levels (mean difference between groups=7 mg/dL, p=0.045) significantly decreased amongst those on the high fiber diet when compared to those on the low-carbohydrate diet. Two-way ANOVA analyses revealed no significant differences in glucose and HbA_{1c} levels between those with diabetes when compared to those without.

In conclusion, weight loss and several CVD risk factors were similar in obese subjects following a high fiber compared to a low-carbohydrate diet, while total and LDL-C levels were lower on the high fiber diet. When examining the macro- and micronutrient composition between groups, high fiber dieters consumed significantly fewer B-vitamins, whereas low-carbohydrate dieters consumed significantly more sodium, cholesterol, and total fat than those in the high fiber group. Therefore, the pro-atherogenic effects of a low-carbohydrate may need to be further examined in future studies.

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CHAPTER 1

INTRODUCTION

A. Statement of the Problem

According to the Centers for Disease Control and Prevention (CDC), a rapid increase in the rates of obesity has occurred within the last 20 years (2009). In fact, it is estimated that in the U.S., more than 72 million adults are obese (Ogden, Carroll, McDowell & Flegal, 2007). Obesity is a major public health concern as it increases one's risk for a number of diseases, such as type 2 diabetes and heart disease. Obesity causes approximately 280,000 adult deaths each year and is the second highest cause of preventable death after smoking (Bautista-Castaño, Molina-Cabrillana, Montoya-Alonso, & Serra-Majem, 2004).

With regard to type 2 diabetes, it is estimated that in the U.S. approximately 21 million individuals suffer from this disease (National Institutes of Health, 2007) and by 2050 this number is expected to increase dramatically (Davis, Forbes & Wylie-Rosett, 2009a). These numbers are of concern because the expected increase in the incidence of type 2 diabetes is closely linked to the projected increase in the rates of obesity. In fact, overweight and obesity are considered the most important predictors of diabetes (Hu, Manson, Stampfer, Colditz, Liu, Solomon et al., 2001). Excess body weight may lead to problems with insulin secretion and/or insulin sensitivity which could cause chronic hyperglycemia. In turn, this may lead to a number of comorbidities such as kidney disease, nervous system disorders, amputations, and cardiovascular disease. However, improved glycemic control and reduced risk for cardiovascular disease were found when participants experienced weight loss (Davis et al., 2009a).

A number of factors have been identified as possible causes of obesity such as an increase in the consumption of energy-dense foods and low levels of physical activity. Currently, there is no consensus among health professionals regarding the treatment of obesity.

1. Weight Loss Diets

A number of diets have been studied over the years, however no one diet appears to be superior with regards to treating obesity and type 2 diabetes. Dansinger and his colleagues (2005) compared the Atkins, Ornish, Weight Watchers, and Zone diets and monitored obese participants' body weight and risk for heart disease. After 1 year, they concluded that all four diets helped reduce body weight with no one diet emerging as superior for weight loss.

With regard to type 2 diabetes, diet recommendations have changed frequently since the 1950s (Davis et al., 2009a). Initially, avoiding simple sugars and consuming 40% of one's calories from carbohydrates, 40% from fat, and 20% from protein was the recommendation for most type 2 diabetics. However, in an effort to reduce complications from cardiovascular disease, the focus shifted to individualized meal plans with no specific recommendations for macronutrient intakes.

2. Effects of Dietary Fiber on Body Weight

Combating obesity using a high fiber diet has been promoted for the last few decades (Trowell & Burkitt, 1986) with somewhat inconclusive results. Through mainly observational studies, researchers have found that fiber may be protective against weight gain (van Dam & Seidell, 2007). After reviewing data from the Nurses Health Study and the Coronary Artery Risk Development in Young Adults (CARDIA) study, it appears that weight gain is inversely related to fiber intake (Liu, Willett, Manson, Hu, Rosner & Colditz, 2003; Ludwig, Pereira, Kroenke, Hilner, Van Horn, Slattery et al., 1999). However, a review of fiber and body weight found that fiber intake was significantly correlated with weight in some but not all studies (Slavin, 2005).

Clinical trials also appear to support the relationship between fiber and weight loss. A prospective study of otherwise healthy individuals found they experienced unexpected weight loss during the first 11 weeks of consuming a low-fat, high fiber diet (Raben, Jensen, Marckmann, Sandstrom & Astrup, 1995). Using elderly participants, Hays, et al. (2004) found significant weight loss after consumption of an *ad libitum* high fiber diet with no calorie restriction. While these results appear promising, researchers have yet to determine whether an increase in fiber intake is truly responsible for the observed weight loss, or whether these effects are mediated by the other aspects of one's diet, such as calorie restriction, protein consumption, and lower fat foods. Additionally, many of these studies were performed in the short-term (less than 6 months). It has been postulated that the body may adapt to high fiber diets leading to only temporary results (Pasman, Westerterp-Plantenga, Muls, Vansant, van Ree & Staris, 1997).

Researchers at Pennsylvania State University examined the role of whole grains on weight loss by placing obese individuals with metabolic syndrome in one of two groups: a diet high in whole grain food sources versus a diet high in refined grains and found both groups lost similar amounts of body fat (Katcher, Legro, Kunselman, Gillies, Demers, Bagshaw et al., 2008). However, those consuming more whole grains lost more abdominal fat than those in the refined grain group. Therefore, it may be necessary to assess body fat distribution in future studies. Examining fiber and its effect on type 2 diabetes, the Finnish Diabetes Prevention study found that overweight middle-aged individuals consuming a low fat, high fiber diet lost more weight than those consuming a high fat, low fiber diet (Lindstrom, Peltonen, Eriksson, Louheranta, Fogelholm, Uusitupa et al., 2006). The researchers also discovered a decreased incidence of type 2 diabetes after a 4-year follow-up period.

Some have speculated that foods that are high in fiber typically have a lower glycemic index, which may delay absorption in the gut, leading to greater feelings of satiety. Yet, consuming foods that have a low glycemic index will not necessarily result in greater weight loss (Sloth, Krog-Mikkelsen, Flint, Tetens, Bjorck, Vinoy et al., 2004).

3. Effects of Dietary Fiber on Blood Lipids

Fiber may not only have a protective effect on weight, but may help decrease low-density lipoprotein cholesterol (LDL-C) levels in the blood. Results of a meta-analysis revealed that a diet high in fiber and carbohydrates compared to a diet moderate in carbohydrate and low in fiber led to significantly decreased LDL-C levels in diabetic individuals (Anderson, Randles, Kendall & Jenkins, 2004). However, this review did not compare high fiber diets with other weight loss diets, such as low-carbohydrate diets.

4. Effects of a Low-Carbohydrate Diet on Body Weight

Recently, low-carbohydrate diets have been gaining popularity. In fact, the CDC has estimated that 85% of Americans are aware of low-carbohydrate diets (Finney-Rutten, Lazarus-Yaroch, Colón-Ramos & Uriyoán, 2008). In short-term studies, these diets appear to be effective in promoting weight loss. For example, after comparing a low-carbohydrate high protein diet to a low-fat diet, researchers found that those on the low-carbohydrate diet lost more weight and had improved cardiovascular indicators when compared to those consuming the low-fat diet (Shai, Henkin & Stampfer, 2008). In 2003, Nordmann, et al. (2006) compared a low-carbohydrate diet to a calorie restricted low-fat diet in obese individuals and found those consuming the low-carbohydrate diet had lost significantly more weight than those on the low-fat diet. However, when results were compared over the long-term, low-carbohydrate diets did not appear to be any more beneficial than a low-fat diet for weight loss (Shai, Henkin & Stampfer, 2008).

5. Effects of a Low-Carbohydrate Diet on Blood Lipids

With regards to blood lipid profiles, low-carbohydrate diets yield mixed results. When comparing a low-fat diet to a low-carbohydrate diet, Brinkworth et al. (2009) found those in the low-fat group had a significant drop in their total and LDL-C levels, while those in the low-carbohydrate group had improved high-density lipoprotein cholesterol (HDL-C) and triglyceride levels even under isocaloric conditions. Low-carbohydrate diets have been criticized because of its potentially detrimental effects of LDL cholesterol levels (Brehm & D'Alessio, 2008). However, further research is needed to determine whether low-carbohydrate diets may or may not improve blood lipid profiles.

Is one diet superior to the other with regards to weight management and cardiovascular indicators?

6. Low Calorie Diets

With most diet studies of those participants that receive treatment, only a small percentage actually lose weight, and of those that do lose weight, many tend to regain it (Bautista-Castaño et al., 2004). The cornerstone for treating obesity has been the use of low-calorie diets (Heymsfield, Harp, Reitman, Beetsch, Schoeller, Erondu et al., 2007). By decreasing the intake of calories, it is presumed that a negative energy balance will be achieved which will lead to subsequent weight loss. However, after decades of research, it appears that low-calorie diets have resulted in only modest weight loss. In fact, individuals tend to lose weight rapidly during the first two weeks of treatment and begin to regain their weight after 26 weeks of treatment. Studies with overweight type 2 diabetics yielded similar results (Davis et al., 2009a).

Various explanations have been proposed with regard to the poor outcomes associated with low-calorie diets. One theory assumes that metabolic adaptations occur within individuals, such that as calorie intake decreases, so does resting metabolic rate. Therefore, as an individual loses weight, they are also losing cell mass in metabolically active tissues, which will in turn lower their total energy expenditure. Additionally, as body weight is lost calories spent walking, climbing stairs, and other weight-related activities begin to decrease. It has also been proposed that as body weight decreases, equilibrium within the body is reached such that an individual will find it very difficult to lose more weight. Lastly, some have claimed that poor diet adherence is to blame.

7. Diet Adherence

It has been known since the 1950s that treating obesity often results in a high rate of failure (Bautista-Castaño et al., 2004). After performing a review of the relevant literature, Heymsfield et al. (2007) discovered that poor diet adherence was the likely cause for the underwhelming weight loss in the majority of study participants. In their study of the four mainstream diets, Dansinger et al. (2005) found a positive correlation between self-reported dietary adherence and failure to fully comply at baseline. Self-reported dietary adherence was also positively correlated with a gradual decrease in reported compliance at the 1-year follow-up. Bautista-Castaño et al. (2004) discovered that in Spanish subjects, significant factors predictive of dietary compliance included being male, participation in fewer past dietary programs, having a lower initial body mass index (BMI), and older age. The authors acknowledged that, with regard to future weight loss studies, it is vital that there be continuous follow-up along with methods for determining dietary adherence.

B. Purpose of the Study

Researchers have yet to compare the effects of a high fiber diet versus a low-carbohydrate diet on weight loss and blood lipids. Therefore, I hope to explore the differences between these two diets on obese participants' BMI, waist circumference, blood lipids (total serum cholesterol, low-density lipoprotein, high density lipoprotein, and triglycerides), and hemoglobin A_{1c}. I also wish to compare the effects of these two diets on those with and without type 2 diabetes.

C. Theoretical Justification

1. High Fiber Diets

Because foods that are higher in fiber delay the digestion and absorption process, it is plausible that individuals will have decreased body weight, lowered BMI values, and have improved blood lipid profiles. The rationale for this is that foods higher in fiber, such as wholegrain breads, have been shown to decrease levels of triglycerides in the blood (Flight & Clifton, 2006) by blocking the absorption of fat and cholesterol in the small intestine, leading to lower blood lipid concentrations (Talati, Baker, Pabilonia, White, & Coleman, 2009). Additionally, foods that are high in fiber tend to increase feelings of satiety (Slavin, 2005), which may lead to a decrease in total daily calorie consumption and a subsequent reduction in body weight. Finally, fiber tends to decrease transit time in the intestines, which may reduce calorie absorption. As total daily calorie consumption decreases, modest weight loss could be expected.

2. Legumes

Pulses such as beans and lentils may also promote weight loss because they are a slow release carbohydrate and because of their high fiber content. They may also prevent cardiovascular disease and possibly diabetes through their lipid lowering and glucose-stabilizing properties (Dilis & Trichopoulou, 2009).

A study by Venn, et al. (2010) discovered that when individuals were placed on a diet rich in pulses and whole grains, individuals experienced greater reductions in waist circumference when compared to a control group. More recently, a randomized control trial was conducted comparing two hypocaloric diets, one that was legume-based and one that was legume-free (Hermsdorff, Zulet, Abate & Martinez, 2011). Those in the legume-based diet achieved significantly more losses in weight, LDL-C, and blood pressure. However, a review of the literature revealed that more studies are needed to determine whether legumes assist with weight management (Williams, Grafenauer & O'Shea, 2008).

With regards to lipid profiles, Zhang et al., (2010) studied 64 middle-aged men and revealed that a high legume, low glycemic index diet significantly reduced both total serum cholesterol and LDL-C levels.

The consumption of legumes may have an effect on type 2 diabetes. A review of the literature revealed that consuming whole grains and legumes is beneficial in the prevention and management of type 2 diabetes (Venn, & Mann, 2004). A randomized clinical trial assigned otherwise healthy Spanish subjects to either a low or high fiber diet (Aller, de Luis, Izaola, La Calle, del Olmo, Fernandez et al., 2003). After 3 months, the high fiber group experienced significantly lower fasting glucose levels when compared to baseline values.

3. Low-Carbohydrate Diets

The relationship between low-carbohydrate diets and weight is not as defined in the literature. Most, if not all, low-carbohydrate diets require a subsequent increase in protein consumption. It has been suggested that this increased protein intake may improve feelings of satiety which may cause individuals to consume fewer calories throughout the day (Halton & Hu, 2004). Furthermore, results of short-term studies imply that HDL cholesterol and triglyceride levels tend to improve more with a low-carbohydrate diet than with a low-fat diet (Brinkworth et al., 2009).

In type 2 diabetics, researchers have discovered that low-carbohydrate diets may improve glycemic control (Davis et al., 2009a) when compared to diets higher in carbohydrate. Additionally, it has been found low-carbohydrate diets may have a positive influence on body weight, waist circumference, triglycerides, and insulin resistance.

D. Research Questions

- When obese individuals (with or without type 2 diabetes) eat a high fiber diet how do they compare to those on a low-carbohydrate diet with regard to:
  - BMI?
  - Waist circumference?
  - Lipid profiles (total, HDL, and LDL cholesterol, and triglycerides)?
- When individuals with type 2 diabetes eat a high fiber diet how do they compare with those on a low-carbohydrate diet with regard to hemoglobin A_{1c} levels?
- Do individuals' lipid profiles differ depending on whether or not they are type 2 diabetic?

E. Significance to Preventive Care

As the rates of obesity continue to climb, it is likely that the incidence of largely preventable diseases, such as cardiovascular disease and type 2 diabetes will as well. However, if individuals could possibly prevent or reverse their weight gain by increasing fiber in their diets, this could have profound effects on the rates of morbidity and mortality not only in the U.S. but throughout the world. With no one diet emerging as being truly beneficial for weight loss, results of this study could provide some evidence in this direction which may lead to new dietary recommendations.

CHAPTER 2

LITERATURE REVIEW

A. Overview

Diets high in fiber may be protective against weight gain (van Dam & Seidell, 2007), however many of these findings came from observational studies. Additionally, researchers have yet to determine the effects of increasing fiber in overweight and obese individuals' diet without calorie restriction. With regards to the popular low-carbohydrate diets, the research is even sparser. Furthermore, the effects these diets have on type 2 diabetics are underrepresented in the literature. In this chapter I will examine: (a) the relationship between fiber and weight, (b) the connection between fiber and blood lipids (c) the link between low-carbohydrate diets and weight, and (d) the relationship between low-carbohydrate diets and blood lipids (e) the effects of various diets on type 2 diabetics, and (g) the effects of bean consumption on weight. Finally, I will summarize this literature, review the relevant methodology, and include a discussion of areas that need further research.

B. Fiber and Body Weight

Weight loss is thought to be a reflection of the balance between energy intake and energy expenditure. Fiber has been repeatedly shown to affect individuals' feelings of satiety (Bellisle, 2008). It has been postulated that foods that contain a higher fiber content may lead to individuals consuming fewer calories throughout the day due to the increased feelings of satiety (van Dam & Seidell, 2007), which in turn may contribute to weight loss. In fact, Slavin and Green (2007) propose three mechanisms by which dietary fiber may promote weight loss: (a) fiber is typically higher in volume when compared to other energy dense foods, yet is typically lower in calories resulting in the displacement of other calories and nutrients in the diet, (b) consuming fiber leads to more chewing, which may lead to increased satiety, (c) fiber slows the absorption of nutrients in the small intestine, increasing the feeling of fullness.

Kromhout et al. (2001) examined the relationship between participants' levels of physical activity, their consumption of dietary fiber, dietary fat, along with their BMI and subscapular body fat. Using an ecological approach, Kromhout et al. investigated middle-aged men in seven countries and concluded that job-related physical activity and dietary fiber were most correlated with subscapular body fat. A negative correlation exists such that as dietary fiber increased, subscapular body fat decreased. However, ecological models introduce their own biases mainly that of the ecological fallacy (Schwartz, 1994) whereby correlations may appear to be present at the ecological level may in fact become larger, smaller, or disappear altogether when examining participants at the individual level. Additionally, the authors examined only work-related physical activity, with no mention of levels of leisure physical activity, which could be a potential confounder.

Howarth, Huang, Roberts, Lin, and McCrory (2007) compared eating patterns and BMI among younger (those between 20 and 59 years) and older (those between 60 and 90 years) adults, using data from the Continuing Survey of Food Intakes by Individuals (CSFII). They found an interaction where low fiber consumption together with a high intake of fat was predictive of BMI. Therefore, no clear correlation between fiber and body weight could be determined.

The idea that a food's glycemic index is related to weight has also been studied. Glycemic index is typically defined as a measure of how much a certain carbohydrate containing food increases one's blood glucose when compared to a standard food (often white bread or pure glucose) (Murakami, Sasaki, Okubo, Takahashi, Hosoi & Itabashi, 2007). Typically, foods that have a lower glycemic index are thought to contain more dietary fiber therefore, a link between lower glycemic index foods and weight loss has also been postulated. One such study by Murakami et al. (2007) found a significant negative correlation between dietary fiber intake and BMI among Japanese women, while glycemic index was significantly positively correlated with BMI. However, it is important to note that correlation does not imply causation; because this was a cross-sectional study, any causal inferences between fiber intake and BMI are difficult to determine.

Contrary to the findings above, Jehn, Patt, Appel, and Miller (2006) found no differences in dietary fiber intake in overweight individuals who maintained their weight loss after a one-year period and those who gained weight after that same time period. Unfortunately, because their sample size was small, it is possible that Jehn et al. may not have had enough power to find a significant effect. Also, it is fairly common for overweight individuals to under-report their food intake (Howarth et al., 2007), which may also affect the results.

C. Fiber and Blood Lipids

Authors in Canada studied premenopausal women (Robitaille, Fontaine-Bisson, Couture, Tchernof, & Vohl, 2005) and discovered that after four weeks those in the intervention group that received 28 grams per day of oat bran saw a significant increase in their high-density lipoprotein cholesterol (HDL-C) when compared to the control group. HDL-C is believed to reduce one's risk for CVD. No significant differences were found with regard to LDL-C. However, because the study only used female participants, results may not be generalizable.

D. Low-Carbohydrate Diets and Body Weight

A meta-analysis conducted by Nordmann et al. (2006) revealed that low-carbohydrate diets may be as effective for promoting weight loss as calorie-restricted diets. The Dietary Intervention Randomized Controlled Trial (DIRECT) compared the effects of three diets on moderately obese subjects: (a) low-fat, calorie restricted (b) Mediterranean, calorie restricted (c) low-carbohydrate, no calorie restrictions (Shai, Schwarzfuchs, Henkin, Shahar, Witkow, Greenberg et al., 2008). After a two-year follow-up, they concluded that the low-carbohydrate diet had a more favorable influence on body weight when compared to the other two diets. However, it should be noted that the participants in this trial were largely male (86%), which may reduce the generalizability of this study.

Brinkworth et al. (2009) compared a low-carbohydrate, high fat diet with a high-carbohydrate, low-fat diet under isocaloric conditions and discovered that both groups experienced similar amounts of weight loss.

E. Low-Carbohydrate Diets and Blood Lipids

The trial conducted by Shai et al. (2008) also concluded that individuals in the low-carbohydrate group had more favorable effects on blood lipids than the low-fat or Mediterranean diets. However, when Nordmann et al. (2006) conducted their meta-analysis on the effects of low-carbohydrate diets versus a low-fat diet, they discovered that total cholesterol and LDL-C levels were significantly improved in the low-fat group.

Brinkworth et al. (2009) compared a low-carbohydrate, high fat diet with a high-carbohydrate, low-fat diet and discovered that the low-carbohydrate group had poorer blood lipid outcomes when compared with the other group. Therefore, there is no clear consensus with regards to low-carbohydrate diets and their effect on blood lipids.

F. Diets and Their Effects on Type 2 Diabetics

Some concern has been expressed regarding the safety of reduced carbohydrate diets in those with type 2 diabetes. However, the American Diabetes Association (ADA) recently acknowledged that low-carbohydrate diets may be effective for weight loss in the short-term (ADA, 2008). Results of a meta-analysis revealed that reduced and/or low-carbohydrate diets may be safe and effective at reducing weight and hemoglobin A_{1c} levels in type 2 diabetics (Dyson, 2004). It is important to note that the majority of the studies analyzed had small sample sizes and were performed in the short term.

After comparing the effects of a low-carbohydrate diet versus a low-glycemic index , reduced-calorie diet in obese individuals with type 2 diabetes, Westman et al. (2008) discovered that those following the low-carbohydrate diet had greater improvements in glycemic control (measured by hemoglobin A_{1c}) than those following the reduced-calorie diet. Additionally, 95.2% of those in the low-carbohydrate group experienced a significant reduction in their diabetes medications, compared with only 65.2% of those in the reduced-calorie group.

After comparing the effects of a high-fat Atkins style diet, a high-protein Zone diet, and a high-carbohydrate, high fiber diet in insulin resistant obese women, McAuley et al. (2005) discovered a greater decrease in body weight, waist circumference, and triglycerides in the Atkins and Zone groups when compared with the high carbohydrate, high fiber diet group. However, McAuley et al. only followed participants for 8 weeks. It is unknown whether any differences between the groups would have been consistent over a longer period of time. Additionally, only women were sampled therefore the generalizability of these results may be limited.

Yancy et al. (2005) assigned 21 overweight type 2 diabetics to a low-carbohydrate diet and followed them for 16 weeks. Results showed that participants significantly decreased their body weight, and fasting serum triglyceride and hemoglobin A_{1c} levels. A smaller study conducted by Boden et al. (2005) required 10 patients with type 2 diabetes to consume their usual diet for 7 days followed by a low-carbohydrate diet for 14 days. At the end of the trial, participants had improved blood glucose profiles, insulin sensitivity and hemoglobin A_{1c} levels. However, neither Yancy et al. nor Boden et al. used a comparison group in their study. Without a comparison group it may be difficult to determine if the improved outcomes were significantly different based on the diet alone.

Contrary to the findings above, Davis et al. (2009b) compared a low-carbohydrate diet with a low-fat diet in type 2 diabetics and discovered that both groups lost a similar amount of weight after 1 year. They also discovered that neither group had significant changes in their hemoglobin A_{1c} levels. A study conducted in Norway placed 19 participants with type 2 diabetes on a 3-day low fat diet (Mostad, Qvigstad, Bjerve & Grill, 2004). Participants were also encouraged to consume foods higher in fiber. After the intervention, no changes in daytime blood glucose levels were found. Additionally, no significant changes in fasting insulin and fasting glucose to insulin ratios were reported. However, because the intervention lasted only 3 days, it is possible that the diets may have had a significant effect on blood glucose and insulin levels if the intervention was continued for a longer period of time. Additionally, the small sample size may have also led to the lack of statistically significant results.

G. Legumes

The randomized clinical trial with Spanish volunteers found that those assigned to a diet that consisted of 30.5 grams of fiber each day versus those that were assigned to eat 10.4 grams of fiber each day had significant decreases in LDL-cholesterol and fasting glucose levels after 3 months (Aller et al., 2004). Because the investigators only followed the participants for 3 months, cholesterol and glucose values may only decrease in the short term.

The study conducted by Hemsdorff et al. (2010) compared hypocaloric legume-rich and legume-free diets amongst randomly assigned participants and followed them for 8 weeks. The authors discovered that those consuming the legume-rich diet had lost significantly more weight than their legume-free counterparts. However, because participants were placed on calorie-restricted diets, it is hard to evaluate whether legumes influence one's daily calorie consumption.

H. Conclusions

Data regarding fiber and various health indicators appear to be somewhat mixed. The link between the intake of dietary fiber and weight loss warrants further research. Additionally, many fiber studies attempt to increase participants' intakes of fiber while restricting calories, I propose no calorie restrictions. In the past, many studies were performed using fiber supplements (Hylander & Rossner, 1983), however the use of legumes will be promoted here.

While the majority of the literature presented here seems to favor a negative correlation between fiber intake and weight, the flaws in their methodology warrants caution when interpreting their results.

Intake of dietary fiber and serum lipids appears to be a bit mixed as well. A negative correlation between fiber consumption and LDL-C has been touted in the media, but may not be as clear in the literature. Therefore, it is important to explore this link further. The connection between a low-carbohydrate diet and weight loss and blood lipids is even more convoluted. Furthermore, much of this research does not include those with type 2 diabetes. Studies that do include type 2 diabetics were often conducted in the short-term, or had small sample sizes or lacked comparison groups (Davis et al., 2009b). As the prevalence of type 2 diabetes continues to rise, it is vitally important that these individuals are adequately represented in the literature and that well-designed experiments are used.

CHAPTER 3

METHODS

A. Study Design

The proposed study aimed to compare a high fiber diet with a low-carbohydrate diet for weight loss and CVD risk factors in obese individuals with or without type 2 diabetes. A prospective, randomized experiment, using a 2x2 complete factorial design was conducted using San Bernardino County, California residents as participants. Data collection began in March 2010 and was largely completed by December 2010. After a one week screening period, participants were randomly assigned to one of two diets: a) a high fiber diet ($\geq$ 40 grams of fiber per day for women, $\geq$ 50 grams of fiber per day for men), or b) a low-carbohydrate diet (< 120 grams carbohydrate per day for both men and women).

Following randomization, participants began a three week preparation phase. No calorie restrictions were placed on either diet nor were they matched on any macronutrient. Individuals were followed for 16 weeks, with five follow-up visits in between. These follow-up visits served to track participants' progress and to reinforce their respective diets. During the initial and final visits, outcomes were measured and blood was drawn. Significant differences in BMI, waist circumference, blood glucose, hemoglobin A_{1c} (HbA_{1c}), and blood lipid profiles between both groups and between those with and without type 2 diabetes were of interest.

B. Participants

Individuals were recruited from the San Bernardino area in California. Flyers were placed within the Diabetes Treatment Center in Loma Linda, California. A newspaper advertisement was also published in the *San Bernardino County Sun* and *The Press-Enterprise*. Campus-wide e-mails and flyers were also sent instructing individuals to complete the online screening survey. After the interview or survey was completed and the individual was deemed to be preliminarily eligible, potential participants were asked to complete the initial screening procedure to determine eligibility. The procedure involved a brief physical exam, drawing of fasting blood samples, and a food frequency questionnaire. They physical exam was performed by a medical doctor (MD) whereas the blood samples were drawn by a licensed venipuncturist. After screening, 173 participants were randomly assigned to their respective diets.

Individuals were eligible to participate if they were 18 years of age or older, with a BMI between 30.0 and 44.0 kg/m^2, and if they spoke English. Type 2 diabetics were only eligible if they had been clinically stable within the past three months, which infers that there had been no change in diabetic medications within the three months prior to screening. Exclusion criteria included: pregnancy, lactation, active cancers, participation in another study/trial, dieted within the last 3 months with weight loss exceeding 4 lbs., currently following a vegan diet, type 1 diabetics, have an active eating disorder, currently suffering from an acute or chronic infection, using Byetta or weight loss medication, or gastrointestinal problems that may be worsened by a high fiber diet.

C. Procedures

1. Screening (Week -2)

Those that respond to the flyers completed a telephone interview with the principal investigators in order to determine if they were preliminarily eligible to participate. If deemed eligible, they were given a screening appointment. At this time, informed consent forms were mailed to them directly. Those that completed the online survey and were deemed eligible were also given a screening appointment.

Approximately 30 to 60 participants were screened each month between March and September 2010. At this time, informed consent documents were signed. During the screening process, participants' blood was drawn to determine eligibility.

After individuals had been approved to participate and provided informed consent, they returned within two weeks for an office visit in order to be randomized to one of the aforementioned groups. Ultimately, 201 participants were screened of which 51.7% were White, 25.3% were Hispanic/Latino, 18.0% were Black/African American, and 5% were of another race.

2. Randomization (Week 0)

Some participants were not eligible for randomization or were lost to follow-up. A total of 173 participants were randomized, with 50.9% of them being White, 25.4% were Hispanic/Latino, 18.5% were Black/African American, and 5.2% were of another race. Additionally, amongst those randomized, 27 were diabetics (12 in the high fiber group, 15 in the low-carbohydrate group).

The process of randomization occurred as follows. Respective diets were written on a small piece of paper and sealed in an envelope. A random numbers table was used to determine the diet written in each envelope. A coin toss determined that those numbers that ended in an even digit would indicate the envelope will contain the low-carbohydrate diet assignment, whereas those numbers that ended in odd digits would indicate the envelope will contain the high fiber diet assignment. Written on the outside of each envelope was a unique three digit number which was recorded and used throughout the study to identify participants. Participants were stratified according to their diabetes status to ensure that diabetics were equally represented in both groups. Married couples that participated in the study were assigned to the same diet group.

Each participant was then educated by a Registered Dietitian (RD) with regards to their respective diets and was provided instructional materials to take home (Appendices A and B). Participants were also given a food journal and instructions on how to complete it.

Fasting lab samples were again drawn to establish baseline values for total cholesterol, HDL-C, LDL-C, triglycerides, and fasting plasma glucose. Baseline measures of weight, waist circumference, hip circumference, and blood pressure were also re-assessed. After randomization, a three-week preparation phase and a one-week induction phase followed.

3. Preparation Phase (Weeks 1-3)

The preparation phase was designed to promote compliance and to prepare participants' bodies for the new dietary program. During week 1 of the preparation phase, participants met with an RD for approximately one hour to discuss their respective diets in more detail. Those in the high fiber group began consuming ½ cup of cooked with one meal each day. Beans did not include green beans or peas, rather kidney beans, lentils, black beans, garbanzo beans, and pinto beans were recommended.

Individuals in the low-carbohydrate group began reducing their intake of carbohydrates while increasing their consumption of protein-rich foods such as fish, eggs, and lean meats. Additionally, both groups were given an Adverse Events Questionnaire (Appendix C). This allowed the investigators to address any side effects the participants may be experiencing, such as frequency and consistency of stools, presence and severity of headaches, muscle cramps, and a space for other complaints. Participants were also instructed to complete a daily food record.

During week 2 of the preparation phase, all participants again met with an RD to assess diet compliance and progress. At this time, those in the high fiber group were instructed to begin consuming ½ cup with two meals each day. Those in the low-carbohydrate group were instructed to reduce their carbohydrate intake to approximately 130 grams per day.

Week 3 of the preparation phase involved a brief phone call from an RD. Those in the high fiber group were instructed to begin eating ½ cup of beans with three meals per day while participants in the low-carbohydrate group were to decrease their carbohydrate intake to less than 120 grams per day.

4. Induction Phase (Week 4)

At this time, participants were ready for the one week induction phase (week 4). Here, both groups ate according to their respective meal plans. Individuals were instructed to continue their daily food diary in order to assess compliance. Additionally, each participant was fed for three days. This was designed to educate volunteers with regards to portion sizes and menu options for their respective diets. Gender-specific menus were designed by RD's to meet the macronutrient requirements of each diet. Meals were prepared by a Chef and distributed at the Loma Linda University Research Kitchen where participants were instructed to consume the meals off-site.

5. Maintenance (Weeks 5 -16)

Subsequent weeks consisted of participants maintaining their respective diets. In order to help with compliance, subjects were asked to continue using their daily food diaries. During weeks 6, 8, 12, and 14, subjects met with an RD to discuss compliance and to assess their body weight, waist circumference, and adverse events. Additionally, three 24-hour dietary recalls were made via telephone by the dietitians between weeks 6 and 15 to further assess compliance. Participants were assessed on two weekdays and one weekend day.

During week 16, the final week of the study, subjects again met with an RD to discuss compliance and reassess participants' anthropometrics. Fasting blood samples that included total cholesterol, HDL-C, LDL-C, fasting plasma glucose, and HbA_{1c} were drawn again.

The table below gives the expected macronutrient composition of the diets in recruited subjects at baseline and of each diet as well as expected changes in CVD risk factors for the two diets.

Table 3.1 Macronutrient Composition of Baseline Diets and Experimental Diets with Expected Changes in Selected Cardiovascular Risk Factors

	Baseline	**High Fiber Diet**	**Low-Carbohydrate Diet**
Macronutrients			
% kcals from Carbohydrate	50-60	60-70	20-30
% kcals from Protein	10-15	10-15	30-40
% kcals from Total Fat	30-35	15-25	40-50
Total Dietary Fiber (g)	10-15	40-50	10-15
Outcomes			
Blood pressure	-	↓	↓
HDL cholesterol	-	=	↑
LDL cholesterol	-	↓	↑
Triglycerides	-	↓	↓

kcals=calories; g=grams

D. Measuring Tools

1. Anthropometrics

All anthropometrics were measured by trained graduate students. Participants' weight was measured without shoes using a calibrated Tanita Digital Large Capacity scale (HD-351). Height was also measured without shoes using a calibrated stadiometer. Blood pressure was taken using a Homedics Automatic Deluxe Blood Pressure Monitor (BPA-101). Individuals were required to sit quietly in a chair for 5 minutes with the blood pressure cuff placed on their left arm and both feet planted on the floor. Two readings were obtained. Waist and hip measurements using a standard tape measure were also performed. Participants' waist circumference was determined using a horizontal measure at the level of the umbilicus and recorded to the nearest tenth of a centimeter. Hip circumference was determined using a horizontal measure at the top of the iliac crest and recorded to the nearest tenth of a centimeter. Two readings of both waist and hip were performed and the measurements were averaged.

2. Lab Samples

Participants were asked to fast overnight for at least 8 hours. Drinking water with usual medications, except insulin or other diabetes medications was allowed on the morning of the blood draw. Blood was drawn between 7 and 11:30 am by a state licensed venipuncturist.

During screening, the following tests were run: complete blood count (CBC), thyroid stimulating hormone (TSH), triglycerides, total cholesterol, HDL-C, LDL-C, HbA_{1c}, fasting plasma glucose, creatinine, aspartate aminotransferase (AST), and alanine transaminase (ALT). At randomization, fasting triglycerides, total cholesterol, HDL-C, LDL-C, and glucose were again drawn.

During screening, three 10 milliliter (mL) red top tubes and two purple top tubes were drawn and centrifuged. At randomization and at the end of the study, one red top tube of 10 mL and two 4 mL purple top tubes for plasma were drawn for a total of 7 tablespoons. The samples were centrifuged and stored at 37 degrees Fahrenheit until they were hand-delivered to the Loma Linda University Medical Center Clinical Laboratory for analysis. Standardized laboratory analyses were used.

3. Dietary Compliance

In order to assess dietary compliance, participants were required to keep logs of their food intake. Individuals were encouraged to write down the types of food they ate, portion sizes, along with the day and time of all meals, snacks, and beverages. These food logs were evaluated by an RD during in-house follow-up visits.

Additionally, RD's made random phone calls during weeks 6 and 15 to perform 24-hour dietary recalls for one weekend day and two weekdays. At this time, the Nutrition Data System for Research (NDS-R) version 2008 was used to enter the 24-hour recall data. This system allowed for a more detailed analysis of compliance as well as providing a standardized method for collecting recall data.

4. Exercise

At baseline, individuals were asked about their physical activity levels. During follow-up visits, any changes in exercise frequency, intensity, and/or duration were noted in participants' charts.

5. Medications

Changes in medications were noted using an open-ended question in the Adverse Events Questionnaire.

E. Data Analysis

Data was entered into SPSS version 15.0 and a 10% sample was re-entered to check for accuracy. A separate data set that excluded dropouts was created and analyzed. Initially, dropouts were included in the analyses using last observation moved forward. However, a second analysis was conducted that included only those participants' that completed the study. Both analyses were compared and no significant differences were observed (data not shown).

Differences in sample characteristics were determined using independent *t* tests for continuous variables or chi-square tests for categorical variables. Statistical analyses were initially performed regardless of whether all test assumptions were met. When test assumptions were not met, non-parametric tests were performed and compared to the initial analyses. If p-values were significantly different, variables were then transformed and re-analyzed.

The first research question attempted to examine the relationship between obese individuals (with or without type 2 diabetes) eating a high fiber diet and how they compare to those on a low-carbohydrate diet with regard to BMI, waist circumference, and lipid profiles. An independent samples *t* test was performed for each of these variables. Here, again, when the data were not normally distributed, analyses were performed and compared with non-parametric tests.

The second and third research questions, respectively, explored the differences in HbA_{1c} levels and lipid profiles between those with type 2 diabetes and those without in order to determine if one diet was more effective in improving these variables. In each of these cases, a two-way ANOVA analysis was performed. Changes between baseline and week 16 were assessed and the interactions between diet and diabetes were analyzed.

To assess dietary compliance, reports from the NDS-R database were exported and analyzed. Variables of interest included percentage of calories consumed from carbohydrates, fat, and protein, as well as total grams of protein, total grams of fiber, and the micronutrient composition of both diets. An independent samples *t* test was performed for each of these variables.

Finally, a Chi-square analysis was employed to determine whether there were significant changes in physical activity levels between groups.

F. Power Analysis

In this study, the analyses used were tests for independent means (*t*-test) and two-way ANOVA. Based on Cohen's (1992) estimation of a medium effect size (d=0.50), power = 80%, and $\alpha = 0.05$, 64 participants were needed in each group for a total of 128 participants. A 10% dropout rate was expected. Therefore, 140 participants were needed in this study. However, the dropout rate was 28.9% as only 123 volunteers completed the study.

G. Limitations

Compliance to the assigned meal plan was a possible threat to validity. Adherence to the newly prescribed diet waned over time. In order to assess compliance, participants were required to keep a food diary. Unfortunately, food diaries may be subject to validity problems; having participants estimate portion sizes can lead to errors. Occasionally, response biases occur whereby participants falsely record certain food items in order to appease the clinician. Additionally, during the telephone interviews with a dietitian, participants were required to recall what they had eaten the previous day. Therefore, recall bias could have occurred.

Attrition was another possible threat to validity. Due to the strict nature of both diets, participants chose to leave the study. Analysis of power revealed that 140 volunteers were needed, however only 123 completed the study. Therefore, there may not have been enough power to detect an effect with regards to the other variables in question. Having monetary incentives for those that complete the study may have helped decrease the attrition rate.

While having the study end at 16 weeks was designed to help control for attrition, this relatively short period of time may not have been long enough to detect significant reductions in weight, waist and hip circumference and blood pressure.

Finally, it should noted that while no significant differences were found between groups, both groups experienced reductions in weight, waist and hip circumference and blood pressure. Therefore, it is plausible that both diets are effective. However, without a control group for comparison, this is difficult to determine.

H. Research Ethics

Prior to the start of the study, uncoerced written informed consent was obtained from all participants. The informed consent included potential risks and benefits of participation, a statement of the confidentiality of all records (including lab results) obtained during the study, information regarding whom to contact in case of research-related illness or injury, and a statement that their participation is strictly voluntary.

The Belmont report identifies three basic principles in human research ethics: respect for persons, beneficence, and justice. By providing informed consent, individuals had the right to decide whether or not to participate in the study. Additionally, all participants regardless of ability or disability were protected from harm. Individuals were also free to leave the study at any time for any reason. By adhering to these values, the *respect for persons* principle was met.

The *principle of beneficence* reflects two main issues: individuals are not to be harmed during the experiment and the benefits for participation are maximized while harm is minimized. While there was no intention to do harm, consequences of consuming a high fiber diet led some to experience gastrointestinal upset, such as stomach cramping, loose or watery stools, increased frequency of bowel movements, etc. Additionally, minor pain, bruising, and/or bleeding occurred at the site of the blood draws for some volunteers. However, any potential harmful effects of treatment were revealed to all participants in the informed consent prior to the beginning of the study.

The *principle of justice* is upheld when study participants are selected because of their relevance to the study. Additionally, this principle states that subjects would likely benefit from the research findings. By recruiting those overweight or obese men and women the benefits of treatment were substantial because of the potential for weight loss.

CHAPTER 4

PUBLISHABLE PAPER

The Effects of a High Fiber Diet vs. a Low-Carbohydrate Diet on Obese Individuals

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ABSTRACT

Background and Aims: Low-carbohydrate diets for obesity treatment are more effective than low fat diets in some studies but may be associated with increases in low density lipoprotein cholesterol (LDL-C). This study examined the relationship between a high fiber diet and a low-carbohydrate diet on weight loss, cardiovascular disease risk factors, and diabetes indicators.

Methods and Results: Using a 2x2 complete factorial design, 173 obese men and women (50.9% White, 25.4% Hispanic, 18.5% Black/African American, and 5.2% of another race) with (20.2%) or without (79.8%) type 2 diabetes were randomized to (a) a high fiber diet ($\geq$ 40 grams of fiber/day for women, $\geq$ 50 grams of fiber/day for men), or (b) a low-carbohydrate diet (<120 grams carbohydrate/day). Body weight and circumferences, BMI, fasting lipid profiles, glucose, HbA_{1c} levels, and blood pressure were assessed after 16 weeks among 123 (71.1%) individuals with complete data. Total cholesterol (mean difference between groups, 9 mg/dL, 95% CI, 0.5 to 16.9) and LDL-C levels (mean difference between groups, 7 mg/dL, 95% CI, 0.2 to 14.5) significantly decreased amongst those on the high fiber compared to the low-carbohydrate diet. There were no significant differences between diets with regards to weight loss, changes in waist and hip circumferences, high density lipoprotein cholesterol (HDL-C), triglycerides, glucose measures and blood pressure.

Conclusions: Weight loss and several CVD risk factors were similar in obese subjects following a high fiber compared to a low-carbohydrate diet, while total and LDL-C levels were lower on the high fiber diet.

INTRODUCTION

Overweight and obesity are considered the most important predictors of type 2 diabetes.[1] The cornerstone for treating obesity has been the use of low-calorie diets. However, after decades of research, it appears that low-calorie diets have resulted in only modest weight loss. Studies with overweight type 2 diabetics have yielded similar results.[2]

The use of low-carbohydrate, high protein, high fat diets (referred to as low-carbohydrate diets) may be effective in promoting weight loss in the short-term. After comparing a low-carbohydrate diet to a low-fat diet, researchers found that those on the low-carbohydrate diet lost more weight and had improved cardiovascular indicators when compared to those consuming the low-fat diet after 6 months.[3] Similarly, a comparison between a low-carbohydrate diet and a calorie restricted low-fat diet revealed that obese individuals consuming the low-carbohydrate diet had lost significantly more weight than those on the low-fat diet after 6 months.[4] Differences between *ad libitum* and calorie restricted diets have also been found. A meta analysis of short term studies revealed that low-carbohydrate dieters lost more weight when *ad libitum*.[5] However, results of a 2-year clinical trial revealed that low-carbohydrate diets did not appear to be any more beneficial than a low-fat diet for weight loss.[6]

When comparing diets that are low in carbohydrate versus those that are low in fat, participants consuming the low-carbohydrate diet had more favorable effects on blood lipids.[7] Furthermore, results of a meta analysis revealed that low-carbohydrate diets may be safe and effective at reducing weight and hemoglobin A_{1c} (HbA_{1c}) levels in type 2 diabetics.[8]

Combating obesity using a high fiber diet has been promoted for the last few decades with somewhat inconclusive results.[9] Dietary fiber may be protective against weight gain, however this is evidenced through observational studies.[6] It has been postulated that foods that contain a higher fiber content may lead to individuals consuming fewer calories throughout the day due to the increased feelings of satiety, which in turn may contribute to weight loss.[7] A review of fiber and body weight revealed that fiber intake was negatively correlated with weight in some but not all studies.[6]

Fiber may not only have a protective effect on weight, but may help decrease low-density lipoprotein cholesterol (LDL-C) levels in the blood. Results of a meta-analysis revealed that a diet high in fiber and carbohydrates compared to a diet moderate in carbohydrate and low in fiber led to significantly decreased LDL-C levels in diabetic individuals.[10] However, this review did not compare high fiber diets with other weight loss diets, such as low-carbohydrate diets.

Legumes such as beans and lentils may promote weight loss because they are a slow release carbohydrate and because of their high fiber content.[11] They may also prevent cardiovascular disease and possibly diabetes through their lipid lowering and glucose-stabilizing properties. Foods higher in fiber may block the absorption of fat and cholesterol in the small intestine, leading to lower blood lipid concentrations.[12]

With regards to glycemic control, a review of the literature revealed that consuming whole grains and legumes may be beneficial in the prevention and management of type 2 diabetes.[13] However, a comparison of an *ad libitum* high carbohydrate diet rich in legumes to an *ad libitum* low-carbohydrate diet has not been thoroughly examined.

The proposed study aimed to compare a high fiber, rich in legumes diet with a low-carbohydrate diet for weight loss and CVD risk factors in obese individuals with or without type 2 diabetes.

METHODS

A. Study Population

A prospective, randomized experiment using a 2x2 complete factorial design was conducted using volunteers from San Bernardino County, California. Data collection began in March 2010 and all 16-week visits were completed by December 2010. After a one week screening period, participants were randomly assigned to one of two diets: a) a high fiber diet ($\geq$ 40 grams of fiber per day for women, $\geq$ 50 grams of fiber per day for men), or b) a low-carbohydrate diet (< 120 grams carbohydrate per day for both men and women).

Following randomization, participants began a three week preparation phase. Both diets were *ad libitum* and were not matched on any macronutrient. Individuals were followed for 16 weeks, including five follow-up visits. These follow-up visits served to track participants' progress and to reinforce their respective diets. During the initial and final visits, outcomes were measured and blood was drawn. Significant differences in body weight, BMI, waist and hip circumferences, blood pressure, blood glucose, HbA_{1c}, and blood lipid profiles between both groups and between those with and without type 2 diabetes were of interest.

B. Participants

Potential participants were asked to complete the initial screening procedure to determine eligibility. The procedure involved a brief physical exam, drawing of fasting blood samples, a diet history, and a food frequency questionnaire.

Individuals were eligible to participate if they were 18 years of age or older, with a BMI between 30.0 and 44.0 kg/m^2, and if they spoke English. Type 2 diabetics were only eligible if they had been clinically stable within the past three months and there had been no change in diabetic medications within the three months prior to screening. Exclusion criteria included: pregnancy, lactation, active cancers, participation in another study/trial, dieted within the last 3 months with weight loss exceeding 4 pounds, currently following a vegan diet, type 1 diabetics, have an active eating disorder (anorexia and/or bulimia), currently suffering from an acute or chronic infection, using Byetta or weight loss medications, or gastrointestinal problems that may be worsened by a high fiber diet.

C. Procedures

1. Screening (Week: -2)

Approximately 30 to 60 participants were screened each month between March and September 2010. Ultimately, 201 subjects were screened. However, 23 were ineligible due to their BMI, medical history, or recent dieting history, therefore 178 completed the screening lab draw.

After individuals had been approved to participate and provided informed consent, they returned within two weeks for an office visit in order to be randomized to one of the aforementioned groups.

2. Randomization (Week: 0)

Randomization was performed by the study coordinator opening opaque envelopes containing a predetermined computer-generated random sequence of the two diets. Participants were stratified according to their diabetes status to ensure that diabetics were equally represented in both groups. Married couples were assigned to the same diet group.

Each participant was then educated by a registered dietitian (RD) with regards to their respective diets and was provided instructional materials to take home. Participants were also given a food journal and instructions on how to complete it. Individuals' physical activity levels were also assessed at this time in order to monitor changes in exercise frequency and/or intensity during the study.

Fasting lab samples were again drawn. Baseline measures of weight, waist circumference, hip circumference, and blood pressure were also assessed. After randomization, a three-week dietary preparation phase and a one-week dietary induction phase followed.

3. Preparation Phase (Weeks: 1-3)

During week 1 of the preparation phase, participants met with an RD for approximately one hour to discuss their respective diets in more detail. Those in the high fiber group began consuming ½ cup of cooked beans with one meal each day. Beans did not include green beans or peas, rather kidney beans, lentils, black beans, garbanzo beans, and pinto beans were recommended.

Individuals in the low-carbohydrate group began reducing their intake of carbohydrates while increasing their consumption of protein-rich foods such as fish, eggs, and lean meats. Additionally, both groups were given an Adverse Events Questionnaire (See Appendix A). Participants were also instructed to complete daily food records.

During week 2 those in the high fiber group were instructed to begin consuming ½ cup of cooked beans 10 to 15 minutes with two meals each day. Those in the low-carbohydrate group were instructed to reduce their carbohydrate intake to approximately 130 grams per day while subsequently increasing consumption of protein-rich foods.

Week 3 of the preparation phase involved a brief phone call from an RD. Those in the high fiber group were instructed to begin eating a ½ cup of beans with three meals per day while participants in the low-carbohydrate group were to decrease their carbohydrate intake to less than 120 grams per day and increase their consumption of protein-rich foods.

4. Induction Phase (Week: 4)

Individuals were instructed to continue their daily food diary. Additionally, each participant was provided 7 meals over the course of three days (2 breakfasts, 3 lunches, and 2 dinners) which were distributed from the Loma Linda University Research Kitchen. Meals were taken away and consumed off-site.

Meal portions differed based on diet and gender. High fiber meals emphasized whole grains (such as whole wheat breads and pasta, brown rice, etc.), vegetables, and fruit. Participants were also provided ½ cup of beans or lentils with breakfast, lunch, and dinner. The low-carbohydrate menu consisted of a large meat, egg, or vegetable protein portion, one to two servings of non-starchy vegetables (lettuce, tomatoes, bell peppers, mushrooms, etc.), and a small fruit serving. Meals were designed to educate participants with regards to portion sizes and menu options for their respective diets. Menus were designed by RD's to meet the macronutrient requirements of each diet.

5. Maintenance (Weeks: 5 -16)

Subsequent weeks consisted of participants maintaining their respective diets. In order to help with compliance, subjects were asked to continue using their daily food diaries. During weeks 6, 8, 12, and 14, subjects met with an RD to discuss compliance and to assess their body weight, waist circumference, and adverse events. Meal plans and recipes were distributed to each participant at week 6. RD's also obtained one 24-hour dietary recall and further assist with dietary compliance.

During week 16, subjects again met with an RD to discuss compliance and reassess participants' anthropometrics.

D. Measuring Tools

1. Anthropometrics

Participants' weight was measured to the nearest tenth of a kilogram (kg) without shoes using a calibrated Tanita Digital Large Capacity scale (HD-351). Height was also measured without shoes using a calibrated stadiometer to the nearest tenth of centimeter. Blood pressure was taken using a Homedics Automatic Deluxe Blood Pressure Monitor (BPA-101). Participants' waist circumference was determined using a horizontal measure at the level of the umbilicus and recorded to the nearest tenth of a centimeter. Hip circumference was determined using a horizontal measure at the top of the iliac crest and recorded to the nearest tenth of a centimeter. Two readings of both waist and hip were performed and the measurements were averaged.

2. Lab Samples

Participants were asked to fast overnight for at least 8 hours. Blood was drawn between 7 and 11:30 am by a state licensed venipuncturist.

Screening lab samples included: complete blood count (CBC), thyroid stimulating hormone (TSH), triglycerides, total cholesterol, HDL-C, LDL-C, HbA_{1c}, fasting plasma glucose, creatinine, aspartate aminotransferase (AST), and alanine transaminase (ALT). At randomization (week 0) total cholesterol, HDL-C, LDL-C, triglycerides, and glucose levels were drawn. At week 16, these samples, in addition to HbA_{1c} were again drawn.

3. Dietary Compliance

In order to assess dietary compliance, participants were required to keep logs of their food intake. Individuals were encouraged to write down all of the foods they ate, portion sizes in addition to the day and time of meals, snacks, and beverages. These food diaries were evaluated by an RD during in-house follow-up visits.

Additionally, participants were called randomly by RD's during weeks 6 and 15 to perform 24-hour dietary recalls for one weekend day and two weekdays. At this time, the Nutrition Data System for Research (NDS-R) software version 2008 developed by the Nutrition Coordinating Center (NCC), University of Minnesota, Minneapolis, MN was used to enter the 24-hour recall data. This program provides a complete nutrient profile for all foods in the database and uses a multiple-pass system of interview methodology. Data entry was guided and standardized by interview prompts.

E. Data Analysis

Data was entered into SPSS (version 15) and a 10% sample was re-entered to check for accuracy. A separate data set that excluded dropouts was created and analyzed.

Initially, dropouts were included in the analyses using the last observation carried forward. A second analysis was conducted that included only those participants' that completed the study. After both analyses were compared, the results did not differ (data not shown) and results for completers are shown.

Main characteristics of the study population prior to and after randomization were stratified according diet assignment. Differences in sample characteristics were determined using independent *t* tests or two-way ANOVA analyses for continuous variables or chi-square tests for categorical variables. Statistical analyses were initially performed regardless of whether all test assumptions were met. When test assumptions were not met, non-parametric tests were performed and compared to the initial analyses. If p-values were significantly different ($p<0.05$), variables were then log-transformed and re-analyzed using SPSS.

RESULTS

A. Participant Characteristics

Baseline characteristics according to diet assignment during the screening process and during randomization are shown in Tables 4.1 and4.2, respectively. Between screening and randomization, 5 individuals withdrew from the study. Therefore, a total of 173 participants were randomized, of which 35 had type 2 diabetes (20.2%): 91 individuals were assigned the high fiber diet (including14 diabetics) and 82 were assigned the low-carbohydrate diet (including 21 diabetics). 50.9% of the volunteers were White, 25.4% were Hispanic/Latino, 18.5% were Black/African American, and 5.2% were of another race. Both groups had a higher percentage of female than male participants.

It should also be noted that there were no significant differences between groups with regards to blood pressure, cholesterol/lipid, and diabetes medications. At the end of the study, one participant in the low-carbohydrate group initiated and three in the high fiber group stopped blood pressure medications. Also, one in the high fiber group initiated and one in the low-carbohydrate group stopped cholesterol-lowering therapies. With regards to diabetes, one individual in the high fiber group began and one in the low-carbohydrate group ceased glycemic control medications. Changes in physical activity levels between groups were not significant.

The two groups differed significantly with regards to race and baseline glucose levels with those in the low-carbohydrate group having higher mean glucose levels. However, this was likely due to the fact that there were more type 2 diabetics in the low-carbohydrate group when compared to the high fiber group. No significant differences were found with regards to anthropometric variables.

By the end of 16 weeks (Fig. 4.1), 123 participants remained (71.1%), with 64 in the high fiber group (including 12 with type 2 diabetes) and 59 in the low-carbohydrate group (including 15 with type 2 diabetes).

B. Anthropometrics and Lab Values

Mean differences between baseline values (week 0) and week 16 according to diet are shown in Table 4.3. Those consuming the high fiber diet significantly decreased both their mean total cholesterol and mean LDL-C levels. For individuals in the low-carbohydrate group, mean total and LDL-C levels increased. Both groups experienced a mean increase in HDL-C and a mean decrease in triglycerides, but these findings were not significant between groups. Both groups decreased their weight, BMI, waist and hip circumference, and blood pressure, however no significant changes were observed between groups.

C. Dietary Compliance

In addition to food diaries, an average of three 24-hour recalls (1 weekend day and 2 weekdays) for each participant were performed at random between week 6 and week 15 using the NDS-R software. Statistical analyses comparing the calorie and macronutrient intakes between the two groups and gender were performed (Table 4.4).

Between groups, there were significant differences in total grams of fat, carbohydrates, protein, and dietary fiber consumed. Low-carbohydrate dieters had significantly higher mean intakes of total, saturated, monounsaturated, polyunsaturated, and trans fats and cholesterol. Those in the high fiber had significantly higher intakes of dietary fiber. Significant differences were also found between groups with regards to mean percentages of calories coming from total fat, saturated fat, monounsaturated fat, polyunsaturated fat, carbohydrates, and protein. Those in the low-carbohydrate group consumed significantly higher mean percentages of protein and total, saturated, monounsaturated, polyunsaturated fats. The groups did not differ with regards to total calories consumed. However, separate analyses revealed significantly higher mean calorie intakes for males.

For those in the high fiber group, median values for total grams of dietary fiber consumed were calculated for both males and females. Amongst male participants, median values were 20.3 g and 53.8 g at the 25^{th} and 75^{th} percentiles, respectively. Median values at the 25^{th} and 75^{th} percentiles for females were 20.8 g and 47.6 g, respectively. Additionally, 13 male (32.5%) recalls had fiber intakes $\geq$50 g whereas 52 female recalls (76.5%) had fiber intakes $\geq$40 g.

DISCUSSION

This study has shown that an *ad libitum* high fiber diet may decrease total cholesterol and LDL-C levels amongst obese individuals with or without type 2 diabetes. While both diets appeared to decrease body weight, waist and hip circumference, and blood pressure, differences between the groups were not significant.

Therefore, this study provides further evidence of an association between a high fiber diet and improved lipid profiles, which coincides with other studies on the subject.[14-15] However, many of these studies limited participants' calories and did not employ the consumption of beans. Therefore, an *ad libitum* diet rich in legumes may help improve blood lipid profiles.

The increase in LDL-C in low-carbohydrate dieters is also similar to research conducted by Nordmann et al. (2006). However, our findings differed from results of other studies. A 2-year clinical trial examined the effects of a low-carbohydrate diet on body weight and cardiovascular disease found decreased blood pressure, LDL-C and triglyceride levels.[21] Results of a 6-month study that compared a low-carbohydrate diet to a low-fat diet showed no increase in plasma lipid concentrations or blood pressure in low-carbohydrate dieters.[22] It has been suggested that the effects of low-carbohydrate diets on LDL-C may be transient and only occur in the short term.[23] Therefore, the effects of low-carbohydrate diets on blood lipids warrants further research.

Separate analyses comparing diabetics and non-diabetics in both groups revealed that diabetics in both groups experienced mean decreases in blood glucose levels between baseline and week 16 when compared with non-diabetics. These results are similar to research that has found both high fiber and low-carbohydrate diets may be effective in reducing blood glucose levels.[16-18] However, it is possible that this difference existed because diabetics had higher blood glucose values at baseline. It is important this is addressed in future studies.

While both groups did not significantly differ with regards to total calorie consumption, they did differ with regards to their macronutrient intakes. The low-carbohydrate diet provided a higher percentage of calories from fat, including saturated fat, trans fat, and cholesterol which may partly explain the increased LDL-C levels.[19] In fact, an increase in dietary cholesterol may have pro-atherogenic effects which may increase cardiovascular disease risk.[20] Therefore, a low-carbohydrate diet may contribute to poorer lipid profiles and a subsequent increased risk of cardiovascular disease.

A. Strengths and Limitations

This study had several limitations. It would have been desirable to have had a third control group for comparison. Additionally, the attrition rate (28.9%) may have prevented us from detecting an effect with some of the variables. It may also have been advantageous to have increased the number of diabetic participants in the study. Generalizability may also be a potential threat to validity because relatively few men were enrolled.

Strengths of the study included the experimental design, the induction and preparation phases which allowed participants to acclimate to their respective diets, providing meals to participants, and the repeat follow-up visits.

B. Conclusions

These findings provide evidence of a diet high in fiber and rich in legumes may improve lipid profiles amongst obese individuals with or without type 2 diabetes. However, longer term studies may be needed to determine whether these diets may improve body weight.

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Table 4.1 Main Characteristics of the Study Population at Screening According to Gender

Factor (n=173)	Male (n=45)	Female (n=128)	p-value
Diabetics (n (%))	10 (21.3)	25 (19.1)	
Non-Diabetics (n (%))	37 (78.7)	106 (80.9)	0.746
Race			
White (n (%))	23 (48.9)	69 (52.7)	
Black/African American (n (%))	8 (17.0)	24 (18.3)	
Hispanic/Latino (n (%))	14 (29.8)	31 (23.7)	
Other (n (%))	2 (4.3)	7 (5.3)	0.916
Age (mean (SD))	47.6 (12.9)	48.1 (10.1)	0.793
Anthropometrics (means (SD))			
Height (cm)	175.6 (7.5)	161.6 (5.6)	<0.001*
Weight (kg)	114.7 (13.9)	93.8 (14.1)	<0.001*
BMI (kg/m^2)	37.1 (3.8)	36.0 (3.9)	0.117
Systolic Blood Pressure (mmHg)	138 (19)	134 (19)	0.322
Diastolic Blood Pressure (mmHg)	91 (15)	89 (13)	0.409
Pulse (bpm)	69 (10)	71 (11)	0.345
Waist (cm)	120.4 (9.6)	109.1 (11.5)	<0.001*
Hip (cm)	117.0 (7.8)	120.1 (10.1)	0.068
Lab Values (means (SD))			
Triglycerides (mg/dL)	152 (96)	134 (85)	0.232
Cholesterol (mg/dL)	185 (40)	190 (39)	0.475
HDL-C (mg/dL)	44 (8)	53 (13)	<0.001*
LDL-C (mg/dL)	121 (32)	120 (33)	0.829
Glucose (mg/dL)	105 (29)	99 (26)	0.135
HbA1c (%)	5.7 (0.9)	5.7 (0.8)	0.976
WBC (bil/L)	7.12 (1.8)	6.96 (2.0)	0.625
RBC (tril/L)	5.07 (0.5)	4.67 (0.3)	<0.001*
Hemoglobin (g/dL)	15.0 (1.2)	13.1 (1.4)	<0.001*
Hematocrit (%)	44.1 (3.3)	39.6 (2.8)	<0.001*
Platelets (bil/L)	253 (55)	285 (73)	0.006*
Creatinine (mg/dL)	0.9 (0.2)	0.7 (0.1)	<0.001*
TSH (uIU/mL)	2.057 (0.9)	2.455 (1.6)	0.038*
AST (U/L)	29 (9)	24 (17)	0.101
ALT (U/L)	41 (21)	28 (21)	<0.001*

SD = standard deviation; * Represents statistically significant values (p<0.05)

Table 4.2 Main Characteristics of the Study Population According to Diet after Randomization.

Factor (n=173)	High Fiber (n=91)	Low-Carbohydrate (n=82)	p-value
Gender (n (%))			
Male	20 (22.0)	25 (30.5)	
Female	71 (78.0)	57 (69.5)	0.203
Diabetics (n (%))	14 (15.4)	21 (25.6)	
Non-Diabetics (n (%))	77 (84.6)	61 (74.4)	0.095
Race (n (%))			
White	51 (56.0)	37 (45.1)	
Black/African American	22 (24.2)	10 (12.2)	
Hispanic/Latino	15 (16.5)	29 (35.4)	
Other	3 (3.3)	6 (7.3)	0.024*
Age (mean (SD))	47.7 (10.2)	49.1 (11.2)	0.402
Anthropometrics (means (SD))			
Height (cm)	165.1 (8.9)	165.2 (8.4)	0.965
Weight (kg)	100.3 (16.1)	99.2 (14.0)	0.998
BMI (kg/m^2)	36.6 (3.8)	36.3 (4.1)	0.654
Systolic Blood Pressure (mmHg)	133 (16)	137 (22)	0.153
Diastolic Blood Pressure (mmHg)	89 (11)	90 (14)	0.739
Pulse (bpm)	70 (11)	72 (11)	0.315
Waist (cm)	111.6 (11. 4)	112.3 (11.4)	0.712
Hip (cm)	119.3 (9.3)	118.8 (9.2)	0.713
Lab Values (means (SD))			
Triglycerides (mg/dL)	140 (79)	140 (75)	0.403
Cholesterol (mg/dL)	190 (34)	189 (37)	0.586
HDL-C (mg/dL)	51 (12)	50 (12)	0.167
LDL-C (mg/dL)	118 (32)	121 (33)	0.416
Glucose (mg/dL)	98 (30)	106 (35)	0.024*
HbA1c (%)[a]	5.6 (0.6)	5.8 (1.0)	0.147
WBC (bil/L)[a]	6.74 (0.2)	7.37 (0.3)	0.109
RBC (tril/L)[a]	4.77 (0.4)	4.77 (0.5)	0.857
Hemoglobin (g/dL)[a]	13.6 (0.2)	13.5 (0.2)	0.830
Hematocrit (%)[a]	40.9 (0.4)	40.5 (0.4)	0.731
Platelets (bil/L)[a]	274 (8)	283 (8)	0.681
Creatinine (mg/dL)[a]	0.8 (0.02)	0.8 (0.02)	0.834
TSH (uIU/mL)[a]	2.244 (0. 2)	2.535 (0.2)	0.241
AST (U/L)[a]	27 (2)	24 (1)	0.425
ALT (U/L)[a]	31 (3)	32 (2)	0.927

SD = standard deviation; [a] Lab values obtained at screening; * Represents statistically significant values ($p<0.05$)

Table 4.3 Differences in Mean Anthropometrics and Metabolic Lab Values from Baseline According to Diet

n=123	High Fiber (n=64)			Low-Carbohydrate (n=59)			
Factor	**Week 0**	**Week 16**	**Δ between week 0 and week 16**	**Week 0**	**Week 16**	**Δ between week 0 and week 16**	**p-value for Δ between groups**
Anthropometrics							
Weight (kg)	100.5 (15.8)	96.4 (15.6)	-4.1 (4.0)	98.3 (13.8)	93.2 (13.2)	-5.2 (4.5)	0.171
BMI (kg/m^2)	36.5 (3.8)	35.0 (4.0)	-1.5 (1.4)	36.0 (3.7)	34.1 (4.1)	-1.9 (1.5)	0.205
Waist (cm)	111.6 (11. 4)	106.1 (11.2)	-5.5 (5.2)	112.3 (11.4)	105.0 (11.6)	-6.5 (4.7)	0.307
Hip (cm)	119.5 (9.5)	114.7 (9.7)	-4.7 (4.9)	117.5 (8.6)	112.8 (10.4)	-4.0 (6.9)	0.499
Systolic Blood Pressure (mmHg)	131 (16)	126 (15)	-4 (10)	137 (23)	123 (18)	-4 (9)	0.962
Diastolic Blood Pressure (mmHg)	89 (11)	85 (9)	-2 (5)	90 (14)	83 (13)	-1 (7)	0.148
Pulse (bpm)	70 (11)	68 (12)	-0.5 (4.1)	72 (10)	71 (10)	-0.2 (2.8)	0.301
Lab Values							
Total Cholesterol (mg/dL)	189 (33)	182 (32)	-7 (21)	190 (37)	192 (39)	2 (24)	0.038*
HDL-C (mg/dL)	51 (13)	52 (14)	0.5 (6)	50 (12)	52 (12)	2 (6)	0.108
LDL-C (mg/dL)	119 (31)	116 (30)	-3 (18)	122 (32)	126 (36)	4 (22)	0.045*
Triglycerides (mg/dL)	139 (74)	126 (67)	-13 (46)	136 (79)	119 (56)	-17 (46)	0.603
Glucose (mg/dL)	100 (30)	96 (28)	-4 (14)	105 (35)	101 (27)	-4 (21)	0.907
HbA_{1c} (%)	5.7 (0.6)	5.6 (0.8)	-0.1 (0.4)	5.8 (1.0)	5.7 (0.8)	-0.1 (0.7)	0.526

* Represents statistically significant values ($p<0.05$)
Significant differences in total cholesterol and LDL-C were evident, where those in the high fiber group experienced a greater mean decrease.

Table 4.4 Dietary Compliance between Week 6 and Week 15 According to Group and Macronutrient Breakdown.[a]

n=123	High Fiber (n=64)	Low-Carbohydrate (n=59)	p-value for difference between groups
Nutrients (means (SD))			
kcals	1487.3 (543.3)	1584.8 (580.5)	0.103
Males	1729.2 (740.1)	1739.5 (672.6)	0.001*[b], 0.013*[c]
Females	1416.7 (450.1)	1506.1 (516.1)	
Total Fat (g)	49.0 (28.8)	74.4 (38.4)	<0.001*
Saturated Fat (g)	14.1 (9.7)	23.8 (13.4)	<0.001*
Monounsaturated Fat (g)	18.7 (12.6)	28.8 (16.7)	<0.001*
Polyunsaturated Fat (g)	11.9 (8.9)	15.4 (11.1)	<0.001*
Trans Fat (g)	1.8 (1.9)	2.1 (2.0)	0.006*
Carbohydrates (g)	209.0 (89.0)	123.4 (62.7)	<0.001*
Protein (g)	70.4 (26.7)	105.8 (39.7)	<0.001*
Total Fiber (g)	37.1 (21.9)	17.3 (10.2)	<0.001*
Males	42.5 (30.3)	19.1 (11.1)	0.069[b], 0.104[c]
Females	35.5 (18.6)	16.4 (9.6)	
% kcals from Carbohydrate	52.4 (11.6)	29.7 (11.5)	<0.001*
% kcals from Protein	19.0 (5.7)	28.4 (9.6)	<0.001*
% kcals from Total Fat	28.2 (10.5)	40.3 (10.1)	<0.001*
% kcals from Saturated Fat	8.2 (4.3)	13.0 (4.4)	<0.001*
% kcals from Monounsaturated Fat	10.8 (4.7)	15.5 (4.5)	<0.001*
% kcals from Polyunsaturated Fat	6.7 (3.6)	8.2 (4.3)	<0.001*
Cholesterol (mg)	169 (136)	446 (277)	<0.001*

kcals=Calories, g=grams; mg=milligrams

[a]Averaged 3 dietary recalls per person (1 weekend day, 2 weekdays)
[b]p-value for differences between genders in the High Fiber Diet
[c]p-value for differences between genders in the Low-Carbohydrate Diet
* Represents statistically significant results ($p<0.05$)

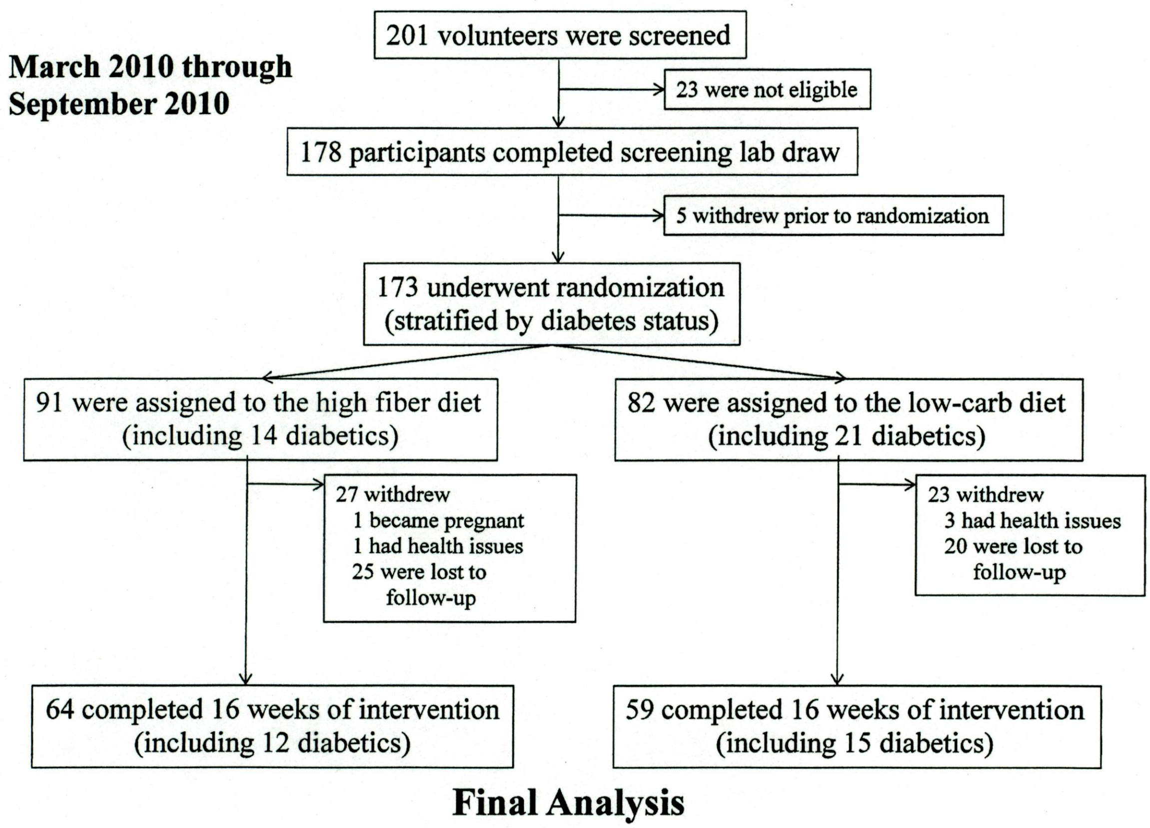

Figure 4.1 Study Timeline

CHAPTER 5

ADDITIONAL FINDINGS

Additional findings may be useful in determining the effects of these two diets on the overall health of participants. Therefore, it is important to assess differences in the lipid profiles between participants with diabetes and those without. Also, examining the micronutrient content of both diets may help determine the effects these diets may have on cardiovascular indicators. Changes in exercise levels and medications between baseline and week 16 will also be discussed to determine their influence on lipid profiles, blood pressure, blood glucose, or HbA_{1c} levels. I will also include a discussion of the reported adverse events of both diets.

A. Changes in Lipid Profiles

It has been well-established in the literature that those with diabetes have an increased risk for cardiovascular disease, including congestive heart failure, myocardial infarction and stroke (Gerstein & Capes, 2002). Diabetics may also have poorer lipid profiles and it has been suggested that they should be on the same lipid-lowering therapies as those with coronary heart disease (Haffner, Lehto, Ronnemaa, Pyorala & Laakso, 1998). Therefore, it is important to assess changes in lipid profiles between diabetics and non-diabetics in both groups.

Using a two-way ANOVA analysis, it was determined that diabetics irrespective of diet, had significantly decreased mean total cholesterol, LDL-C and triglyceride levels when compared to those without diabetes (Table 5.1). Therefore, both diets may reduce cardiovascular disease risk in those with type 2 diabetes.

Table 5.1 Mean (SD) Metabolic Lab Values According to Time, Diet, and Diabetes

n=123	**High Fiber (n=64**			**Low-Carbohydrate (n=59)**			
	Week 0	**Week 16**	**Δ between week 0 and week 16**	**Week 0**	**Week 16**	**Δ between week 0 and week 16**	**p-value for main effect of Δ between DM vs. Non-Dm**
Factor							
Total Cholesterol (mg/dL)							
Diabetic							
Yes (n=27)	194 (34)	171 (31)	-23 (21)	189 (49)	183 (53)	-4 (24)	
No (n=96)	188 (33)	185 (32)	-3 (20)	191 (32)	195 (34)	6 (25)	0.003*
HDL-C (mg/dL)							
Diabetic							
Yes (n=27)	46 (11)	47 (10)	0.7 (5.5)	47 (10)	49 (11)	2 (5)	
No (n=96)	53 (13)	53 (14)	0.4 (6.0)	51 (12)	53 (13)	2 (7)	0.859
LDL-C (mg/dL)							
Diabetic							
Yes (n=27)	121 (34)	105 (28)	-16 (17)	119 (44)	120 (52)	0.8 (19.3)	
No (n=96)	118 (30)	118 (30)	0.0 (17.5)	123 (28)	129 (29)	6 (22)	0.018*
Triglycerides (mg/dL)							
Diabetic							
Yes (n=27)	192 (87)	156 (87)	-36 (46)	183 (118)	144 (76)	-39 (63)	
No (n=96)	127 (65)	119 (60)	-8 (45)	121 (53)	111 (46)	-10 (37)	0.004*

SD=Standard Devation; * Indicates statistically significant values ($p<0.05$)

B. Comparison of Micronutrients

Micronutrients such as the fat soluble and water soluble vitamins, minerals, as well as sodium and cholesterol intakes are important when determining the effects these diets may have on overall health (Table 5.2). However, few studies address these factors.

Table 5.2 Dietary Compliance between Week 6 and Week 15 According to Group and Micronutrient Breakdown.[a]

n=123	High Fiber (n=64)	Low-Carbohydrate (n=59)	p-value for difference between groups
Means (SD)			
Fat soluble vitamins			
Vitamin A (mcg RAE)	580.7 (456.3)	729.0 (602.3)	0.009*
Vitamin D (mcg)	2.7 (2.6)	5.0 (5.3)	<0.001*
Vitamin E (mg total alpha-tocopherol)	8.0 (6.0)	9.1 (10.7)	0.126
Vitamin K (mcg)	133.2 (134.0)	180.1 (211.6)	0.012*
Water soluble vitamins			
Thiamin (B1) (mg)	1.4 (0.6)	1.4 (1.8)	0.035*
Riboflavin (B2) (mg)	1.6 (0.8)	2.1 (0.9)	<0.001*
Niacin (B3) (mg)	20.0 (9.3)	23.6 (11.5)	0.001*
Pantothenic acid (mg)	4.5 (1.9)	5.9 (2.4)	<0.001*
Folate (mcg)	478.2 (266.5)	353.8 (187.3)	<0.001*
Cobalamin (B-12) (mcg)	5.3 (22.1)	5.9 (4.8)	0.722
Vitamin C (mg)	88.5 (81.0)	95.1 (169.2)	0.633
Minerals			
Sodium (mg)	2446 (1141)	2973 (1308)	<0.001*
Calcium (mg)	745.0 (375)	895.5 (402)	<0.001*
Zinc (mg)	10.2 (5.0)	12.3 (5.5)	<0.001*

* Represents statistically significant results (p<0.05)

1. Fat Soluble Vitamins

Low-carbohydrate dieters had significantly higher mean intakes of vitamins A, D, and K. Increased consumption of these nutrients may be partly explained by the fact that animal products such as meat, eggs, and dairy, which were encouraged in the low-carbohydrate group, are good sources of many vitamins, such as vitamins A and D (NIH, 2011a). No significant differences were found with regards to vitamin E consumption.

2. Water Soluble Vitamins

Those in the low-carbohydrate group consumed significantly more thiamin, niacin, riboflavin, and pantothenic acid on average when compared with high fiber dieters. Many of the protein-rich foods that were encouraged in the low-carbohydrate diet are good sources of riboflavin, niacin, and pantothenic acid (NIH, 2011a). However, high fiber dieters consumed more folate on average. Cereals, breads, and some legumes such as beans are typically a good source of folate which may account for the higher mean intakes within the fiber group (NIH, 2011b). These results differ from past research conducted by Gardner, et al. (2010) who found that low-carbohydrate dieters had an increased risk for thiamin and folate deficiencies. However, this analysis only included data from an 8-week trial therefore, results may have differed in the long-term. There were no significant differences between groups with regards to vitamin C intakes.

3. Minerals

Low-carbohydrate dieters consumed more mg of calcium, sodium, and zinc on average when compared to high fiber dieters. Red meat, poultry, seafood, and dairy are typically good sources of zinc (NIH, 2011c). Dairy foods are also typically high in calcium. Therefore, this may explain the differences found between groups. With regards increased sodium consumption, researchers have found similar results when examining nutrient intakes for those following the Atkins Diet (Yunsheng, Pagoto, Griffith, Merriam, Ockene, Hafner, et al., 2007; Anderson, Konz & Jenkins, 2000). High sodium intakes have been associated with increased risk of cardiovascular disease, such as hypertension and stroke (Law, 2000).

Therefore, when compared to a high fiber diet, low-carbohydrate dieters appear to have higher mean intakes of some of the micronutrients listed above, however because of the increased sodium intakes, a low-carbohydrate diet may lead to poorer cardiovascular disease indicators.

C. Adverse Events

During follow-up visits, participants completed a brief open-ended questionnaire that assessed adverse events since their last visit (Appendix C). Amongst high fiber dieters (Table 5.3), the most common complaints were excess gas and bloating, which reflects similar findings found in previous studies (Chen et al., 2006). Participants with these complaints were instructed to consume an over the counter gas reliever (i.e. Gas-X or Beano). This typically resolved the issue, whereas in other instances, these symptoms simply waned over time.

With regards to the low-carbohydrate group, constipation and fatigue were reported most frequently. This coincides with other low-carbohydrate studies, such as the one performed by Yancy, et al. (2004). Participants were instructed to increase their consumption of protein-rich foods such as meat, eggs, poultry, and cheese, which may have a constipating effect. Also, the reduction in carbohydrates may lead to a state of ketosis which may lead to the increased fatigue (Bravata, Sanders, Huang, Krumholz, Olkin, Gardner et al., 2003). A 26 year old male was hospitalized due to kidney stones, however this patient continued with subsequent follow-up visits after physician clearance. It should be noted that many adverse events resolved on their own.

Table 5.3 Frequency of Reported Adverse Events after Randomization According to Diet

	High Fiber (n=91)	Low-Carbohydrate (n=82)
Event (Frequency (%)†)		
Gastrointestinal		
Gas	9 (10)	1 (1)
Stomach cramps	6 (7)	0 (0)
Constipation	2 (2)	4 (5)
Rectal bleeding	0 (0)	1 (1)
Bad Breath	2 (2)	0 (0)
Raw/scaly lips	0 (0)	1 (1)
Nighttime dry mouth	1 (1)	0 (0)
Increased appetite	1 (1)	0 (0)
Decreased appetite	1 (1)	0 (0)
Heartburn	0 (0)	2 (2)
Decreased thirst	1 (1)	0 (0)
Sensitive/receding gums	0 (0)	1 (1)
Food tasting bland	0 (0)	1 (1)
Nighttime hunger	1 (1)	0 (0)
H. pylori infection	1 (1)	0 (0)
Renal		
Green urine	0 (0)	1 (1)
Kidney stones	0 (0)	1 (1)
Excessive urination	1 (1)	0 (0)
Urinary leakage	1 (1)	0 (0)
Musculoskeletal		
Hip pain	0 (0)	1 (1)
Muscle cramps	1 (1)	1 (1)
Aching feet	0 (0)	1 (1)
Swelling	2 (2)	1 (1)
Circulatory		
Dizziness	1 (1)	0 (0)
Hypoglycemia	0 (0)	1 (1)
Fatigue	2 (2)	3 (4)
Increased bruising	1 (1)	0 (0)
Reproductive		
Change in menstrual cycle	2 (2)	0 (0)
Total reported adverse events	36	21

†Frequency percentage was calculated using respective *n* values for each diet

D. Changes in Physical Activity

As this was a randomized trial of two diets, the study was adequately designed to assess whether changes in body weight were due to diet. However, changes in physical activity also affect body weight. Thus we assessed whether there were differences in physical activity between the groups. Participants were asked during follow-up visits about their current physical activity levels and changes in type of activity, intensity and/or duration were noted. Chi-square analysis yielded no significant differences between groups from baseline (Table 5.4). Therefore, any observed changes in the outcome measures of interest were likely not due to changes in physical activity levels.

Table 5.4 Changes in Physical Activity from Baseline According to Diet Assignment

Level of Change (n(%)†)	High Fiber (n=64)	Low-Carbohydrate (n=59)	p-value for difference between groups
Decrease	7 (11)	10 (17)	
No change	48 (75)	38 (44)	
Increase	7 (11)	8 (14)	
Increase vigorously	2 (3)	3 (5)	0.624

†Frequency percentage was calculated using respective n values for each diet

E. Changes in Medications

Changes in blood pressure, lipid-lowering, and glycemic control medications and dosage were assessed as part of the Adverse Events Questionnaire. Chi-square analyses revealed no significant differences between groups with regards to changes in medications from baseline (Table 5.5). Therefore, changes in medications likely did not significantly influence study outcomes.

Table 5.5 Prevalence of Medications among the Sample Population at Baseline and Week 16 According to Diet

	Week 0 (n=123)		Week 16 (n=123)		
	High Fiber (n=64)	**Low-Carbohydrate (n=59)**	**High Fiber (n=64)**	**Low-Carbohydrate (n=59)**	**p-value for difference in proportion**
Blood Pressure medication (n (%))					
Yes	30 (46.9)	24 (40.7)	27 (42.2)	25 (42.4)	0.157
No	34 (53.1)	35 (59.3)	37 (57.8)	34 (57.6)	
Lipid-lowering medication (n (%))					
Yes	18 (28.1)	9 (15.3)	19 (29.7)	8 (13.6)	0.157
No	46 (71.9)	50 (84.7)	45 (70.3)	51 (86.4)	
Diabetes medication (n (%))					
Yes	6 (9.4)	9 (15.3)	7 (10.9)	8 (13.6)	
No	58 (90.6)	50 (84.7)	57 (89.1)	51 (86.4)	0.657

CHAPTER 6

CONCLUSIONS

A. Summary and Findings

The results of the present study indicate that a high fiber diet rich in legumes may contribute to a reduction in body weight and improved blood lipid profiles in obese individuals. While a low-carbohydrate diet also decreased body weight, the difference between the diets was not statistically significant. In addition, total cholesterol and LDL-C were higher on the low-carbohydrate versus the higher fiber diet. Participants in both groups experienced reductions in waist and hip circumferences, blood pressure, blood glucose, and HbA_{1c} levels. These differences were not significant between the two diets. When examining the macro- and micronutrient composition between groups, high fiber dieters consumed significantly fewer B-vitamins, whereas low-carbohydrate dieters consumed significantly more sodium, cholesterol, and total fat than those in the high fiber group. Therefore, the pro-atherogenic effects of a low-carbohydrate may need to be further examined in future studies.

When comparing the lipid profiles of participants with type 2 diabetes to those without, those with diabetes significantly decreased their total cholesterol, LDL-C, and triglyceride levels. However, because of the low number of diabetics enrolled in the study this may need to be explored further in order to be able to generalize these findings.

B. Limitations

While this study followed participants for 4 months, longer than many other studies, it is difficult to determine whether the effects of the diets would have persisted over a longer period of time. Therefore, following participants for a longer period of time may have been beneficial.

Additionally, the attrition rate (28.9%) may have prevented us from detecting an effect with some of the variables. Implementing stricter volunteer screening procedures that addresses the individuals' motivations for participation may help to increase retention rates. Additionally, having tangible rewards for study completion (i.e. certificates, monetary compensation) may also be beneficial.

It may also have been advantageous to have increased the number of diabetic participants in the study in order to make stronger conclusions about the relationship between these two diets and their effects on this population. Involving endocrinologists during recruitment phases may have aided in this.

Generalizability may also be a potential threat to validity because relatively few men were enrolled. However, different ethnic groups were adequately represented.

C. Areas for Future Research

During the first 4 weeks of treatment, participants were enthusiastic and much weight loss was achieved. However, as the months passed by, even though satisfaction was high, the novelty of the diets began to subside and maintenance became an issue. Therefore, researchers may wish to address the importance of participants' motivation on diet maintenance when planning future studies.

Additionally, the feasibility of following a high fiber diet rich in legumes for 4 months was a concern. However, I soon learned that many participants thoroughly enjoyed this diet. The relationship between bean consumption and body weight therefore is not only feasible, but a fascinating area of research. In fact, this study will continue to follow participants for the full year and longer term effects of these diets will be of interest. Other questionnaires will also be assessed, including changes in stress and depression scores.

D. Implications for Preventive Care Practice

When prescribing diets for obese individuals, this study provides evidence of the effectiveness of either a high fiber diet or a low-carbohydrate diet for short term weight loss. However, a high fiber diet rich in legumes may not only be feasible but may also improve blood lipid profiles, specifically total cholesterol and LDL-C. Both diets may also be effective for improving lipid profiles and glycemic control in type 2 diabetics, however, further research is warranted before strong conclusions can be made.

If either of these diets were to be followed in the longer term, micronutrient consumption may be of concern. When compared to the low-carbohydrate group, those on the high fiber diet consumed fewer B-vitamins. However, low-carbohydrate dieters had increased cholesterol and sodium intakes when compared to high fiber dieters, which may contribute to an increased risk for cardiovascular disease.

In conclusion, diets of vastly different macronutrient concentrations are feasible strategies for promoting short-term weight loss in obese individuals, however Preventive Care Specialists must be aware of the potential longer term implications on overall health and wellness.

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APPENDIX A

GUIDE TO HIGH FIBER DIET

	Foods to choose	Foods not allowed
Breads, cereals, grains	Whole wheat breads (100% whole wheat or whole grain) Regular oatmeal Whole grain and high fiber ready-to-eat cereals (cheerios, shredded wheat, fiber 1, raisin bran, bran cereals) Brown rice Whole wheat pasta Corn tortillas Whole grain pancakes and waffles	White bread Refined and sugary ready-to-eat cereals (rice krispies, kellogg K, trix, fruit loops) Instant oatmeal, cream of rice, cream of wheat White rice White pasta Flour tortilla Chips, crackers Pancakes and waffles made with refined flour Muffins, doughnuts, breakfast pastries, pop tarts
Vegetables	All vegetables: raw, cooked, canned, frozen Salads	Fried vegetables
Fruits	All fresh or frozen fruit Dried Fruits	Fruits canned in syrup Fruit juice
Milk and dairy foods **<u>Limit</u>** 2 servings per day	<u>Serving size</u> 1 cup fat-free, 0.5%, 1% milk 1 cup soy milk 1 cup low-fat and non-fat yogurt ½ cup cottage cheese 1 ounce low-fat cheese	Regular cheese (cheddar, swiss) Pudding Ice cream
Protein foods, meats **<u>Limit</u>** Meat, chicken or fish to 2 servings per day 1 serving = 3 oz cooked meat or the size of a deck of cards	Cooked beans (black beans, kidney beans, limas, navy beans, garbanzos) Cooked lentils and peas Tofu Soy products (meat analogs) 2 servings (3 oz per serving) a day of lean beef, chicken, turkey or fish. Can be broiled, sautéed or roasted. 3 eggs per week	Fried chicken Breaded or fried fish
Fats and Oils	Vegetable oil (olive, canola, soybean) Salad dressing Peanut butter Olives Avocado	Butter Margarine
Sweets	Diet drinks and soda	Cakes, cookies brownies, candy, pies

APPENDIX B

GUIDE TO LOW-CARBOHYDRATE DIET

	Foods to choose	**Foods not allowed**
Starchy foods **Limit** 2 servings per day for women 3 servings per day for men	Serving size 1 slice bread 1/4th bagel ½ English muffin ½ cup cooked oatmeal ½ cup cooked rice ½ cup cooked pasta ½ cup cooked beans, lentils or peas 1 small tortilla (4 inch) 3/4th cup ready-to-eat cereal	More than 2 servings per day for women or 3 servings per day for men of starchy foods
Vegetables **Limit** Starchy vegetables (corn, potatoes, yellow squash or carrots) to ½ cup per day	Broccoli, zucchini, green beans, mushrooms, asparagus, spinach and other green leafy vegetables Lettuce, cabbage and other salad greens Tomatoes Peppers, cucumbers, celery, radishes	More than ½ cup of starchy vegetables
Fruits **Limit** 3 servings per day	**Serving size** 1 medium fruit (apple, pear, banana, peach, orange) ½ cup chopped fresh or frozen fruit 1 cup strawberries or melon 1/4th cup dried fruits	Fruits canned in syrup Fruit juice
Milk and dairy foods	Fat free, 0.5%, 1% milk Soy milk, unsweetened Low fat and non-fat yogurt, unsweetened Cottage cheese White cheese Cheddar, swiss, gouda, mozzarella cheese Eggs	Sweetened yogurt Sweetened soy drinks Ice cream
Protein foods and meats	Beef, chicken, turkey, fish Hamburger Cold meats Tofu Soy products (meat analogs) Eggs	Fried chicken Breaded or fried fish
Fats and Oils	Vegetable oil (olive, canola, soybean) Salad dressing Peanut butter Olives Avocado	Butter Margarine
Sweets	Diet drinks and soda	Cakes, cookies brownies, candy, pies

APPENDIX C

ADVERSE EVENTS QUESTIONNAIRE

Please mark with an "X" on the line how you would rate changes in the following areas:

How has your **Frequency of Stools** changed since the *last evaluation?
Much Less Frequent No Change Much More Frequent

|--------------------------------------|---------------------------------------|

How has your **Consistency of Stools** changed since the *last evaluation?
Very Watery No Change Very Hard

|--------------------------------------|---------------------------------------|

Do you suffer from Headaches?

[ ] Yes [ ] No

If yes, answer the following 2 questions:

How has your **Frequency of Headaches** changed since the *last evaluation?
Much Less Frequent No Change Much More Frequent

|--------------------------------------|---------------------------------------|

How has your **Severity of Headaches** changed since the *last evaluation?
Much Less Severe No Change Much More Severe

|--------------------------------------|---------------------------------------|

Do you suffer from Muscle Cramps?

[ ] Yes [ ] No

If yes, answer the following 2 questions:

How has your **Frequency of Muscle Cramps** changed since the *last evaluation?
Much Less Frequent No Change Much More Frequent

|--------------------------------------|---------------------------------------|

How has your **Severity of Muscle Cramps** changed since the *last evaluation?
Much Less Severe No Change Much More Severe

|--------------------------------------|---------------------------------------|

*if this is your first visit, please answer based on your experience over the past month

Have you had any other complaints since you started the diet? If so, please write them down in the space provided.

Have you changed any medications since you started the diet? If so, please write down the changes in the space provided.

*if this is your first visit, please answer based on your experience over the past month

APPENDIX D

IRB APPROVAL FORM

INSTITUTIONAL REVIEW BOARD

Extension Requested - Approval Notice (Expedited)

IRB# 59217

OFFICE OF SPONSORED RESEARCH • 11188 Anderson Street • Loma Linda, CA 92350
(909) 558-4531 (voice) • (909) 558-0131 (fax)

To:	**Tonstad, Serena**
Department:	**Health Promotion & Education**
Protocol:	*A very high fiber diet versus a low-carbohydrate diet for weight loss in obese men and women with and without type 2 diabetes*

Your request to extend the protocol indicated above has been reviewed administratively.

Extension Request:	**Approved**
Risk to research subjects:	**Minimal**
Approval period begins	**19-Oct-2010** and ends **18-Oct-2011**
Stipulations of approval are:	**Exclude individuals weighing less than 110 lbs.**

Consent Form

If this study was approved on the condition that a consent form is required AND subjects are still being enrolled, only the consent form bearing the IRB authorization stamp can be used. This will become your OFFICIAL consent form for the dates specified and should be used as the new master for making copies to give prospective subjects.

- [x] Master consent form with up-dated authorized stamp is enclosed.
- [ ] Updated consent form not required. Approval limited to data analysis or follow-up of currently enrolled subjects only.
- [ ] Not applicable; IRB approved a waiver of informed consent, as noted above.

IRB Communications

Please continue to notify the IRB in writing of any modifications or adverse events relating to the approved research protocol. Your assistance in providing the PI's name and the protocol's IRB # on all communications with the IRB about this project will expedite necessary communications.

Thank you for your cooperation in LLU's shared responsibility for the ethical use of human subjects in research.

Signature of IRB Chair/Designee: R L Rigsby MD

Loma Linda University Adventist Health Sciences Center holds Federalwide Assurance (FWA) No. 6447 with the U.S. Office for Human Research Protections, and the IRB registration no. is IORG226. This Assurance applies to the following institutions: Loma Linda University, Loma Linda University Medical Center (including Loma Linda University Children's Hospital, LLU Community Medical Center), Loma Linda University Behavioral Medicine, and affiliated medical practices groups.

IRB Chair:
Rhodes L. Rigsby, M.D.
Department of Medicine
(909) 558-2341, rrigsby@llu.edu

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APPENDIX E

INFORMED CONSENT

LOMA LINDA UNIVERSITY
School of Public Health

A very high fiber diet versus a low-carbohydrate diet for weight loss in obese men and women with and without type 2 diabetes

Informed Consent Document

This is a research project by Dr. Serena Tonstad, preventive medicine physician in the School of Public Health at Loma Linda University. The information below will inform you about a research study in which you may be interested in participating. Please take your time and read the information carefully before deciding whether or not you wish to participate in this study.

Why is this study being done?
You are invited to participate in this research study because your body mass index falls within the desired range for this study (BMI 30-42 kg/m^2). The aim of this study is to evaluate the effects of a diet that is rich in fiber (from beans, salads, vegetables, whole grains and fruit) compared to a high protein/low carbohydrate diet (from beef, pork, chicken, fish, and leafy salad vegetables) by comparing weight loss, side effects, appetite, hormones, and risk factors for heart disease. The study will last for 1 year and will include 140 participants, half of whom must have type 2 diabetes.

What is involved in this study?
This is a 1 year randomized controlled clinical trial. You will be assigned to 1 of 2 diets using a random method similar to a coin toss:

1. High fiber with at least 50 grams of fiber/day for men or at least 40 grams of fiber/day for women. You will be required to eat a pre-meal dose of fiber-rich food, almost always beans, 10-15 minutes before all three meals every day to reach the required amount of fiber/day.

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A sample of a day's menu is as follows:

Breakfast	Lunch	Dinner
***Garbanzo Beans* Blueberry Bagel Cream Cheese Banana	*Black Beans* Ham or Turkey and Swiss sandwich Trail Mix Apple	*Lentil Salad* Spaghetti with Meat Sauce Whole Wheat Roll

**Pre-meals are in Italics

2. Low carbohydrate diet with dietary carbohydrate restricted to <120g/day.

   A sample of a day's menu is as follows:

Breakfast	Lunch	Dinner
3-egg Omelet with Avocado, Mozzarella Cheese and Tomato Decaf Coffee with Cream	8 oz Beef Round Steak Spinach and Mixed Leaf Salad with Mushrooms, Onions, Celery, and Parmesan Cheese	9 oz Salmon Baked Kale topped with Garlic, Lemon and Sesame Seeds

In either group, you will be required to eat a large breakfast, moderate lunch, and a light supper (supper at least 3 hours before going to bed). There will be no caloric restrictions. You must be willing to accept and follow whichever of the two diets you are randomly assigned in order to participate in this study.

This study involves 13 visits in the course of 1 year. The purpose of these visits is to provide nutritional counseling and blood tests on certain visits. All the study visits are required. There will be blood drawings at visits 1, 2, 9, and 13. This will add up to 4 blood drawings totaling 7 tablespoons. At the first visit, 5 tubes totaling 3 tablespoons will be obtained. At the other 3 blood drawings, 3 tubes totaling just over 1 tablespoon each will be obtained. Over the course of the entire study 7 tablespoons will have been obtained. The results of the blood tests after the first one will not be reported to study participants until after the end of the study.

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A summary of what will occur over the course of the 52 weeks follows:

Screening visit (visit 1, week -2)	At the initial visit, you will have your weight and height measured to determine whether your body mass index (BMI) qualifies for the study. Your blood samples will be collected to determine that there is no existing disorder that would make it unsafe for you to take part in the study.
Randomization visit (visit 2, week 0)	At this visit, blood samples will be collected. Weight, waist circumference, and resting blood pressure will be measured. You will also be randomly assigned your diet and meet with a dietician for counseling on how to follow your diet and how to fill out your daily diet diary.
Preparation phase (visit 3, week 1 -3)	During this phase you will begin to accustom yourselves and your bodies to the changes in your diet. Those in the high-fiber group will gradually introduce the fiber into their diet. Those in the low-carbohydrate group will decrease their carbohydrate intake. During week 1, you will be required to come to the Diabetes Treatment Center to consult with the dietician and review your daily diet diary. During weeks 2 and 3 you will receive a phone call from the dietician to help you work through any difficulties that you may experience.
Induction phase (visit 4, week 4)	You will start eating according to your full diet. You will be required to consume an assigned week day meal from Tuesday to Friday morning that will be provided for you at the Diabetes Treatment Center or packaged to eat at home. You will be required to continue on your assigned diet at home for the rest of the study.
Maintenance visits (every 2 weeks through week 16, months 5, 6, 9 and 12)	Every 2 weeks to the 16th week, then at months 5, 6, 9, and 12 you will be required to come to the Diabetes Treatment Center to measure your weight loss and consult with the dietician to review your daily diet diary and discuss any difficulties. Blood samples will be collected week 4, week 16, and month 12. There will be three unscheduled telephone calls between weeks 6 and 16 to ask you what you ate during the day before the phone call. There will be three more unscheduled telephone calls between months 5 and 12.

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Who can take part?

Obese men and women (BMI 30-42 kg/m^2) over the age of 18, who are not pregnant or planning to become pregnant, not lactating, do not have active cancer, are not participating in another trial, have not dieted within the past 3 months with weight loss of more than 4 lbs, and are not vegans can take part in this study. If you have been placed on a special treatment by your doctor or you are being treated for other medical or surgical problem, you may need the consent of your doctor to certify that you are fit to participate in this study.

What are the risks of the study?

Pain and minor bleeding or bruising at the site of needle prick are possible risks of participating. Other possible risks include diarrhea, constipation, headaches, or muscle cramps associated with change in diet and weight loss.

Are there benefits to participating in the study?

You will be fed for 4 days at the Diabetes Treatment Center for free and will be provided some foodstuffs appropriate for your assigned diet. You will also have the opportunity of knowing your blood test results for obesity, and you may also benefit from a significant weight reduction if the goals of the study are achieved. Also, the information obtained from this study may help us understand how the body reacts to different types of diets and develop better alternatives for weight management.

What are my rights as a participant?

Participation in this study is voluntary. Your decision whether or not to participate or terminate at any time will not affect your present or future medical care/relationship to the school, medical center, or Diabetes Treatment Center. If you decide to stop, please inform the study investigator.

Significant New Findings

Should your health decline, should severe side effects occur, or new scientific developments occur indicating this study is not in your best interest or should your physician feel that participating in the study is no longer in your best interest, then study participation would be stopped and other options would be discussed.

How will my privacy be protected?

All of the information collected during this study will be kept strictly confidential. Your personal information will be kept in a secured place including password protection in a computer database. Additionally, after all information is collected, your name will be deleted from the information and it will be replaced with a serial number called an identifier. Any publication resulting from this study will refer to the participants as a group. See attached authorization for Use of Protected Health Information Policy regarding your rights.

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Are there any costs or other payments?

There are no costs to you for participating in this study. The blood tests will be performed at no cost to you

Whom do I call if I have questions about my rights as a research participant?

If you wish to contact an impartial third party not associated with this study regarding any question or complaint you may have about this study, you may contact the Office of Patient Relations, Loma Linda University Medical Center, Loma Linda, CA 92354, by calling at (909) 559-4647 or emailing at patientrelations@llu.edu for information and assistance.

Informed consent statement

I have read the contents of this consent form, and have listened to the verbal explanation given by the investigator. My questions concerning this study have been answered to my satisfaction. I hereby give voluntary consent to participate in this study. This consent does not waive my rights or the does it release the investigator, institution or sponsors from their responsibilities. I may call the principle investigator, Serena Tonstad, MD, PhD, at Loma Linda University, Department of Health Education and Promotion during routine office hours at (909) 558-4741 or Debbie Clausen, RN, MSN, nurse manager for the Diabetes Treatment Center at (909) 558-3022 if I have additional questions or concerns. I have been given a copy of this form for future reference. I have been given a copy of the California Experimental Subject's Bill of Rights.

I hereby give voluntary consent to participate in this study.

Subject name (print) Signature Date

Investigator's Statement

I have reviewed the contents of the consent form and the California Experimental Subject's Bill of Rights with the person signing above. I have explained potential study risks and benefits

Investigator name (print) Signature Date

Initials ________

Date ________

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APPENDIX F

AUTHORIZATION FOR USE OF PHI

OSR# 59217

INSTITUTIONAL REVIEW BOARD

Authorization for Use of Protected Health Information (PHI)

Per 45 CFR §164.508(b)

OFFICE OF SPONSORED RESEARCH
Loma Linda University • 11188 Anderson Street • Loma Linda, CA 92350
(909) 558-4531 (voice) / (909) 558-0131 (fax)

TITLE OF STUDY: A very high fiber diet versus a low-carbohydrate diet for weight loss in obese men and women with and without type 2 diabetes

Loma Linda University
Adventist Health Sciences Center
Institutional Review Board
Approved 10/22/09 **Void after** 10/21/2010
59217 **Chair** R-L-Rigsbyme

PRINCIPAL INVESTIGATOR: Serena Tonstad

Others who will use, collect, or share PHI: Debbie Clausen, Wayne Dysinger, Joan Sabate, Neal Malik, Lisa Griffith, Hildemar Dos Santos, Robyn Heidenreich, John Lii

The study named above may be performed only by using personal information relating to your health. National and international data protection regulations give you the right to control the use of your medical information. Therefore, by signing this form, you specifically authorize your medical information to be used or shared as described below.

The following personal information, considered "Protected Health Information" (PHI) is needed to conduct this study and may include, but is not limited to: name, address, telephone number, date of birth, and the results of all tests and procedures performed.

The individual(s) listed above will use or share this PHI in the course of this study with the Institutional Review Board (IRB) of Loma Linda University, health care providers who provide services to you in connection with this study, and central labs.

The main reason for sharing this information is to be able to conduct the study as described earlier in the consent form. In addition, it is shared to ensure that the study meets legal, institutional, and accreditation standards. Information may also be shared to report adverse events or situations that may help prevent placing other individuals at risk.

All reasonable efforts will be used to protect the confidentiality of your PHI, which may be shared with others to support this study, to carry out their responsibilities, to conduct public health reporting and to comply with the law as applicable. Those who receive the PHI may share with others if they are required by law, and they may share it with others who may not need to follow the federal privacy rule.

Subject to any legal limitations, you have the right to access any protected health information created during this study. You may request this information from the Principal

Investigator named above but it will only become available after the study analyses are complete.

- The authorization expires upon the conclusion of this research study.

You may change your mind about this authorization at any time. If this happens, you must withdraw your permission in writing. Beginning on the date you withdraw your permission, no new personal health information will be used for this study. However, study personnel may continue to use the health information that was provided before you withdrew your permission. If you sign this form and enter the study, but later change your mind and withdraw your permission, you will be removed from the study at that time. To withdraw your permission, please contact the Principal Investigator or study personnel at 909 558 3022 (Diabetes Treatment Center).

You may refuse to sign this authorization. Refusing to sign will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are entitled. However, if you do not sign this authorization form, you will not be able to take part in the study for which you are being considered. You will receive a copy of this signed and dated authorization prior to your participation in this study.

I agree that my personal health information may be used for the study purposes described in this form.

Signature of Patient *or* Patient's Legal Representative	Date
Printed Name of Legal Representative (if any)	Representative's Authority to Act for Patient
Signature of Investigator Obtaining Authorization	Date

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OSR 10/27/2009