AN ABSTRACT OF THE THESIS OF

Taylor Kathryn Bryant for the degree of Master of Science in Nutrition and Food Management presented on January 8, 2009.
Title: Diet and Exercise Intervention Strategies: Preventing Metabolic Syndrome in Middle-Aged Women.

Abstract approved:

Melinda M. Manore

The purpose of this study is to determine whether a 12-week nutrition and physical activity (PA) intervention program for middle-aged, pre-menopausal women at risk for Metabolic Syndrome (MetS) would reduce their risk factors. Ten overweight women (mean ± SD: age = 47 ± 3y; Body Mass Index = 31.0 ± 3.1 kg/m²) at risk for MetS were recruited and completed all phases of the program**.** At pre- and post-intervention participants completed 4-day weighted food records and PA logs. The intervention was focused on increasing whole grains, fruits and vegetables (servings/day), reducing saturated fat (g/day) and increasing PA (minutes/day). Participants significant increase in whole grains (Δ = 2.6 servings/day, $p = 0.005$), fiber (Δ = 6.9 g/day, $p < 0.03$) and PA (Δ = 39 minutes/day, $p < 0.0001$, n = 9), while significantly decreasing saturated fat intake (Δ = 7.5 g/day, P = 0.02). Fruit, vegetable and total fat intake did not change significantly. Body weight (kg) and % body fat did not change. The program was successful by fostering positive lifestyle behaviors known to reduce

risk of MetS such as increased PA and improving some dietary factors. A larger sample size may be needed to see greater improvements in whole fruit, vegetable and total fat intake in a 12-week period.

Diet and Exercise Intervention Strategies: Preventing Metabolic Syndrome in Middle-Aged Women

by
Taylor Kathryn Bryant

A THESIS

submitted to

Oregon State University

in partial fulfillment of
the requirements for the
degree of

Master of Science

Presented January 8, 2009

Commencement June 2009

Master of Science thesis of Taylor Kathryn Bryant presented on January 8, 2009.

APPROVED:

Major Professor, representing Nutrition and Food Management

Chair of the Department of Nutrition and Exercise Sciences

Dean of the Graduate School

I understand that my thesis will become part of the permanent collection of Oregon State University libraries. My signature below authorizes release of my thesis to any reader upon request.

Taylor Kathryn Bryant, Author

ACKNOWLEGEMENTS

When I first started at Oregon State University (OSU) the path I chose was not the most direct. Although, it did lead me exactly where I wanted to be, a registered dietitian with a masters in Nutrition and Food Management. My destination would not have been reached without the financial support I received from the OSU athletic department, the Annie Lindsay Fellowship, the College of Health and Human Sciences graduate assistantship and the support from the many wonderful people in my life.

This research project was a collaborative effort involving many dedicated individuals all striving to improve the health and wellbeing for the public, particularly middle-aged women. First I would like to thank Dr. Rebecca Donatelle, PhD., professor in the department of Public Health. Her vision made this research project possible. Special thanks are extended to the rest of the PROMIS research group, Melinda Manore, PhD., RD., CSSD., Alexix Walker, PhD., professor in Women's Studies, Kari Pilolla, MS., Nutrition and Food Management PhD. candidate, Jennifer Jabson, MPH., Public Health PhD. Candidate and Verna Ourada, Women's Studies MS candidate.

I would also like to state my sincere gratitude and appreciation to my graduate committee. Dr. Jeff Widrick was one of the best professors I have had throughout my academic career. His energy and brilliance made learning exciting and I thank him for that. Ingrid Skoog, MS., RD., CSSD., has had one of the greatest impacts on not only my career, but also on my life. She has been the most inspiring mentor, friend and now colleague one could only hope to have.

Ingrid encouraged me to do my very best and to never stop asking our favorite question…why? Last, but certainly not least, I would like thank Dr. Melinda Manore, PhD., RD., CSSD. Dr. Manore has been there for me every step of the way, guiding me through the most difficult process one could only imagine when they start their graduate experience. Her support, kindness and wisdom were never taken lightly. I thank her for believing in me and pushing me to reach my full potential.

I am forever grateful to my family and many friends who helped me through my academic career. Without their support I would not have made it this far. I want to give a special thanks to Kari Pilolla. Throughout my graduate studies Kari has been a wonderful friend and much needed support system while being away from my family. Had she not been working by my side during this study I may not have had the confidence or determination to continue. I am indebted to my amazing family who never let me forget how proud they were and never stopped believing in me. Thank you for all the support and encouragement you continue to give. Above all, I wish to thank my patient and loving fiancé Charlie. His thoughtfulness and unwavering support helped me accomplish one of my most challenging achievements. Always putting my goals and dreams first, he remained strong and positive at the times I needed it the most. I will be forever grateful for his patience and loving support.

TABLE OF CONTENTS

TABLE OF CONTENTS (Continued)

LIST OF FIGURES

LIST OF TABLES

LIST OF APPENDICES

Diet and Exercise Intervention Strategies: Preventing Metabolic Syndrome in Middle-Aged Women

Introduction

As the incidence of obesity has increased, the interrelationship between visceral abdominal fat and insulin resistance has been recognized as a heterogeneous clinical disorder now called metabolic syndrome (MetS). This metabolic disorder has previously been termed "syndrome X" and "insulin-resistance syndrome"(Aas et al., 2006; Iribarren et al., 2006; Liberopoulos, Mikhailidis, & Elisaf, 2005; Reaven, 1988; Thanopoulou et al., 2006). MetS is a combination of three or more interrelated medical abnormalities that increase the risk for cardiovascular disease (CVD) and progression to Type 2 diabetes. These medical abnormalities are characterized by a large waist circumference, hypertriglyceridaemia, low high density lipoprotein (HDL)-cholesterol, high blood pressure and a high fasting blood glucose (Iribarren et al., 2006; Moller & Kaufman, 2005; Thanopoulou et al., 2006). Based on the National Health and Nutrition Examination Survey III (NHANES III) data, the prevalence of MetS can range from 20% to 30% of the middle-aged population. In the United States (US) the prevalence of MetS in middle-aged individuals is increasing as obesity and sedentary lifestyles also increase (Carr, 2003; Park et al., 2003). While both men and women are affected by MetS, women are particularly vulnerable as they age. After adjusting for confounding variables such as body mass index (BMI), age, physical activity and household income, Carr (2003), found that as women reach post-menopausal status they face a 60% increased risk for MetS. In addition, women have a particularly high risk of CVD that is attributed to MetS. It is estimated that half of all cardiovascular episodes in women are related to MetS (Carr, 2003; Ford, Giles, & Dietz, 2002; Grundy et al., 2005). As women transition from pre- to post-menopause, many features of MetS emerge, which include: 1) increased intra-abdominal body fat, 2) increased low density lipoprotein (LDL)-cholesterol and triglyceride (TG) levels and reduced HDL-cholesterol, and 3) an increase in glucose and insulin levels (Carr, 2003; Cassells & Haffner, 2006). Since women tend to develop MetS after menopause along with other diseases, intervention during middle-life (pre-menopause) may reduce or delay the onset of chronic diseases.

Despite the growing evidence suggesting that these risk factors are modifiable and preventable with lifestyle change, little has been done to help prevent these problems before women experience the physiological changes brought on by menopause that exacerbate MetS. Research in lifestyle modification, particularly related to diet, weight loss and physical activity appear to be the most promising mechanism to curb MetS. However, intervention studies focusing specifically on prevention of MetS on pre-menopausal, middle-aged women at risk for MetS were not found during the literature review for this paper. Most intervention studies for MetS combine men and women in their studies, study only post-menopausal women, include women of all ages (18 years and older) or use women who already have Type 2 diabetes, MetS or CVD, none focus specifically on at risk, middle-aged, pre-menopausal women.

Throughout this paper, we will discuss research studies that include pre-menopausal, middle-aged women who are at risk for developing MetS.

The purpose of this study is to determine whether a nutrition and physical activity intervention program for at risk, middle-aged, pre-menopausal women will reduce their risk factors for MetS. A reduction in risk factors would subsequently reduce the onset of Type 2 diabetes and CVD. The outcomes of this study are critical to improving the health, longevity and quality of life for mid-life women as they age. We anticipate this research will aid in the development of intervention programs to decrease the incidence of MetS in at risk, middle-aged women. This in turn will improve overall health, decrease medical costs, and improve the quality of life for many women as they age.

Our *long-term goal* is to develop and test an intervention strategy that will result in effective and sustained risk reduction for MetS in at risk middle-aged women (40-60y). The *objective* of this pilot study was to determine whether a 12-week educational and psychosocial intervention program, focusing on nutrition, physical activity and psychosocial support would significantly improve lifestyle behaviors for decreasing the onset of MetS and Type 2 diabetes for at risk pre-menopausal, middle-aged women. Our *central hypothesis* was that risk for MetS and Type 2 diabetes increases as women progress into post-menopausal status, engage in sedentary lifestyles and maintain a poor diet low in fresh fruits, vegetables and whole grains. We *hypothesized* that by increasing programmed, moderate intensity physical activity (brisk walking) ≥ 150 minutes/week, increasing consumption of whole grains, fresh fruits and vegetables and lowering total fat and saturated fat intake, participants at risk for developing MetS will lower their risk factors. The research questions to be addressed are listed below.

Research Question #1: Following the 12-week intervention, do participants report participating in more minutes of moderate intensity programmed physical activity (such as brisk walking) per week than before the intervention program? *Rational*: Increased physical activity, leads to enhanced insulin sensitivity mediated by an increase in post-receptor insulin signaling and GLUT-4 translocation, thus improving glucose uptake (Kirwan et al., 2000).

Outcome Measure	Method of Assessment
Increased minutes of purposeful physical activity (brisk walking)	• 4-day activity records/pre-post (minutes/day)

Research Question #2: Following the 12-week intervention, do participants report consuming more whole fruit, vegetable and whole grain servings per day than before the intervention program? *Rational*: Whole grain consumption has been shown to improve insulin sensitivity, slow gastric emptying, leading to a decrease in total energy intake and reduce LDL-cholesterol levels beyond levels achieved with a diet low in saturated, *trans*-fatty acids and cholesterol alone (McKeown, 2004). Diets rich in whole fruits and vegetables may act as a protecting agent, due to their increased level of potassium, folate, phytochemicals and antioxidants. Diets high in vegetables and some whole fruits also have a low glycemic load and potential aid in weight management (He et al., 2004). Fruits, vegetables and whole grains can also decrease blood glucose levels due to their high fiber content (Joshipura et al., 2001).

Outcome Measure	Method of Assessment
Increase in servings of whole fruits, vegetables and whole grains	• 4-day diet records/pre-post • Food Processor SQL 2006, used to analyze diet and servings (servings/day)

Research Question #3: Following the 12-week intervention, do participants report consuming fewer grams of saturated fat per day than before the intervention program? *Rational*: Diets higher in polyunsaturated fat and lower in saturated fat may reduce the risk of CVD by lowering LDL-cholesterol levels (Golay & Bobbioni, 1997).

Outcome Measure	Method of Assessment
Decrease in saturated fat consumption grams/day	• 4-day diet records/pre-post • Food Processor SQL 2006, used to analyze diet and servings (grams/day)

Review of Pertinent Literature

Over the past decade, metabolic syndrome (MetS) has emerged from a minimally discussed health issue to one of the most prevalent combinations of costly and deadly risk factors (Borgman & McErlean, 2006; Cassells & Haffner, 2006; Eddy, Schlessinger, & Kahn, 2005; Ford et al., 2002). The Third Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults National Cholesterol Education Program Adult Treatment Panel III (NCEP ATP III) defined MetS as having three or more of the following characteristics in the same person (see Table 1):

1. Abdominal obesity
2. Hypertriglyceridaemia
3. Low High Density Lipoprotein (HDL)-cholesterol
4. High blood pressure
5. High fasting blood glucose levels (National Cholesterol Education Program (NCEP), 2002) (see Table 1).

This complex disorder is considered to be a Type 2 diabetes and cardiovascular disease (CVD) risk factor, yet it is composed of multiple metabolic abnormalities, each one posing its own CVD risk (Table 1) (Borgman & McErlean, 2006; Pannier et al., 2006).

Table 1. Clinical Identification of the Metabolic Syndrome

Risk Factor	Defining Level
Abdominal Obesity	Waist Circumference
Men	>102 cm (>40 in)
Women	> 88 cm (> 35 in)
Triglycerides	≥ 150 mg/dL (1.69 mmol/L)
HDL-Cholesterol	
Men	< 40 mg/dL (1.03 mmol/L)
Women	< 50 mg/dL (1.29 mmol/L)
Blood Pressure	≥130/≥85 mmHg
Fasting Glucose	≥110 mg/dL (6.1 mmol/L)

Table adapted from (Borgman & McErlean, 2006; National Cholesterol Education Program (NCEP), 2002).

The following review of literature will discuss the unique and specific challenges middle-age women face with MetS, the mechanisms of MetS, the relationship between MetS and Type 2 diabetes and nutrition and physical activity prevention strategies for chronic disease. Individual risk factors and the strategies for reducing these modifiable risk factors for MetS will then be discussed, including the role of nutrition, physical activity and lifestyle intervention. Prevention research examining MetS as a separate and independent risk factor for the onset of Type 2 diabetes and CVD is limited. Therefore, the majority of the research discussed here is based on Type 2 diabetes prevention strategies, and to a lesser extent based on prevention of MetS and CVD. Ultimately, Type 2 diabetes and CVD develop as a result of uncontrolled MetS. Prevention strategies for both MetS and CVD are similar; therefore, depending on the resource, each disease will be referred to both separately and together throughout the paper.

Similar to many chronic diseases, as individuals age the prevalence of MetS drastically increases, peaking in men aged 50-70 years and women aged 60-80 years (Park et al., 2003). With increasing age and post-menopausal status, the risk of MetS in women increases to 60%, even after adjusting for confounding variables such as Body Mass Index (BMI), age, physical activity and household income (Carr, 2003; Iribarren et al., 2006). Women have a particularly high risk for developing CVD as they transition into menopause (the leading cause of mortality for women in the United States (US) and Canada). Research now estimates that half of all cardiovascular episodes in women are related to the MetS (Iribarren et al., 2006; Pannier et al., 2006).

Metabolic Syndrome Mechanisms

During the transition from pre- to post-menopause, women experience several physiological changes that markedly increase MetS risk, particularly when coupled with increases in energy intake and decreases in physical activity. These changes lead to inadequate diet and active lifestyle behaviors that significantly impact risk. The following list of physiological changes occur as abdominal obesity increase. These changes will be followed by a detailed discussion of how the changes contribute to MetS: 1. There is an increase in intra-abdominal fat and a reduction in lean body mass due to reduced physical activity and exercise capacity. In addition, there is an increase in energy intake, or no change to compensate for the decrease in energy expenditure contributing to the increase in intra-abdominal fat. 2. The reduction in physical activity and subsequent increase in intra-abdominal fat leads to an increased secretion of apolipoprotein-B (apo-B) -containing particles. Excess apo-B containing particles results in hypertriglyceridemia and increased hepatic lipase (HL) activity, resulting in an increase in low density lipoprotein (LDL)-cholesterol, triglyceride (TG) levels and reduced HDL-cholesterol levels. 3. The resulting dyslipidemia decreases the normal suppression of free fatty acids (FFAs) arising from adipose tissue, leading to an accumulation of FFAs and impairment of glucose uptake in peripheral tissue, increased hepatic gluconeogenesis, and reduced hepatic clearance of insulin, thus insulin resistance (Carr, 2003; Carr et al., 2004; Homko & Trout, 2006; Moller & Kaufman, 2005).

Hypertriglyceridemia and Insulin Resistance

Intra-Abdominal Obesity. The accumulation of centrally distributed (intra-abdominal) fat has emerged as a CVD risk factor independent of overall obesity (Carr, 2003; Carr et al., 2004; Grundy et al., 2005; Opie, 2007). Increased intra-abdominal fat is associated with a higher risk of hypertriglyceridemia, small dense LDL-cholesterol particles, hypertension, increased insulin resistance, increased FFA uptake into peripheral tissues and decreased adiponectin (Colditz, Willett, Rotnitzky, & Manson, 1995; Despres, 1993; Norris et al., 2005).

Apo-B secretion and Insulin Resistance. Depending on the distribution site in the body, adipose tissue deposits vary in responsiveness to hormones that regulate lipolysis. Although there are many hormones that regulate lipolysis, norepinephrine and cortisol have been found to have the most impact on intra-abdominal fat (Wajchenberg, 2000). Adipose accumulation in the abdominal region, particularly the intra-abdominal region, has a higher lipolytic response to norepinephrine than the gluteal region. Cortisol may also contribute to this enhanced lipolysis by further inhibiting the anti-lipolytic effect of insulin. Together these factors contribute to an exaggerated release of FFAs from the abdominal adipocytes into the blood stream (Carr & Brunzell, 2004; Carr et al., 2004; Cassells & Haffner, 2006; Rader, 2007; Russell, 2001).

Elevated plasma FFA concentration leads to inappropriate regulation of glucose production, hepatic glucose utilization and increased storage of adipose tissue in peripheral tissue. Once the liver is fully saturated with glycogen (about 5% of total liver mass), it no longer needs glucose to make glycogen and shunts excess glucose to be metabolized, producing FFAs from the glucose metabolite, Acyl-CoA. The additional influx of FFAs to the liver further stimulates the synthesis of TG and the secretion of apo-B (the primary apolipoprotein of LDL particles), as well as other apo-B-containing particles leading to the assembly and secretion of very low density lipoproteins (VLDL) in attempt to maintain homeostasis regarding TG and fatty acid (FA) content. This accumulation of intracellular lipid metabolites appears to bring about hepatic insulin resistance (Rader, 2007).

Apo-B is the structural protein of atherogenic lipoproteins including VLDL, intermediate density lipoproteins (IDL) and LDLs. Increased resting plasma FFA causes a rise in albumin-bound FA, a source of VLDLs, leading to increased plasma levels of apo-B. The plasma apo-B level reflects the total number of atherogenic particles in the blood, with high levels indicating hypertriglyceridemia (Ginsberg, Zhang, & Hernandez-Ono, 2006). When TG levels are elevated, LDL particles become enriched in TGs, activating an increase in hepatic lipase (HL) activity. Increased activity of HL reduces the size of the TG-rich LDL and TG-rich HDL particles to form smaller, denser particles by hydrolyzing and releasing the TGs into the peripheral tissues. The apo-protein associated with HDL may disassociate from the TG-rich HDL particle and be cleared by the kidneys, reducing HDL particles, thus, HDL-cholesterol (Ginsberg et al., 2006; Rader, 2007; Russell, 2001). In addition to the reduction in HDL particle size by increased HL activity, during insulin resistance, there is a decrease in post-heparin plasma lipoprotein lipase (LPL) activity which further contributes to a low HDL-cholesterol (Holland et al., 2007; Murdoch, Carr, Hokanson, Brunzell, & Albers, 2000). An increased number of small, dense LDL and HDL particles and ultimately a decreased number of HDLs is a consistent feature of dyslipidemia related to intra-abdominal obesity, as well as insulin resistance.

As insulin facilitates the oxidation of glucose in adipocytes, it also inhibits intracellular lipase from hydrolyzing TG to release FAs, inhibiting the breakdown of fat in adipose tissue. Reduced insulin clearance in the liver, along with elevated FFA concentrations, leads to an increase in peripheral insulin concentrations and over production of glucose, thus leading to peripheral insulin resistance (Carr & Brunzell, 2004; Carr et al., 2004; Cassells & Haffner, 2006; Cnop et al., 2003; Rader, 2007; Russell, 2001). See Figure 1.

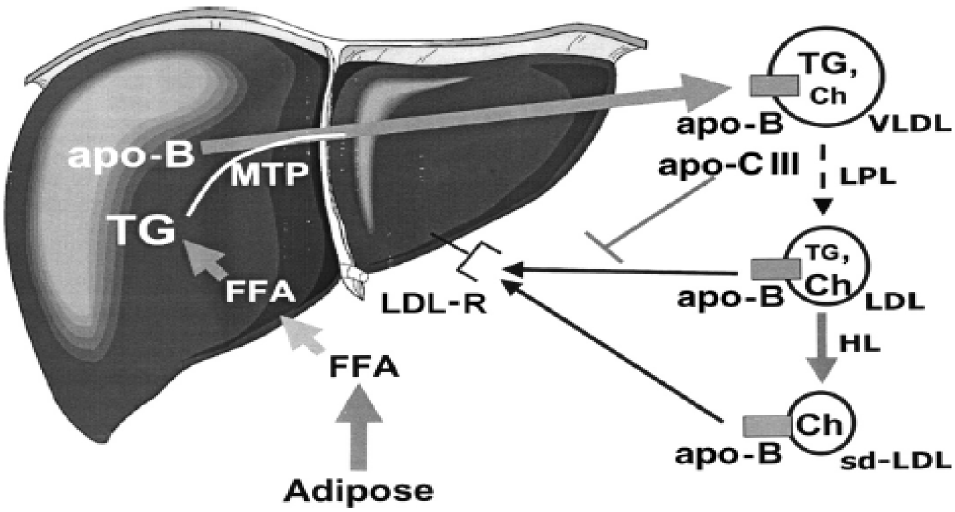

Figure 1. Mechanisms of dyslipidemia in insulin resistance are driven by increased influx of free fatty acids (FFAs) from adipose tissue to the liver. FFAs promote increased triglyceride synthesis in the liver, which can lead to the secretion of very-low-density lipoprotein (VLDL). apo _ apolipoprotein; Ch _ cholesterol; LDL _ low-density lipoprotein; LDL-R _ LDL receptor; LPL _ lipoprotein lipase; MTP _ microsomal triglyceride transfer protein; HL _ hepatic lipase; sd-LDL _ small, dense LDL; TG _ triglyceride. Rader (2007). *(Permission to use granted from Dr. Rader)*

Effects of Menopause

Estrogen and progesterone promote the accumulation of gluteo-femoral (lower body) fat in women before the onset of menopause (Carr, 2003). As women enter menopause the secretion of estrogen and progesterone ends. Testosterone secretion, along with androstenedione (a male hormone produced by the adrenal gland) persists during menopause and can be converted in body fat to estrogen (i.e., estradiol). While this process allows for the continuance of estrogen, it is produced at much lower levels than before menopause (Carr, 2003; Colditz et al., 1995; Despres, 1993). These hormone changes can lead to alterations in body fat distribution, even in the absence of weight gain. With diminishing estrogen and increasing testosterone secretions, body fat distribution shifts from the female, gluteal (lower body) region, to the male android (abdominal) region, as seen in the following study (Ainy, Mirmiran, Zahedi Asl, &

Azizi, 2007; Carr, 2003; Lin et al., 2006; Mesch et al., 2006; Rosano, Vitale, & Tulli, 2006).

In a recent study, Phillips et al. (2008) studied 78 women, 58 pre-menopausal (age 18-50 y) and 20 post-menopausal (46-81 y), to examine the relationship between insulin, adiposity variables and sex hormones for risk factors for myocardial infarction (MI) due to CVD and MetS. Women included in the study were healthy, sedentary (no regular vigorous physical activity program > 180 minutes/week), weight stable (no weight change > 10% within the past year), no history of drug or alcohol abuse, free of CVD, and no hormone or other medications known to influence lipid levels or body composition. Results showed that adipose levels were higher in post-menopausal women and the distribution was also distinctly different than pre-menopausal women, residing in the abdominal region versus the gluteal region. They also found that visceral adipose tissue (VAT) explained the correlation between obesity and risk factors for MI in women, although only making up 4.3% and 8.8% in pre-menopausal and post-menopausal women, respectively (Phillips, Jing, & Heymsfield, 2008).

In addition to understanding the relationship between obesity and risk factors for MI in women, Phillips et al. (2008), found that total adipose tissue (TAT), subcutaneous adipose tissue (SCAT) and VAT correlated positively with age. Their results showed that VAT had the strongest correlation with age, even after controlling for TAT ($p < 0.001$), SCAT ($p < 0.001$) and waist circumference ($p = 0.15$). Correlations with VAT also appeared to be stronger with TG, HDL-cholesterol, glucose and free (non-protein bound) testosterone (FT) compared to

TAT or SCAT. Since all adipose variables increased with age, Phillips et al. (2008) controlled for age in correlations with adipose variables. After controlling for age and VAT, all significant correlations of insulin and FT with risk factors for MI were eliminated except for FT-triglycerides in post-menopausal women. These findings suggest that VAT accumulation may explain the correlations of obesity, insulin and testosterone with risk factors for MI in women. This accumulation of VAT may effect the expression of insulin resistance and increase FT levels in women as they age. This indicates that other factors such as insulin resistance or sex hormone levels, which are both closely linked to obesity, could effect VAT accumulation, in addition to being affected by it (Phillips et al., 2008).

These findings indicate that as women advance towards menopause they experience physiological changes that both independently and collectively elevate their risk for developing MetS (Carr, 2003; Hayes, 2006; Homko & Trout, 2006; Iribarren et al., 2006; Moller & Kaufman, 2005; Pannier et al., 2006). These physiological changes occur in all middle-age women, though some women have additional risk factors such obesity, inactivity and poor eating habits that may exacerbate the changes compared to their healthier counterparts. Although menopause inevitably brings about these changes, all women can modify their diet, physical activity and lifestyle behaviors to reduce their increased risk as they enter menopause.

Metabolic Syndrome and Type 2 Diabetes

The increasing prevalence of obesity has been paralleled with increases in prevalence of MetS (Liberopoulos et al., 2005; Lin & Pi-Sunyer, 2007). As the rates of overweight and obesity continue to increase, defined as a BMI of ≥30 kg/m^2), MetS will continue to be a significant medical challenge. MetS also increases risk of Type 2 diabetes (United States Department of Health and Human Services (DHHS), 2001). Type 2 diabetes is defined as a life-long disease marked by high levels of glucose in the blood. It occurs when the body does not respond correctly to insulin, the hormone released by the pancreas (The Diabetes Prevention Program (DPP), 2002).

As with diabetes and obesity, the incidence of MetS increases with age. Research, using the criteria of the NCEP ATP III, found that the prevalence of MetS in US adults ages 20 years and older was 23.7% with the prevalence reaching 43.5% in adults aged 60-69 years and 42.1% for those 70 years of age and older (Moller & Kaufman, 2005). Subsequent studies also using the ATP III criteria suggested increased risk for Type 2 diabetes, with almost 70% of those with diabetes also meeting criteria for MetS (Cassells & Haffner, 2006; Iribarren et al., 2006).

Type 2 diabetes is a serious and costly chronic disease that affects 20.8 million Americans (Fujimoto, 2000). The complications that result from this disease are a significant cause of morbidity that can lead to mortality associated with the damage or failure of various organs such as the kidneys and nerves. Individuals with Type 2 diabetes are also at a significantly higher risk for coronary heart disease (CHD), peripheral vascular disease, and stroke (The Diabetes Prevention Program (DPP), 1999). When Type 2 diabetes is treated there can be positive effects on hyperglycemia, although normalization of blood glucose levels rarely occur, which is why prevention rather than early detection is so important (The Diabetes Prevention Program (DPP), 1999).

As individuals' age, become inactive and are overweight or obese, their risk for developing Type 2 diabetes increases. Research in 1999 indicated that 61% of all adults are overweight or obese, with 300,000 obesity related deaths each year, leading to an economic cost of $117 billion in 2000 (United States Department of Health and Human Services (DHHS), 2001). The number of individuals diagnosed with Type 2 diabetes has been steadily increasing since 1982. In 2005,1.5 million new cases in people ages 20 years and older were diagnosed (United States Department of Health and Human Services (DHHS), 2001). The Center for Disease Control and Prevention (CDC) reported a doubling in the number of Americans with diabetes from 1980 to 2004 from 5.8 million to 14.7 million (Centers for Disease Control and Prevention (CDC), 2003). The following chart (Figure 2), illustrates the marked increase in millions of individuals diagnosed with Type 2 diabetes each year (Centers for Disease Control and Prevention (CDC), 2003).

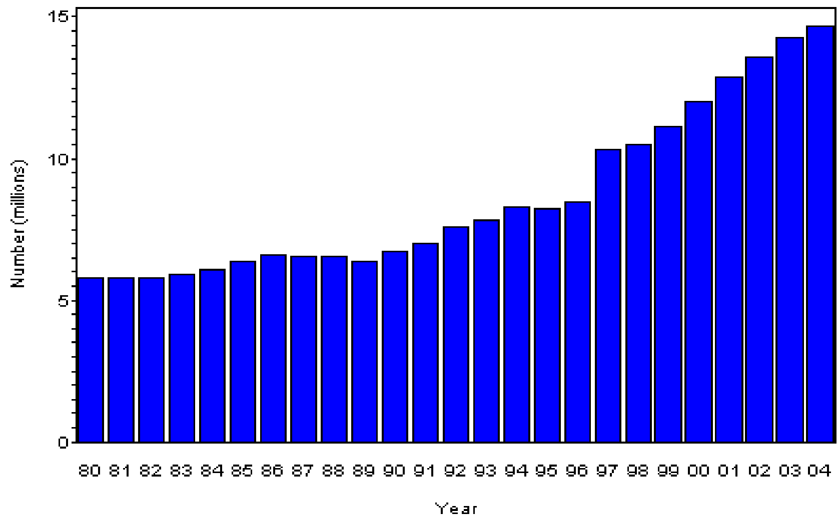

Figure 2. Prevalence of Diabetes in the United States from 1980-2004 (Centers for Disease Control and Prevention (CDC), 2003). Prevalence estimates were age-adjusted using estimates of the 2000 U.S. population as the standard. The numbers in the table are rounded and may not sum to totals.

The following section presents a general overview on the importance of reducing modifiable risk factors related to MetS. This will be followed by a review of the prevention strategies related to nutrition, physical activity and lifestyle interventions needed to reduce MetS risk factors.

Risk Factors of Metabolic Syndrome

Evidence from epidemiologic studies indicate that MetS, Type 2 diabetes, CVD and CHD are greatly influenced by the same modifiable lifestyle behaviors (Corpeleijn et al., 2006; Eriksson, 2006; Tuomilehto et al., 2001). The lifestyle behaviors having the greatest impact on these chronic diseases include an inadequate diet, physical inactivity, smoking, and/or overweight/obesity (Eriksson, 2006; Willett, 2002). These modifiable lifestyle behaviors account for over 90% of MetS and Type 2 diabetes, 70% of stroke, 70% of colon cancer and 80% of CHD incidences (Willett, 2002).

The NCEP ATP III analyzed associated prevention strategies from findings of randomized, controlled clinical trials examining risk factors for MetS, Type 2 diabetes, CVD (National Cholesterol Education Program (NCEP), 2002). Many of the participants within these clinical trials were at risk for CVD. Findings from these clinical studies strongly influenced the development of new NCEP clinical guidelines for management and testing of high blood cholesterol and related disorders. The new guidelines included nutrition and physical activity recommendations, which will be discussed later in this review (Grundy et al., 2005; National Cholesterol Education Program (NCEP), 2002). The ATP III is an updated report from the ATP I and ATP II. In addition to treatment for those with CVD, the ATP III added a new focus on primary prevention in persons at risk for CVD. The new features of the ATP III pertinent to this study focus on risk reduction, aimed at improved blood lipid profile, especially lowering LDL-cholesterol and prevention of MetS. These factors are listed in Table 1 and Table 2 (National Cholesterol Education Program (NCEP), 2002).

Table 2
Classification of LDL, total, and HDL-cholesterol (mg/dL)*

LDL Cholesterol	Classification
< 100	Optimal
100-129	Near or Above Optimal
130-159	Borderline High
160-189	High
≥ 190	Very High
Total Cholesterol	Classification
< 200	Desirable
200-239	Borderline High
≥ 240	High
HDL Cholesterol	Classification
< 40	Low
≥ 60	High

*LDL = Low density lipoprotein, HDL = high density lipoprotein
Tables adapted from (National Cholesterol Education Program (NCEP), 2002)

Evidence statements by NCEP regarding modifiable risk factors such as LDL-cholesterol, total-cholesterol, and HDL-cholesterol are as follows (National Cholesterol Education Program (NCEP), 2002):

- Strong causal relationship between elevated LDL-cholesterol and increased CVD risk
- Elevated serum TGs are associated with increased risk for CVD
- A low HDL-cholesterol level is strongly and inversely associated with risk for CVD
- Atherogenic dyslipidemia commonly occurs in persons with premature CVD and is strongly associated with abdominal obesity, obesity, and physical inactivity
- Hypertension is a major independent risk factor for CVD
- Diabetes is a major, independent risk factor for CVD
- Obesity is a major, modifiable risk factor for CVD
- Physical inactivity is a major, modifiable risk factor for CVD
- High intakes of saturated fatty acids and cholesterol directly raise LDL-cholesterol concentrations

Nutrition and the Prevention of Chronic Diseases

The role of nutrition in prevention of chronic diseases has been studied for years with copious amounts of research done specifically on the role of diet in the prevention of Type 2 diabetes and other related chronic diseases. For the purpose of this paper, the following review will focus on three areas of nutrition (dietary fat, whole grains, whole fruit and vegetables) in prevention of MetS, Type 2 diabetes and CVD. Section one will discuss the impacts of total dietary fat intake, especially saturated fat intake on excess body weight, Type 2 Diabetes, and CVD. Sections two and three will discuss the impacts of whole grain and whole fruit and vegetable consumption on health and chronic disease prevention.

Dietary Fat Intake

Excess Body Weight and Type 2 Diabetes. The relationship between excess dietary fat intake and its direct impact on increased body weight and risk for developing Type 2 diabetes will be discussed in the following section. Excess body fat, particularly intra-abdominal fat, is a primary risk factor for the development of MetS and Type 2 diabetes. The increase in body fat is the result of an imbalance between energy intake and energy expenditure, particularly decreased physical activity and increased energy intake, especially dietary fat intake (Summers et al., 2002). Since dietary fat contains almost twice the energy (calories) per gram than protein or carbohydrate, a diet high in dietary fat will contain more calories per bite than a diet consisting of moderate protein and carbohydrates and lower fat.

When total energy intake exceeds energy expenditure weight gain is inevitable. In a state of energy balance body weight remains the same. It has been hypothesized that higher levels of total dietary fat intake, particularly saturated and *trans*-fat, significantly contribute to an increase in body fat, independent from an increase in total energy consumption or changes in physical activity (Golay & Bobbioni, 1997). While body weight may not change, the composition of body weight may shift from lean tissue to adipose tissue. High intakes of dietary fat have also been hypothesized to contribute to insulin resistance, whether or not changes in energy balance or weight gain occurred (Schulze & Hu, 2005).

The impact of dietary fat intake and weight gain on Type 2 diabetes has recently been examined. The San Luis Valley Diabetes Study (SLVDS) set out to estimate and describe the relationship between dietary fat intake and weight gain in adults, and how these factors alter insulin resistance. This long-term, longitudinal observational study examined all known diabetic individuals living in two designated counties in Colorado, as well as 1351 individuals with no history of Type 2 diabetes. Etiologic and prognostic risk factors associated with Type 2 diabetes were examined over a 14-year period to evaluate whether the relationship between weight gain and dietary fat intake varies according to relative insulin resistance (Mosca, Marshall, Grunwald, Cornier, & Baxter, 2004). Participants had blood drawn after an overnight 8-hour fast then were given an oral glucose tolerance test (OGTT) with a 75g glucose beverage followed by two more blood draws at 1 and 2 hours post glucose consumption (Mosca et al., 2004). Each participant was tested up to three times during the 14-year study.

Insulin resistance was evaluated at each visit and was determined by increases in the Quantitative Insulin Sensitivity Check Index (QUICKI) based on fasting insulin and glucose levels (Mosca et al., 2004). Participants were also asked to complete a self-reported physical activity questionnaire and a 24-hour diet recall.

Results from the SLVDS showed a significant positive relationship between percent of energy intake derived from dietary fat (25%, 35% 45%) and weight gain for both men and women ($p = 0.0017$). While most diets high in dietary fat also tend to be higher in total energy intake, the positive relationship between dietary fat intake and weight gain still held even after adjusting for total energy intake. The relationship between percentage of energy from fat intake and weight gain was stronger with women than men ($p = 0.0002$). Unfortunately type of dietary fat consumed was not classified (Mosca et al., 2004). Furthermore, individuals with the highest insulin resistance (highest relative risk) gained the most weight and consume the most dietary fat compared to individuals with lower or no insulin resistance on a similar diet using 24-hour diet recalls ($p = 0.0025$). The authors indicated that high fat intake, coupled with lower carbohydrate intake, may cause a reduction in post-prandial insulin removal. In addition to reduced insulin clearance, diets rich in dietary fat may lead to reduced oxidation of fatty acids in adipose tissue, contributing to weight gain. Regardless of the mechanism for the positive relationship between dietary fat intake and weight gain, findings from this study suggest that lowering dietary fat intake would lower Type 2 diabetes risk factors, particularly in individuals with insulin resistance (Mosca et al., 2004). Although this study did not discriminate between types of fat, other research has found that the type of dietary fat may be important for increasing the risk of Type 2 diabetes.

Research by Salmeron, Hu et al. (2001), investigated the impact of total dietary fat intake on risk factors for Type 2 diabetes, and the impact of specific types of dietary fat. This 14-year follow-up study was based on the Nurses' Health Study, which is funded by the National Institutes of Health and was established by Dr. Frank Speizer in 1976. Food frequency questionnaires were added in 1980 (Salmeron et al., 2001). This follow-up study examined the long-term relationships between total dietary fat intake, which included all types of dietary fat, and the risk for development of Type 2 diabetes. This study found that the amount of total dietary fat intake, along with total saturated fat and monounsaturated fat intake, were associated with an increased risk of diabetes, after adjusting for age and BMI. The relationship was not significantly associated with the risk of diabetes after controlling for all known risk factors, such as physical activity, alcohol, parental history of diabetes and cigarette smoking. Researchers found that by replacing 5% of energy from saturated fat and *trans*-fat with polyunsaturated fat, the risk for diabetes was deceased by 35% ($p < 0.0001$) and 40% ($p < 0.0001$), respectively. An increase of 2% in dietary *trans*-fat intake increased the relative risk for Type 2 diabetes ($p = 0.0006$). Conversely risk was decreased by 28% when *trans*-fat was replaced with dietary carbohydrate ($p < 0.001$) and by 40% when replaced with polyunsaturated fat ($p < 0.0001$) (Salmeron et al., 2001). Unlike with the SLVDS, this study did not find significant correlations with total fat and saturated fat intake and increased risk for Type 2 diabetes. Though in this study, there were findings suggesting that dietary intake of polyunsaturated fat and *trans*-fat have significant influences on the relative risk for developing Type 2 diabetes. Both the SLVDS and the 14-year Nurses' Health Study follow-up found dietary fat intake, either the specific types or total fat, to significantly increase the risk for developing Type 2 diabetes. We do know that excess body weight can be a risk factor for Type 2 diabetes, and that dietary fat leads to increased energy and weight gain. Further research is needed to examine total fat intake and the impact of each type of dietary fat on relative risk for Type 2 diabetes.

<u>Role of Dietary Fat and CVD.</u> Not only has excess total dietary fat intake been shown to increase risk for Type 2 diabetes, it has also been shown that high intakes of saturated fat increases the risk for CVD. This relationship was demonstrated in a 20-year follow-up of the Nurses' Health Study. This study examined 78,778 US women, all of whom were free of known CVD and Type 2 diabetes at the beginning of the study (Oh, Hu, Manson, Stampfer, & Willett, 2005). An initial follow up at 14 years showed that younger women (under age 65) consumed more dietary fat and participated in less physical activity than women ≥ 65 years of age. After the initial follow up, it was hypothesized that the relationship between specific types of fat and risk of CVD was stronger in younger women compared to those ≥ 65 years of age. To reduce the impact of diet changes over time and errors in dietary assessment, dietary measurements were repeatedly measured over the 14 years of the study (number of times not listed). A food frequency questionnaire was used to measure usual diet, total dietary fat intake, and specific types of dietary fat intake, including saturated fat, monounsaturated fat, polyunsaturated fat and *trans*-fat. The endpoint for

participants was non-fatal myocardial infarction or fatal CVD, occurring after the first questionnaires were administered in 1980 (Oh et al., 2005).

Of the 78,778 women followed up after 20 years, 1,766 incident cases of CVD (1,241 non-fatal myocardial infarctions and 525 CVD deaths) were documented. Women included in the study were grouped in quintiles according to their total intakes of specific types of dietary fat. Each quintile was then examined to investigate trends over time. Age adjusted analysis revealed higher intakes of each type of dietary fat by younger women. Younger women consuming more dietary fat also had lower level of physical activity and fiber intake. After adjusting for age (continuous), total fat intake was significantly associated with increased risk of CVD ($p = 0.001$), although in a multivariate analysis the association was attenuated and not significant ($p = 0.49$). In addition to total dietary fat intake, intakes of saturated fat, monounsaturated fat, polyunsaturated fat, and *trans*-fat were each significantly associated with risk of CVD in the age adjusted analysis. More specifically, high polyunsaturated fat intake had the most significant impact in lowering risk for CVD ($p = 0.002$), while high intakes of *trans*-fat had the greatest significant impact on increasing the risk for CVD ($p < 0.001$).

These findings appeared to be much stronger in women younger than women 65 years of age or older (Oh et al., 2005). A possible explanation given by the authors for decreased association of dietary fat intake and CVD as women age, may be the decline in the predictability of blood cholesterol levels and CVD due to co-morbid diseases affecting blood lipids. Often as individuals advance in age other risk factors contribute to the increased risk for CVD, such as a greater prevalence of other chronic diseases, or a decline in overall health status or metabolic changes associated with aging (Oh et al., 2005). Since younger women are often free from chronic diseases and generally healthier than women over the age of 65, the stronger association between blood cholesterol and dietary fat intake and CVD risk is reasonable. While high dietary fat intake and high blood cholesterol can have negative health risks, the direct association with dietary fat intake and CVD risk may be clearer in younger women living without co-morbid diseases.

Similar results were found in a clinical trial by British researchers investigating the fat intake of individuals diagnosed with Type 2 diabetes (Summers et al., 2002). After completing a 3-day diet record, a registered dietitian assessed participants' usual intakes. Once baseline diets were established, participants in this cross-over study were randomly assigned to a diet rich in saturated fat or polyunsaturated fat for a 5-week period. Each participant was instructed by the registered dietitian on how to effectively change their diets to meet their assigned groups' fat intake goals without losing weight. Three-day dietary records were collected weekly to ensure that participants were making the necessary adjustments in their usual diet to meet their fat intake goals.

To examine the effects of the randomized diet on insulin sensitivity and body fat distribution, participants had fasting blood samples and magnetic resonance imaging (MRI) measurements taken pre- and post-randomization. The

MRI measurements were taken along with waist and hip skin-fold and circumference measurements to assess abdominal fat distribution. Results from these assessments indicated that when participants were assigned a diet rich in polyunsaturated fat they had an overall lower energy intake ($p = 0.07$), significantly lower total fat intake ($p < 0.01$), and a significantly increased polyunsaturated to saturated fatty acid ratio ($p < 0.01$). Total abdominal, visceral fat and WHR were not affected by dietary change, although subcutaneous fat area significantly decreased for both men and women and women alone following the polyunsaturated fat diet compared to the saturated fat diet ($p = 0.001$) as shown in the MRI. Improvements were also seen in insulin sensitivity ($p = 0.02$) following the polyunsaturated fat diet, which was measured using a double-antibody radioimmunoassay method. No changes were seen in HDL-cholesterol, TGs, glucose or other metabolite concentration besides a significant decrease in LDL-cholesterol ($p = 0.001$) (Summers et al., 2002).

There results were comparable to those found in the Nurse's Health Study, suggesting that lower intakes of total dietary fat along with higher intakes of polyunsaturated fats, replacing saturated fats improve CVD and Type 2 diabetes risk factors and decrease relative risk, while higher intakes of *trans*-fat increase metabolic risk factors for CVD and Type 2 diabetes (Meyer, Kushi, Jacobs, & Folsom, 2001; Salmeron et al., 2001). Individuals in this study were free-living with no report provided on physical activity involvement and its possible impact on CVD risk.

There has been conflicting results regarding the way dietary fat intake can increase the risk of developing Type 2 diabetes and MetS. Diets high in fat can indirectly increase risk by increasing total energy consumption, resulting in weight gain, which is a risk factor for Type 2 diabetes. Results from the 20-year Nurse's Health Study follow-up found that individuals whom regularly consume diets rich in fat may also be more likely to engage in sedentary lifestyles, leading to increased weight gain (Oh et al., 2005). Unfortunately, limited research has shown a direct link connecting excess total dietary fat intake to increased risk of developing MetS, Type 2 diabetes and CVD (Meyer et al., 2001; Mosca et al., 2004; Oh et al., 2005; Salmeron et al., 2001; Summers et al., 2002). Whether diets rich in total fat intake lead to increased weight gain by increasing total energy intake or by modifying effects of insulin resistance and substrate oxidation is still unclear. Though evidence does indicate that reducing total dietary fat intake, particularly saturated and *trans*-fat, can have a positive impact on ones health.

Whole Grain Intake

Consumption of whole grain products have been shown to reduce the risk for developing MetS, Type 2 diabetes, CVD, stroke and cancer (Hu et al., 2001; Jacobs & Gallaher, 2004; Liu, Manson, Lee et al., 2000; Liu, Manson, Stampfer et al., 2000; Meyer et al., 2000). The underlying mechanism for the relationship of whole grain consumption and chronic disease prevention may be the interaction of several biologically active components found in whole grains, including dietary fiber, vitamin E, magnesium and folate (Slavin, Martini, & Jacobs, 1999). The relationship between these biologically active components may work through multiple pathways such as; reduction in blood lipids, reduction in blood pressure, an increase in insulin sensitivity and improvement in blood glucose control (Liese et al., 2003; McKeown, Meigs, Liu, Wilson, & Jacques, 2002; Murtaugh & Jacobs, 2003). The possible pathways by which these constituents may contribute to reducing the risk for MetS, diabetes and CVD will be reviewed in the following sections.

Biologically Active Components of Whole Grains. Three major biological components found in whole grains have been independently shown to positively impact blood lipids, blood pressure and blood glucose control. The following will discuss the direct and indirect impacts and hypothesized mechanisms of dietary fiber, magnesium and folate on chronic disease prevention.

Dietary Fiber. Epidemiologic studies have revealed that dietary fiber may independently decrease blood glucose, insulin, and serum lipid concentrations in both diabetic and pre-diabetic individuals (Liese et al., 2003; Riccardi & Rivellese, 2000). Dietary fiber has also been shown to decrease the insulinemic response to dietary carbohydrates by delaying absorption after a meal. Soluble fibers (such as oats, apples, pears, dried beans and carrots) form a gel-like substance when dissolved in water. This gel-like substance causes food to swell and move slower, increasing the time food stays in the intestines (Chandalia et al., 2000). When food stays in the intestines for longer periods of time it can reduce the feelings of hunger and overall food intake (Liese et al., 2005). The satiety effect of dietary fiber has an indirect impact on decreasing the intake of less nutrient dense foods that may be higher in saturated fat and total energy, thus decreasing weight gain.

Magnesium. Magnesium has been found to play a role in lowering insulin concentrations and in glucose metabolism (Chandalia et al., 2000; Hu et al., 2001; Kao et al., 1999; Lopez-Ridaura et al., 2004; Song, Manson, Buring, & Liu, 2004). Although the mechanisms are poorly understood, epidemiological studies indicate that inadequate magnesium intake may be an independent risk factor for the development of Type 2 diabetes. These studies have demonstrated that increased magnesium intake may aid in lowering TG and increase HDL-cholesterol (Hu et al., 2001; Kao et al., 1999; Lopez-Ridaura et al., 2004; Song et al., 2004; Song, Manson, Buring, Sesso, & Liu, 2005). Research exploring the relationship between magnesium intake and prevention of MetS found supporting evidence.

A recent study, the Coronary Artery Risk Development in Young Adults (CARDIA) study, followed 4,637 young adults (18 – 30 yrs), free from MetS and Type 2 diabetes at baseline for 15 years to understand the impact of magnesium intake on MetS risk (He et al., 2006). Results showed that individuals in the highest 2 quartiles of magnesium intake (166.6 and 225.3 mg/1000 kcal/day) had significantly lower risk of MetS ($p = 0.01$) compared to those in the lowest quartiles, after adjusting for potential dietary and non-dietary confounders. Magnesium intake was also inversely related to individual components of MetS, particularly with fasting glucose (median magnesium intake: 190.6 mg/1000 kcal,

$p < 0.01$), waist circumference (median magnesium intake: 192.1 mg/1000 kcal, $p < 0.01$), and HDL-cholesterol (median magnesium intake: 192 mg/1000 kcal, $p < 0.01$) (He et al., 2006). The exact mechanism for the relationship between magnesium intake and risk for MetS is not completely understood. Although experimental data suggest that through its role as a cofactor for numerous enzymes, magnesium may directly regulate cellular glucose metabolism and may interact with cellular calcium homeostasis, influencing insulin secretion (Barbagallo et al., 2003). The influence of magnesium on the release and activity of insulin may affect be exacerbated by inadequate magnesium intake. Hypomagnesemia has been shown to worsen insulin resistance leading to hyperglycemia (McKeown, 2004; Meyer et al., 2000; Slavin et al., 1999). Also, during severe hyperglycemia the kidneys may lose their ability to retain magnesium, resulting in an increased loss of magnesium in the urine and decreased levels in the blood. In older adults, correcting magnesium depletion may improve insulin response and action (McKeown, 2004; Meyer et al., 2000; Slavin et al., 1999).

*Folate.*Dietary intake of folate has been shown to have a lowering affect of plasma homocysteine concentrations. Elevated homocysteine concentrations have been related to an increased CVD risk (Montonen, Knekt, Jarvinen, Aromaa, & Reunanen, 2003; Verhoef et al., 1997). The predominant nutritional cause of elevated homocysteine concentrations is inadequate folate intake. Research by Rimm et al. (1998) examined the direct impact of folate to CVD risk using data from the Nurse's Health Study. This 14-year follow-up study found that women consuming higher amounts of folate (696 g/day), from either food or supplement sources, had lower risk for CVD, particularly when their folate intake was well above the 1989 RDA (180 µg/day) ($p < 0.01$). This significant association was still seen even after accounting for confounding variables such as healthy lifestyle behaviors, other vitamin and mineral intake and age (Rimm et al., 1998). The specific mechanism by which folate aids in reducing risk for developing CVD is not completely understood aside from its role in transulfuration pathways to convert homocysteine to cysteine to maintain homocysteine homeostasis (Joshipura et al., 2001; Joubert & Manore, 2006; Rimm et al., 1998). Although data are insufficient to recommend a specific amount of vitamins such as folic acid to lower homocysteine levels, total folate intakes of 400 µg/day or more are associated with desirable homocysteine levels (Rimm et al., 1998; Verhoef et al., 1997).

Whole Grains and CVD. Researchers have examined the impact of whole grain consumption versus the constituents of whole grains on CVD. Findings suggest that the whole may have a greater impact on prevention than its separate parts. The Framingham Offspring Study, based on the offspring of the Framingham Heart Study cohort in 1971, examined the influence of whole grains on CVD risk (McKeown et al., 2002). This longitudinal, community based study examined several metabolic markers of CVD risk and the association between whole grain and refined grain intake. Participants completed a semi-quantitative 126-item food frequency questionnaire indicating usual dietary habits within the past year in addition to a complete physical. The physical included an OGTT, measurements of lipid profile and blood pressure measurement. Results showed that individuals consuming greater amounts of whole grains (fifth quintile, mean of 20.5 servings/week), consumed an overall more balanced diet, consisting of moderate protein and carbohydrate intake and lower fat intake. Individuals in the fifth quintile consumed significantly more dietary fiber (~21.2 g/day, $p < 0.001$), a higher percentage of polyunsaturated fat (~6.1% of total fat/day, $p < 0.001$), more whole fruit (~10.9 servings/wk, $p < 0.001$) and vegetables (~23.2 servings/week, $p < 0.001$). Those in the fifth quintile also consumed fewer saturated fats (~9.6% of total fat/day, $p < 0.001$) and meat (~ 2.6 servings/week, $p < 0.001$) compared to those consuming fewer whole grains (McKeown et al., 2002).

After adjusting for potential confounding variables and dietary factors associated with diets high in whole grains, significant inverse associations with whole grain intake and WHR (mean difference: 0.1; p for trend <0.005), LDL-cholesterol (mean difference: 0.12 mmol/L; p for trend = 0.02) and fasting insulin concentrations (mean difference: 6 pmol/L; p for trend = 0.03) were observed. The negative association between low whole grain intake and high fasting plasma insulin levels was significantly greater for obese individuals (BMI ≥ 30kg/m^2; p for trend = 0.003) than for non-obese individuals (BMI <30kg/m^2; p for trend = 0.10). Obese individuals in the study, (n = 624) consuming 0-5 servings of whole grains/wk, had higher fasting insulin concentrations (256 – 280 pmol/L) compared to non-obese individuals (n = 2123) consuming 0 - 5 servings/wk (184 – 196 pmol/L) (McKeown et al., 2002).

Along with the negative associations of fasting insulin concentrations and low whole grain consumption, McKeown et al. (2002) found significant positive associations with higher amounts of whole grain intake with other risk factors for MetS. Participants consuming more whole grains had significantly lower BMI scores (mean difference: 0.5; p for trend = 0.06), higher HDL-cholesterol (mean difference: 0.3 mmol/L; p for trend = 0.16), lower total cholesterol (mean difference: 0.11 mmol/L; p for trend = 0.06), and lower TG concentrations (mean difference: 0.11 mmol/L; p for trend = 0.07). In order to examine specific nutrient risk factors contained within whole grains, metabolic risk factors were individually adjusted for intake of fiber, folate, magnesium and vitamin E. After adjusting for specific nutrients, the association between whole-grain intake and improvements in both WHR and LDL-cholesterol levels remained significant ($p < 0.005$ and $p = 0.02$, respectively). The relationship between whole grain intake and fasting insulin concentration was slightly weakened with the adjustment for magnesium and fiber. These findings suggest that the high-fiber content of whole grains may be a key component in lowering lipid concentrations preventing weight gain, or promoting weight loss by increasing satiety. The benefits of whole grain consumption and reducing the risk for CVD act in similar ways to reduce the risk for Type 2 diabetes.

Whole Grains and Type 2 Diabetes. The relationship between whole grain intake and Type 2 diabetes has been analyzed by both epidemiological and observational studies. Research by Liese et al. (2003) examined whole grain consumption using data from the Insulin Resistance Atherosclerosis Study

(IRAS) Exam I, 1992-1994. They found an association between increased consumption of whole grains and Type 2 diabetes. These results are similar to those reported by McKeown et al. (2002). They recruited 1,600, free-living, middle-aged (40-69 year of age) participants from four clinical centers, representing 3 different categories of glucose tolerance status, including normal (n = 718), impaired (n = 369), and non-insulin taking Type 2 diabetes (n = 537). Each participant was required to attend 2 data collection visits after a 12-hour fast and to abstain from physical activity 24-hours prior to each visit. The first visit determined glucose tolerance status using a 2-hour, 75 g OGTT, while insulin sensitivity was assessed using the frequency sampled intra-venous-glucose-tolerance test at the second visit.

To calculate usual food and nutrient intake, a 1-year, semiquantitative 114-item food-frequency questionnaire, modified for ethnic food choices to accommodate participants in all four clinical centers was administered. Physical activity was also measured using a 1-year activity recall instrument, providing frequency and duration expressed as metabolic equivalent tasks (METs) to assess energy expenditure of participants. A MET equals work rate compared to a standard resting metabolic rate. They also measured height, weight and waist circumference.

The average intake of whole grain servings (0.8 servings/day) did not differ for ethnicity, sex or glucose tolerance status. The average insulin sensitivity was 2.16 min/μU/mL and the average fasting insulin was 113.8 pmol/L (normal = 14.3-122 pmol/L). Results showed that higher whole grain intake was positively correlated ($p = 0.001$) with insulin sensitivity but not with fasting insulin ($p = 0.048$), before adjusting for confounding variables (number of servings not provided). Whole grain intake was still significantly associated with higher insulin sensitivity values after adjusting for age, sex, ethnicity, clinic site and total energy intake ($p = 0.001$). Significant associations were also found between increased intake of whole grains and their effectiveness on lowering fasting insulin concentrations, after adjusting for the above confounding variables ($p = 0.020$). Finally, results showed that increasing whole grain intake by one serving/day leads to higher insulin sensitivity (increased by 0.23 min/µU/mL), and lower fasting insulin concentrations (decreased by 5.7pmol/L).

Liese et al. (2003) also examined the relationship between BMI, insulin sensitivity and increased whole grain consumption in middle-aged men and women. After adjusting for BMI and waist circumference, the effect of increased whole grain intake and insulin sensitivity was attenuated ($p = 0.03$). BMI and waist circumference are the two factors most associated with the mediating pathway for insulin sensitivity. To further explore the relationship of whole grains and insulin sensitivity, they examined the constituents of whole grains, including dietary fiber, magnesium, zinc, and vitamin E. They found significant associations with insulin sensitivity and fiber ($p = 0.015$) and magnesium ($p = 0.046$), but no relationships between these variables and fasting insulin concentrations ($p = 0.322$) (Liese et al., 2003). Overall, the findings indicated that higher dietary intakes of whole grains may be associated with increased insulin sensitivity and lower fasting insulin concentrations.

Dietary Fat and Fiber Intake. To better understand the relationship between dietary fat and whole grain intake and their impact on MetS, the Finnish Diabetes Prevention Program (FDPP) examined the relationships of both dietary factors on risk reduction. They investigated the association of dietary macronutrient composition, particularly dietary fat and whole grain intake, and energy density on changes in body weight and waist circumference.

Overweight, middle-aged men (n= 172) and women (n = 350) with impaired glucose tolerance were randomly assigned to a control group or an intensive diet and exercise counseling group. Participants in the control group received “standard care,” characterized as a general overview of diet and exercise at baseline only. The intensive dietary and exercise counseling group were given personalized dietary counseling by a registered dietitian seven times within the first year and every three months subsequently for three years. Results showed that participants consuming a low-fat, high-fiber diet lost more weight compared to participants consuming high-fat, low-fiber diets, with the intensive diet and exercise group showing greater gains in weight loss (Lindstrom, Peltonen et al., 2006). Consistent with previous research, these findings suggest that a low dietary fat and a high fiber intake are significant predictors of weight loss and progression to Type 2 diabetes.

Whole Fruit and Vegetable Intake

Whole fruit and vegetable intake has been correlated with decreasing the risk for developing chronic diseases. Data relating to the direct mechanisms by which fruit and vegetable intake may reduce the risk for chronic diseases are limited. However fruit and vegetables can reduce oxidative stress and decrease inflammation, two possible mechanisms associated with risk reduction for MetS. Below we discuss these two mechanisms in more detail and their relationship to reducing the risk for developing MetS, Type 2 diabetes and CVD.

Oxidative Stress. Fruits and vegetables contain beneficial nutrients and phytochemicals with antioxidant properties that are protective against the development of MetS, CVD and Type 2 diabetes. (He et al., 2004; Liu et al., 2004; Song et al., 2005). The antioxidant properties of fruits and vegetables, such as carotenoids, vitamin C, vitamin E and flavonoids, protect against the development of Type 2 diabetes by reducing oxidative stress that interferes with the glucose uptake by the cells (Hollman & Katan, 1999). The oxidative stress associated with Type 2 diabetes results from on going instability of blood glucose levels, and causes non-enzymatic glycation of plasma proteins. The antioxidants found in whole fruits and vegetables can inactivate reactive oxygen species, thus, delaying or preventing oxidative damaged caused by prolonged periods of hyperglycemia (Hollman & Katan, 1999; Joshipura et al., 2001).

Inflammation. Another possible mechanism by which the consumption of fruits and vegetables may reduce the incidence of chronic diseases is their ability to reduce systemic inflammation. Reduction in systemic inflammation is aided by beneficial compounds found in whole fruit and vegetables aside from antioxidants including, flavanoids, phytates and isoflavones (Bazzano, Serdula, & Liu, 2003; Sheard et al., 2004). The effect by which whole fruits and vegetables reduce systemic inflammation is evidenced by their ability to reduce plasma C-reactive protein (CRP).

A recent report suggested CRP to directly promote CVD through a complement-mediated process. In this process CRP binds to ligands that are exposed in damaged tissue, such as tissue injury of ischaemic necrosis in heart attacks and strokes, that then activates complement. Compliment, which is a thermolabile substance normally present in serum, is destructive to certain bacteria and other cells sensitized by a specific complement-fixing antibody. This complement-fixing antibody forms a membrane attack complex that leads to destruction of the cell and increased myocardial and cerebral infarct size. The consumption of fruits and vegetables have an effect on lowering CRP concentrations, thus reducing the risk of CVD (Pepys et al., 2006). To examine this relationship, Exmaillzadeh et. al (2006) looked at the association of fruit and vegetable intake on blood CRP concentrations and the prevalence of the MetS among middle-aged (40-60 year of age) female teachers. This cross-sectional study examined 486 female teachers without a history of CVD, diabetes, cancer or stroke and who were not taking medications that would effect serum lipoprotein, blood pressure and carbohydrate metabolism (Esmaillzadeh et al., 2006).

A food frequency questionnaire was administered to all participants by a trained registered dietitian to ensure accurate reporting. Anthropometric measurements were taken (weight, height and waist circumference) and BMI and WHR was calculated. Physical activity patterns were assessed and expressed as

MET hours per week. Blood was drawn after a 12-hour fast, and measured for FBG, serum TG, HDL-cholesterol and CRP concentrations (Esmaillzadeh et al., 2006).

Participants consuming higher amounts of fruits and vegetables (quintiles ranging from 98-362 g/day of fruit and 121-231 g/day of vegetables), were younger, more physically active, less likely to be obese, had lower anthropometric measures and a lower prevalence of MetS (39% lower risk). See Table 3 for serving equivalents). These participants also consumed less dietary cholesterol, meat, and refined grains, and consumed more dietary fiber and whole grains. High intakes of fruits and vegetables alone and combined, were also inversely associated with plasma CRP concentrations. After adjusting for confounding variables such as BMI, waist circumference, and age, the inverse association remained significant. Mean plasma CRP concentrations decreased with increasing fruit intake (1.94, 1.79, 1.65, 1.61, and 1.56 mg/L, p for trend < 0.01). A similar trend was also observed with vegetable intake, as vegetable intake increased, CRP decreased (2.02, 1.82, 1.58, 1.52, and 1.47 mg/L, p for trend < 0.01). When fruit and vegetable intakes were combined, there was an even greater inverse relationship between fruit and vegetable intake and CRP (Esmaillzadeh et al., 2006).

Individuals in the highest fruit and vegetable intake group (362 g/day of fruits and 231 g/day of vegetables, refer to Table 3 for serving equivalents) had lower risk of having MetS (p < 0.01, same value for both fruits and vegetables), even after adjusting for confounding variables such as CRP concentrations and lifestyle characteristics. The results from this study provide further evidence for the importance of consuming fruits and vegetables on a daily basis to lower risk of the MetS, by to lowering CRP concentrations. Participants in the highest quintiles for fruit and vegetable consumption (362 ± 6, 307 ± 9, respectively) also had an overall healthier lifestyle, including an increase in physical activity, measured in METs (16.6 and 17.1 MET-h/wk, highest vs. 12.5 and 12.7 MET-h/wk, lowest), and lower sedentary activities compared to those who consumed fewer servings of fruit and vegetables per day (98 ± 7, 142 ± 7, respectively). These findings support current research regarding the combination of nutrition and physical activity resulting greater disease prevention benefits.

Table 3. Fruit and Vegetable Servings and Gram Equivalents

Vegetable Servings/day	**Gram Equivalents**	**Fruit Servings/day**	**Gram Equivalents**
1 Medium Raw Carrot	72g	1 Nectarine, raw w/o pit, 2 ¼" diameter	136g
1.5 cups Spinach	84 g	¾ cup Fresh Blueberries	108g
½ cup Sweet Red Pepper	75g	1 Banana w/o peel, 8 ¾" long	118g
Total	**231g**		**362g**

Physical Activity and Prevention of Chronic Diseases

Despite numerous, well documented clinical studies showing the health benefits of regular physical activity, approximately 15% of men and 17% of women are completely inactive, and engage < 10 minutes of moderate to vigorous physical activity per week (Slack, 2006). Only 47% of men and 43% of women in the US achieve the national recommendations for moderate to intense physical activity of ~ 30 minutes/day (Slack, 2006), even though these recommendations are widely known (United States Department of Health and

Human Services and the Department of Agriculture (USDA), 2005). Research has shown that individuals who are physically fit seem to be protected against developing CVD and other related chronic diseases such as MetS and Type 2 diabetes (Lee, Blair, & Jackson, 1999; Slack, 2006; United States Department of Health and Human Services (DHHS), 2001; United States Department of Health and Human Services and the Department of Agriculture (USDA), 2005).

Physical Activity and CVD

While research has shown physically fit individuals to be protected against developing many chronic diseases, a study by Vatten et al. (2006) examined whether obese individuals (BMI > 30 kg/m^2) who engaged in high levels of physical activity, are also protected. This study investigated whether physical activity could modify or reduce cardiovascular mortality for obese individuals in the same way it reduces mortality for physically fit, non-obese individuals (BMI < 25 kg/m^2). Using a 16 year follow-up Norwegian health survey, Vatten and colleagues, found a negative association between amount of physical activity and cardiovascular related death for both men and women. Their results showed a gradual increase in cardiovascular mortality with decreasing physical activity levels for both men and women ($p < 0.001$). When comparing physically active obese individuals (BMI > 30 kg/m^2) to physically active lean individuals (BMI < 25 kg/m^2) and cardiovascular mortality rate, they found that obese women had only slightly higher mortality rates than their lean counterparts, and similar mortality rates at all levels of BMI. However, men in this study differed, showing an increasing mortality rate as BMI increases and having significantly higher rates of mortality than their lean counterparts (Vatten, Nilsen, Romundstad, Droyvold, & Holmen, 2006). The outcomes of this study suggest that engaging in high levels of physical activity, regardless of BMI, lead to a decrease in cardiovascular mortality rates in women.

Physical Activity and Type 2 Diabetes

There have been many studies examining the relationship between physical activity and the prevention to chronic diseases such as Type 2 diabetes. The studies described below were chosen based on the participants (women, middle-aged women or middle-aged men and women) selected. Type 2 diabetes risk and level of physical activity were investigated in a prospective cohort study that examined the relationship between sedentary behaviors, particularly television viewing, and risk of obesity and Type 2 diabetes in women (Hu, Li, Colditz, Willett, & Manson, 2003). The Nurse's Health Study was used to collect 68,497 women, who were free from Type 2 diabetes, CVD and cancer. Time spent watching television was inversely associated with risk of obesity and Type 2 diabetes with a 14% increase in risk of diabetes for every 2 hours of television watching per day. Women engaging in brisk walking showed a significant decrease in risk for Type 2 diabetes with every 1 hour/day of brisk walking leading to a 34% reduction in Type 2 diabetes (Hu et al., 2003). Findings from this study indicated that individuals who decrease sedentary activity and increase moderate physical activity, to the level recommended by the United States

Department of Health and Human Services and the United Stated Department of Agriculture, can reduce their risk for developing preventable chronic diseases (United States Department of Health and Human Services (DHHS), 2001; United States Department of Health and Human Services and the Department of Agriculture (USDA), 2005). Other studies researching the impact of physical activity in middle-aged adults found similar results supporting the national physical activity recommendations positive impact on disease prevention.

A community based study aimed at reducing risk factors for Type 2 diabetes by increasing physical activity found similar results to Hu and colleagues (2003). Jenum et. al, (2006), developed a low-cost community-based intervention program to promote physical activity among middle-aged adults in a low-income, urban district with a high total and CVD mortality rates, high prevalence of Type 2 diabetes, obesity, and physical inactivity. Considering the dynamics of the population observed (low-income, urban district), the program included strategies intended to increase awareness, improve knowledge, and change attitudes toward physical activity. These strategies were implemented by leaflets, reminders of the health benefits, local meetings, stands, and mass media communication activities. The intervention strategy involved organized walking groups, group sessions for indoor activities, and individual counseling sessions bi-annually during fitness tests. The intervention results were compared to a similar district without intervention strategies. The results showed a 9.5 % increase in physical activity ($p = 0.008$), and a 25% relative risk reduction ($p = 0.005$) in the proportion of inactive people in the intervention group compared to

5% relative risk reduction in the control group (p value not provided). Increases in BMI were significantly lower in the intervention district ($p < 0.001$), in addition to higher rates of body mass reduction compared to the control district ($p < 0.01$) (Jenum et al., 2006). Overall, this study found that even modest increases in physical activity can result in beneficial changes in reducing risk factors for Type 2 diabetes, obesity and CVD. Physical activity cannot only reduce the risk of developing MetS, obesity, CVD and Type 2 diabetes, but it can also improve risk factors in those already diagnosed with Type 2 diabetes.

Investigative research on the impact of physical activity for reducing risk factors for individuals with Type 2 diabetes found significant results. Walker and colleagues (1999) examined the effects of moderate intensity walking (1-hour/day for at least 5 days/week for a total of 12 weeks) for CVD risk factors on post-menopausal women previously diagnosed with Type 2 diabetes and in normal-glycemic women with first-degree relatives with Type 2 diabetes. All participants, regardless of group, were overweight/obese, with similar body weight, BMI, total body fat, waist circumference, completion time of the 1.6 km walking test, and estimated VO_{2max}. Both groups significantly improved their 1.6 km walking time, and their VO_{2max} with the intervention. Following the intervention, the normal-glycemic women had no significant changes in body weight, BMI, waist circumference, upper or lower body fat mass or total fat mass. In contrast, women with Type 2 diabetes had significant reductions in body weight, upper body fat, and waist circumference. These women also had greater significance in improvement in hemoglobin A1c (HbA1c), FBG concentrations, total cholesterol and LDL-cholesterol, while normal-glycemic women had only significant decreases in HbA1c, total cholesterol and LDL-cholesterol (Walker, Piers, Putt, Jones, & O'Dea, 1999). This study indicates the importance of physical activity not only in reducing relative risk factors for Type 2 diabetes and CVD, but also in improving existing risk factors, which can significantly improve the health for many individuals living with Type 2 diabetes.

Nutrition and Physical Activity Interventions

Research shows that engaging in daily physical activity, consuming a diet rich in whole grains, whole fruits and vegetables and low in saturated fat, decreases the risk for developing chronic diseases. The following section will focus on the importance of engaging in healthy lifestyle behaviors before reaching diagnosis level to prevent or delay the onset of chronic diseases. The two major intervention studies discussed below were comparable to the present study; the Diabetes Prevention Program (DPP) and the FDPP (refer to Table 5 for a breakdown of each study). Both of these studies focused on improving lifestyle behaviors through intervention methods, including; minutes/day of physical activity and improved dietary patterns (decrease total dietary fat and saturated fat intake and increase intake of whole grains, fruits and vegetables).

Diabetes Prevention Program (DPP)

A multi-site 3-year research study by the National Institutes of Health (NIH), the DPP randomized clinical trial, confirmed that reducing individual chronic disease (MetS, Type 2 diabetes and CVD) risk factors is achievable and essential in preventing or delaying the onset of such chronic diseases (Wing et al., 2004). This clinical trial included 3,234 persons at 27 centers in the US who were at high risk for developing Type 2 diabetes (1,043 male, 2,191 female, 68%). All participants were overweight (BMI ≥ 24 kg/m²), had a FPG of ≥ 95 to < 126 mg/dL and a 2-hour post 75 g glucose load of ≥ 140 mg/dL and < 200 mg/dL, were ≥ 25 years of age (The Diabetes Prevention Program (DPP), 1999).

The development of Type 2 diabetes, the primary outcome of this study, was diagnosed using an annual 75 g OGTT or a fasting glucose test, every 6 months, or when other symptoms consistent with diabetes are observed. Secondary outcomes included cardiovascular risk profile, changes in glycemia, beta-cell function, insulin sensitivity, renal function, body composition, physical activity, nutrient intake, and health-related quality of life, all of which are connected to the onset of diabetes. Sedentary lifestyle, obesity and overweight were the primary modifiable risk factors used to achieve research goals (The Diabetes Prevention Program (DPP), 1999).

Participants were randomly assigned to standard lifestyle recommendations (diet and physical activity) plus placebo or Metformin (glucose lowering drug) or to intensive lifestyle intervention that included diet and physical activity treatments. All participants, regardless of which group, received written information and a 20-30 minute individual session with a case manager, at which the importance of a healthy lifestyle for the prevention of Type 2 diabetes was addressed. The following recommendations for weight loss and physical activity were reviewed annually with all participants:

- achieve and maintain a weight reduction of at least 7% of initial body weight by;
- following the Food Pyramid Guidelines and the equivalent to the NCEP diet (previously mentioned),
- achieve and maintain a level of physical activity of ≥ 150 min/week (equivalent to ~700 kcal/week) through;
- moderate intensity activity (such as walking or bicycling).

The intensive lifestyle arm received the same goals as participants in the standard lifestyle recommendations, although approach to attaining the goals was more intensive and individualized. Intensive lifestyle participants received physical activity interventions of ≥ 150 minutes/week in addition to supervised exercise sessions twice a week and supplemental group classes involving physical activity, each course lasting 4-6 weeks long. To facilitate the attainment and adherence of these goals, the following interactive interventions were provided:

- training in diet, physical activity, and behavior modification skills, with frequent (no less than monthly) support for behavior change, such as strategies for:
    - self-monitoring, goal setting, stimulus control, problem solving and relapse prevention training
- diet and physical activity interventions that are flexible, sensitive to cultural differences, and acceptable in the specific communities in which they are implemented
- a combination of individual and group intervention,
- a combination of a structured protocol (in which all participants receive certain common information),
- the flexibility to tailor strategies individually to help a specific participant achieve and maintain the study goals emphasis on self-esteem, empowerment, and social support

The intensive lifestyle intervention group reduced the incidence of developing Type 2 diabetes by 58%; while incidence of Type 2 diabetes in the Metformin group was reduced by 31% after a 3 year follow-up. By the end of the core curriculum, the physical activity goal of ≥ 150 min/wk was achieved by 74% of the intensive lifestyle intervention group and 67% at the final 3-year visit. The 7% weight loss goal was achieved by 49% at the end of core curriculum and 37% at the final visit. This large clinical trial was the first to examine Americans at high risk for developing Type 2 diabetes, showing substantial evidence that Type 2 diabetes can be prevented or delayed, and that individuals at high risk can easily be identified (Knowler et al., 2002; The Diabetes Prevention Program (DPP), 2002). In addition, regardless of ethnicity, race, or sex, changes in lifestyle behaviors with diet and physical activity that result in even small reductions in weight, can significantly decrease or prevent the onset of Type 2 diabetes, with changes in lifestyle having a greater affect than medication (Wing et al., 2004).

The Finnish Diabetes Prevention Program (FDPP)

The DPP results were similar to those found in the FDPP (Lindstrom, Ilanne-Parikka et al., 2006; Tuomilehto et al., 2001). Participants in the Finnish DPP had characteristics similar to those selected in the US DPP and were randomly assigned to a lifestyle intervention program involving moderate intensity physical activity for at least 30 minutes/day or a control group. The intervention group was offered an individualized physical activity plan, supervised facility-based aerobic and resistance training three times/week for 6-12 months free of charge, in addition to the nutrition interventions discussed in more detail previously. The physical activity intervention resulted in a 43% reduction in relative risk for developing Type 2 diabetes (Tuomilehto et al., 2001).

While both of these monumental intervention studies found greater reductions in risk for developing Type 2 diabetes with intensive lifestyle interventions involving diet and physical activity, neither study endorses the importance of diet versus physical activity in prevention of chronic diseases, indicating that both diet and exercise are equally important (Knowler et al., 2002; Tuomilehto et al., 2001).

The SLIM Study

Corpeleijin and colleagues (2003, 2006) investigated whether a lifestyle intervention program could improve glucose tolerance and insulin sensitivity. This randomized controlled intervention program recruited 147 participants who were at high risk of glucose intolerance (those > 40 years of age, family history of Type 2 diabetes or a BMI ≥ 25 kg/m^2) from a large existing cohort of the general population. Participants included in the study were screened for impaired glucose tolerance (IGT) with a standard OGTT. Individuals previously diagnosed with Type 2 diabetes, other than gestational diabetes, or any other chronic disease were excluded from the study and those with IGT were invited back for a second OGTT for inclusion at a mean 2-hour glucose concentration was between 7.8 and 12.5 mmol/L. Any participant taking medications known to interfere with glucose metabolism or anyone participating in vigorous physical activity or an intensive weight loss program within the year prior to participation were also excluded. Participants in the intervention group (n = 27) were given dietary recommendations by a registered dietitian after completing a 3-day weighed food record following randomization. Dietary recommendations were based on the Dutch guidelines for a healthy diet consisting of at least 55% total energy intake from carbohydrates, total dietary fat below 30-35% total energy intake, saturated fat below 10% total energy intake and a cholesterol intake of < 300 mg/day. Follow-up visits were scheduled every three months to review dietary intake and recommendations. The intervention group was also encouraged and given individual advice on how to increase moderate physical activity to at least 30 minutes/day for a minimum of five days/week. At the start of the intervention participants were given well-defined goals and encouraged to participate in an exercise program, including both aerobic and resistance training, designed for the study. Participants had free access to all training sessions and were encouraged to attend at least 1 hour/week. The control group received only oral and written information regarding the benefits of eating a healthy diet, weight loss and increasing physical activity.

After one year, the lifestyle intervention group reduced body weight ($p < 0.01$), BMI ($p = 0.01$) and increased VO_{2max} ($p = 0.01$). There was also a significant decrease in 2-hour glucose values (9.0 mmol/L to 8.1 mmol/L, $p = 0.01$) and fasting insulin (17.9 mU/L to 15.5 mU/L, $p = 0.04$). Significant decreases were seen in total dietary fat (35.9% to 30.7% of total energy intake, $p < 0.01$) and saturated fat intake (13.6% to 11.3% of total energy intake, $p = 0.01$).

Fiber intake significantly increased from 2.7 g/230 kcal/day to 3.3 g/230 kcal/day ($p < 0.01$).

Table 4 a. Characteristics of participants

Study	Sample Size	Length of Follow-up (years)	Age at baseline (years) Mean (SD)	Sex % female	Setting; race/ Ethnicity	BMI at baseline (kg/m²) Mean (SD)	Inclusion criteria	Sampling method
Diabetes Prevention Research Group (DPP)(2002)	3,234	Mean 2.8 (range, 1.8-4.6)	50.6 (10.7)	68	Multicenter, USA trial; 55% white, 20% African American	34.0 (6.7)	BMI > 24 kg/m², FPG 95-125 mg/dL (5.2-6.9 mmol/L) and 2-h 75g OGTT PG 140-199 mg/dL (7.8-11.0 mmol/L)	Self-and provider-selected from clinic and community
Finnish Diabetes Prevention Program (FDPP) Tuomilehto et. al (2001)	522	Mean 3.2 (range, 1.6-6.0)	55.0 (7.0)	67	Finland; NR	31.1 (4.6)	BMI ≥ 25 kg/m², IGT (2-h post prandial plasma glucose 140-200 mg/dL [7.8-11.0 mmol/L]) and FBG < 140mg/dL (7.8 mmol/L)	Epidemiologic Surveys and opportunistic population screening
The SLIM Study Mensink et. al (2003)	114	1.0	56.6 (7.2)	43	The Netherlands; Caucasian	29.4 (3.6)	Mean 2-h 75g OGTT BG > 140 mg/dL (7.8 mmol/L) and < 225 mg/dL (12.5 mmol/L); FBG < 140 mg/dL (7.8 mmol/L)	Patients in existing community cohort at high risk for DM, given OGTT

Definitions: BMI; Body Mass Index, FPG; Fasting Plasma Glucose, OGTT; Oral Glucose Tolerance Test, IGT; , BG; Blood Glucose, PG; Plasma Glucose; NR, not reported

Table 4 b. Intervention Characteristics

Study	General intervention Characteristics	Dietary intervention	Physical Activity intervention	Behavioral intervention	Comparison group care
Diabetes Prevention Research Group (DPP) (2002)	**Duration:** Average 2.8 years; range 1.8 – 4.6 years **Frequency:** 16 lessons in first 24 wks, then once monthly **Number of contacts:** 40 **Group/individual:** Lessons were individual; some follow-up group sessions **Medium:** In person **Facilitator:** Case Manager ("lifestyle coach"), usually a Dietitian	16 lessons covering diet, exercise and behavioral modification **Goal:** 7% weight loss; low calorie, low fat diet (following the Food Pyramid Guidelines and equivalent to the NCEP diet)	Intensive lifestyle arm: moderate-intensity exercise, supervised sessions twice a week, with supplemental group classes (each course lasting 4-6 wks) **Goal:** ≥ 150 minutes/wk;	Goal setting, individual case managers support, individualization, culturally sensitive materials and strategies, motivational strategies	**Control:** Standard lifestyle: written information from case manager and annual 30-minute individual sessions on healthy lifestyles
Finnish Diabetes Prevention Program (FDPP) Tuomilehto et. al (2001)	**Duration:** Mean 3.2 years **Frequency:** 7 sessions with Dietitian during the first year, then every 3 months **Number of contacts:** 15 **Group/Individual:** Individual dietary advice **Medium:** In person **Facilitator:** Dietitian, other unclear	Low-fat, high-fiber diet **Goal:** BMI <25 kg/m², 5 to 10 kg weight loss, < 50% carbohydrates, < 30% fat, < 300 mg/day cholesterol, increase fiber	Individualized exercise plan regarding moderate activity, supervised facility-based aerobic and resistance training three times per week for 6-12 months **Goal:** 30 mins/day,	Food records; goal setting	**Control:** General written and oral information at baseline and annually
The SLIM Study Mensink et. al (2003)	**Duration:** 1 year **Frequency:** Every 3 months for individual dietary intervention, weekly for physical activity training **Number of contacts:** 5 for dietary; 52 for supervised physical activity **Group/Individual:** Combined **Medium:** In person **Facilitator:** Exercise physiologist, Dietitian	**Goal:** 5-7% weight loss, 55% of diet as carbohydrate, 30-35% of diet as fat, < 300 mg cholesterol/day Based on Dutch Guidelines for a healthy diet	1-hour weekly training sessions with trainer for moderate physical activity, aerobic and resistance training **Goal:** 30 mins/day, at least 5 days/wk	Goal Setting	**Control:** Initially given written information about healthy diet and physical activity

Table 4 c. Outcomes: Changes Due to Intervention (Pre-Post)

Study	Δ Weight (kg)	Δ BMI (kg/m²)	Δ HbA1c (%)	Δ BP (mmHg)	Δ Serum Insulin, (μU/ml)	Δ FPG (mg/dL)	Δ Total Cholesterol (mg/dL)	Δ HDL (mg/dL)	Δ LDL (mg/dL)	Δ TG (mg/dL)
Diabetes Prevention Research Group (DPP)(2002)	-5.5 (-5.7 –5.3)	NR		NR		-4.94±0.36 $p < 0.001$	NR			NR
Finnish Diabetes Prevention Program (FDPP) Tuomilehto et. al (2001)	-4.2 ± 5.1 ($p< 0.001$) Vs. control	NR		Systolic: -5 ± 14 ($p=0.007$) Diastolic: -5 ± 9 ($p=0.02$)	FS: -2 ± 9 ($p = 0.14$) 2Hr post OGTT: -29 ± 64 ($p= 0.001$)	-4 ±12 ($p< 0.001$)	-5 ± 28 ($p=0.14$)	2 ± 7 ($p=0.06$)	NR	-18 ± 51 ($p=0.001$)
The SLIM Study Mensink et. al (2003)	- 2.8 ± 1.8 ($p < 0.01$) Vs. control	-0.9 ± 0.5 ($p = 0.01$) Vs. control	-0.2 ± 0.1 ($p = 0.12$) Vs. control	NR	-15 ± 10 ($p = 0.06$) Vs. control	-0.1 ± 0.1 ($p = 0.05$) Vs. control	-5 ± 1.5 (mg/MJ) ($p = 0.04$) Vs. control	NR	NR	NR

Definitions: BMI, body mass index; HbA1c, glycated hemoglobin A1c; NR, not reported, BP, Blood Pressure; FS, Fasting Serum Insulin

Table 4 d. Outcomes: Post Intervention, Mean (SD), Change Scores, Diet and Physical Activity

Study	Total Energy Intake (kcals/d)	Total Fat intake	SFA intake	PUFA Intake	MUFA Intake	Fiber Intake	Whole Grain Intake	Whole Fruit Intake	Vegetable Intake	Physical Activity
Diabetes Prevention Research Group (DPP)(2002)	- 449 p = NR	-6.5 ± 7.7 % En p<0.0001	-2.7± 3.3 % En p<0.0001	-1.0 ± 1.9 % En p =0.003	NR	1.4 ± 8.1 P = NR	NR	1.0 ± 14.3 p = 0.009	2.6 ± 10.4 p = NR	74% met goal of ≥ 150 mins/week, 87% reached 227 ± 212 mins/week p < 0.001
Finnish Diabetes Prevention Program (FDPP) Tuomilehto et. al (2001)	NR	87% decreased intake P = 0.001, 47% had < 30 % En	26% had <10 % En from SFA	NR	NR	+ 1.7 g/1000 kcal/day p =0.007	NR	NR	72% increased intake	36% increased, 86% > 4 hrs/week
The SLIM Study Mensink et. al (2003)	- 230 ± 0.35 p = 0.07 Vs. control	-5.2 ± 0.9 %En p < 0.01 Vs. control	-2.3 ± 0.3 %En p = 0.01 Vs. control	-0.5 ± 0.3 %En p = 0.28 Vs. control	-2.1 ± 0.4 %En p = 0.02 Vs. control	+ 0.6 ± 0.1 (g/MJ) p < 0.01 Vs. control	NR	NR	NR	+ 2.4 ± 1.1 *VO_{2max} p = 0.01) Vs. control

%En; % of total energy, SFA; saturated fat, MUFA; monounsaturated fat, PUFA; polyunsaturated fat, * VO_{2max} (ml/O_2/kg/FFM $^{-1}$/min $^{-1}$

Guidelines and Recommendations for Prevention

Research outcomes related to chronic disease prevention have identified the necessity for, and the effectiveness of, the combination of diet and physical activity strategies. Evidence taken from the studies previously discussed, were used to initiate nutrition and physical activity guidelines and recommendations for all individuals, though particularly for those at risk for developing pre-MetS, MetS, Type 2 diabetes and CVD. The following recommendations are from both US government organizations and professional associations.

Nutrition Guidelines and Recommendations

Research findings regarding the relationship between dietary intake that is low in total dietary fat and saturated fat intake, and rich in whole grains, fruits and vegetables, have shown a positive inverse relationship, particularly in regards to chronic disease prevention. The following guidelines and recommendations were established based on original and review research findings.

Government Recommendations: 2005 Dietary Guidelines. The 2005 Dietary Guidelines for Americans was developed through joint efforts of the US Department of Health and Human Services (DHHS) and the US Department of Agriculture (USDA) (United States Department of Health and Human Services and the Department of Agriculture (USDA), 2005). The Dietary Guidelines deliver science-based advice for reducing risk of chronic disease and in overall health promotion through nutrition and physical activity (United States Department of Health and Human Services and the Department of Agriculture (USDA), 2005).

These guidelines discuss both nutrition and physical activity but focus more on nutrition, which will be outlined in this section. The DHHS-USDA clearly states that good health is directly related to nutrition (diets rich in whole grains, fruits vegetables and low if total fat and saturated fat), which is essential for growth, development and preventing deaths related to poor diet and sedentary lifestyles. Specific chronic diseases and related conditions associated with poor diet include CVD, hypertension, dyslipidemia, Type 2 diabetes, overweight and obesity. The intended goal of the Dietary Guidelines is to deliver recommendations regarding food components and individual nutrients for the general public to adopt (United States Department of Health and Human Services and the Department of Agriculture (USDA), 2005). Summarized key recommendations include:

- Consume a variety of nutrient-dense foods and beverages within and among the basic food groups while choosing foods that limit the intake of saturated and *trans* fats, cholesterol, added sugars, salt, and alcohol.

- To maintain body weight in a healthy range, balance calories from foods and beverages with calories expended.

- Consume a sufficient amount of fruits and vegetables while staying within energy needs. Two cups of fruit and 2½ cups of vegetables per day are recommended for a reference 2,000-calorie intake, with higher or lower amounts depending on the calorie level.

- Choose a variety of fruits and vegetables each day. In particular, select from all five vegetable subgroups (dark green, orange, legumes, starchy vegetables, and other vegetables) several times a week.

- Consume 3 or more ounce-equivalents of whole-grain products per day, with the rest of the recommended grains coming from enriched or whole-grain products. In general, at least half the grains should come from whole grains.

- Consume 3 cups per day of fat-free or low-fat milk or equivalent milk products.

- Keep total fat intake between 20 to 35% of total energy, with most fats coming from sources of polyunsaturated and monounsaturated fatty acids, such as fish, nuts, and vegetable oils.

- Consume less than 10% of calories from saturated fatty acids and less than 300 mg/day of cholesterol, and keep *trans* fatty acid consumption as low as possible.

Government Recommendations: NCEP. The Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (ATP III), based their nutrition recommendations on randomized, controlled clinical trials. Recommendations from ATP III follow a multifactorial lifestyle approach to reduce CHD risk factors, designated as therapeutic lifestyle changes which include:

- < 7 % of total calories as saturated FAs
- Intakes of *trans*-fatty acids should be kept low. Liquid vegetable oil, soft margarine, and *trans*-fatty acid-free margarine are encouraged
- Less than 200 mg per day of cholesterol
- Up to 20% of total calories as monounsaturated FA, should come from vegetable sources, including plant oils and nuts
- Up to 10% of total calories as polyunsaturated fat and can replace saturated fat
- Limit carbohydrate intake to 60% of total calories, 50% for those with MetS, elevated TG or low HDL-cholesterol
- Most carbohydrates should come from whole grains, fruits and vegetables
- 20-30 g/day of dietary fiber
- Soy protein is acceptable as a replacement for animal food products containing animal fats

- Plant stanol/sterol esters (2 g/day) are an option for LDL-cholesterol lowering
- Higher intakes of omega-3 FA in the form of fish or vegetable oils should be used for CHD risk reduction

Professional Association Recommendations: ADA. The American Diabetes Association (ADA) produced a position statement, *Nutrition Recommendations and Interventions for Diabetes* to address the growing rates of overweight, obesity and diabetes (American Dietetics Association (ADA), 2007). The ADA position statement, a product of a systematic technical literature, provides Medical Nutrition Therapy (MNT) recommendations for health care providers, people with diabetes and those at risk for diabetes (American Dietetics Association (ADA), 2007). Using an evidence based approach to raise awareness for the benefits of nutrition interventions, the ADA also considered the patients treatment goals, strategies to attain their goals and changes the patient is willing to make in the development of their MNT recommendations. ADA nutrition recommendations for the prevention of diabetes and related diseases are in agreement with those proposed by the USDA Dietary Guidelines, NCEP and ATP III.

Professional Association Recommendations: AHA. The American Heart Association (AHA) Nutrition Committee developed nutrition and lifestyle recommendations aimed at reducing the risk for developing CVD and other related chronic diseases. The 2006 recommendations stem from scientific evidence from authoritative documents, previous AHA scientific statements, other evidence-based reviews, seminal studies and national surveys. Since CVD is the number one killer of Americans, the AHA has designed their recommendations to provide guidance for adults and children over the age of 2 years. Recommendations were also aimed at providing public health and clinical health care professionals' guidance in the prevention of chronic diseases, particularly CVD. The 2006 AHA recommendations for nutrition include:

- Balance energy intake and physical activity to achieve or maintain a healthy body weight
- Consume a diet rich in vegetables and fruits
- Choose whole-grain, high-fiber foods
- Consume fish, especially oily fish, at least twice a week
- Limit intake of saturated fat to < 7% of energy, *trans*-fat to < 1% of energy, and cholesterol to < 300 mg per day by:
    - Choosing lean meats and vegetable alternatives;
    - Selecting fat-free (skim), or 1%-fat, and low-fat dairy products; and
    - Minimizing intake of partially hydrogenated fats
- Minimize intake of beverages and foods with added sugars
- Choose and prepare foods with little or no salt
- If you consume alcohol, do so in moderation

Physical Activity Guidelines and Recommendations

Lifestyle recommendations for the prevention of chronic diseases are not based solely on nutrition. Nutrition recommendations are made in conjunction with physical activity recommendations due to the vast health benefits gained with regular physical activity (Sigal, Kenny, Wasserman, & Castaneda-Sceppa, 2004).

<u>2008 Physical Activity Guidelines for Americans</u>. The 2008 Physical Activity Guidelines for Americans was developed by a joint effort from the DHHS and USDA, the contents of which compliment the Dietary Guidelines for Americans. The goal of these guidelines is to provide guidance to reduce the risk

for chronic disease by promoting physical activity and healthy eating. The major research findings on the health benefits of physical activity in these guidelines include:

- Regular physical activity reduces the risk of many adverse health outcomes
- Some physical activity is better than none
- For most health outcomes, additional benefits occur as the amount of physical activity increases through higher intensity, greater frequency, and/or longer duration
- The health benefits of physical activity occur for people with disabilities
- The benefits of physical activity far outweigh the possibility of adverse outcomes
- Most health benefits occur with at least 150 minutes (2 hours and 30 minutes) a week of moderate-intensity physical activity, such as brisk walking. Additional benefits occur with more physical activity
- Both aerobic (endurance) and muscle-strengthening (resistance) physical activity are beneficial
- Health benefits occur for children and adolescents, young and middle-aged adults, older adults, and those in every studied racial and ethnic group

The key guidelines for adults include the health benefits listed above and recommendations to include some physical activity, at any amount as opposed to being sedentary. Physical activity intensity recommendations vary from moderate-intensity for 150 minutes/week to vigorous-intensity for 75 minutes/week, and in episodes of at least 10 minutes spread throughout the day. Muscle strengthening activities for 2 or more days/week, at moderate or high intensity that involve all major muscle groups are encouraged for additional health benefits. Any physical activity beyond these recommendations will aid in additional health benefits (DHHS, 2008).

Government Recommendations: US Surgeon General. The US Surgeon General's Call to Action to Prevent and Decrease Overweight and Obesity 2001 encourages individuals to engage in ≥ 30 minutes of moderate intensity activities on most, if not all, days of the week to attain positive physical activity related health benefits (DHHS, 2001). Apparent health benefits attained by regular physical activity provided by the Surgeon General's report include:

- Reduces the risk of developing common chronic diseases
- Reduces the risk of dying prematurely
- Reduces the risk of dying from heart disease
- Reduces the risk of developing high blood pressure
- Helps reduce blood pressure in people who already have high blood pressure
- Reduces the risk of developing colon cancer
- Reduces feelings of depression and anxiety
- Helps control weight
- Helps build and maintain healthy bones, muscles, and joints
- Helps older adults become stronger and better able to move about without falling
- Promotes psychological well-being

Physical activities and intensities suggested range from washing and waxing an automobile (less vigorous, more time) to brisk walking (moderately vigorous, medium time) to running (more vigorous, less time) providing individuals options and variety in achieving their physical activity goals. The 2001 Surgeon General's report also emphasizes that beginning physical activity at any level will have health benefits and that slowly increasing duration, frequency and intensity will increase health benefits, although it does not have to be strenuous to have these benefits (DHHS, 2001).

Government Recommendations: ATP III. The ATP III identifies physical inactivity as a major modifiable risk factor for MetS, CVD and other related chronic disease. Physical inactivity is recommended to be a direct target for clinical intervention, focusing on improving the overall health status of the patient through safe and effective modes of physical activity (National Cholesterol Education Program (NCEP), 2002). Regular physical activity is emphasized in particular in the ATP III for its benefits in preventing and managing MetS by following the Surgeon General's physical activity recommendations (National Cholesterol Education Program (NCEP), 2002). In accordance with ATP III and the Surgeon General's physical activity recommendations, the ADA recommends ≥ 30 minutes of aerobic activity at least 3 times/week while the American College of Sports Medicine (ACSM) recommends ≥ 30-60 minutes/day, most days of the week (American College of Sports Medicine (ACSM), 2000; American Dietetics Association (ADA), 2007). The 2005 Dietary Guidelines for Americans also recommends regular physical activity to reduce sedentary lifestyles, improve health, psychological sense of well-being, and to maintain or achieve a healthy body weight. In conjunction with nutrition recommendations, the 2005 Dietary Guidelines also recommends the following:

- To reduce the risk of chronic disease in adulthood:
    - Engage in at least 30 minutes of moderate-intensity physical activity, above usual activity, at work or home on most days of the week.
- For most people, greater health benefits can be obtained by engaging in physical activity of more vigorous intensity or longer duration.
- To help manage body weight and prevent gradual, unhealthy body weight gain in adulthood:
    - Engage in approximately 60 minutes of moderate to vigorous intensity activity on most days of the week while not exceeding caloric intake requirements.
- To sustain weight loss in adulthood:
    - Participate in 60-90 minutes of daily moderate intensity physical activity while not exceeding caloric intake requirements. Some

people may need to consult with a healthcare provider before participating in this level of activity.
- Achieve physical fitness by including cardiovascular conditioning, stretching exercises for flexibility, and resistance exercises for muscle strength and endurance (American Dietetics Association (ADA), 2007; United States Department of Health and Human Services and the Department of Agriculture (USDA), 2005).

The preceding evidence-based research and subsequent guidelines and recommendations, demonstrated the importance for combining nutrition and physical activity in prevention strategies. Reducing modifiable risk factors was recognized as having substantial positive effects in decrease the onset of MetS, Type 2 diabetes and CVD. While both men and women benefit from improving risk factors, research has identified remarkable physiological changes experienced by women as they transition from pre- to post-menopausal status. These changes lead to their subsequent increased prevalence and severity of modifiable risk factors. This increase in risk factors leads to an increase in rate of chronic disease onset (Carr, 2003; Colditz et al., 1995; Homko & Trout, 2006; Hu et al., 2001). Research demonstrating the increased risk factors women are faced with as they enter menopause, signifies the importance of effective nutrition and physical activity interventions starting during pre-menopausal status to prevent the onset of MetS and other chronic diseases. Therefore this study will expand on previous findings for the effectiveness of nutrition and physical activity based intervention programs emphasizing the effectiveness and need for such programs in middle-aged, pre-diabetic, pre-menopausal women.

Research Design and Methods

This study was part of a larger pilot study that examined the influences of lifestyle on women's health and health related behaviors. In addition to the everyday influences and choices that affect women's health, this study also examined nutrition and physical activity behaviors and how those behaviors impacted their risk factors for chronic disease, specifically metabolic syndrome (MetS). The following methods pertain to the research questions for the diet and physical activity intervention strategies used in this intervention.

Study Design/Target Population and Recruitment

Women ages 35-60 years were recruited through physicians in the Good Samaritan and Corvallis Clinic regional medical systems, flyers were posted at Oregon State University (OSU) and advertisements were placed in the Corvallis Gazette Times. Interested participants called the OSU researchers and were asked a series of screening questions related to the study; age, weight, height, medical history, current medications and current physical activity practices. Women eligible after the phone screen were scheduled for further inclusion testing. Specific inclusion criteria for this study were: 1) English speaking and English writing ability, 2) age 35-60y, 3) fasting glucose of ≥ 92 mg/dL (5.0 mmol/L), but not diabetic, < 126 mg/dL (7.0 mmol/L), 4) waist circumference of > 88 cm (> 35 in), 5) triglycerides (TGs) of > 150 mg/dL OR a blood pressure level of >130/85 mmHg, 6) no medications for elevated blood glucose/lipids or blood pressure, and no existing conditions such as cardiovascular disease (CVD) or mobility issues that would preclude involvement in a physical activity-based intervention. The first 15 women who met eligibility requirements were part of the intervention, although only 10 subjects completed all aspects of the intervention and were included in the results. Subjects were provided with a description of the study over the phone and in writing. If they agreed to participate, they were mailed a packet of questionnaires to complete and asked to attend an introductory session where they would be given specific information about the study. All participants signed an informed consent form. This study was approved by the OSU Institutional Review Board (IRB) for human subjects.

Experimental Design

This 12-week diet and physical activity intervention collected baseline measures for weight, height, waist circumference, body composition, 4-day diet and physical activity records, sub-maximal exercise test, and fasting blood draw for the assessment of glucose, insulin, HbA1C, lipids (high density lipoprotein (HDL)-cholesterol, low density lipoprotein (LDL)-cholesterol, total cholesterol, and TGs). Participants attended weekly classes on nutrition and physical activity or 12-weeks. Each week participants completed diet and physical activity logs that reflected servings of fruits, vegetables and whole grains consumed and minutes of moderate physical activity (in most cases walking). Subjects were also trained on how to monitor blood glucose using an Ascensia Contour Meter ®, Bayer Corporation (Pittsburg, Pennsylvania) to record fasting blood glucose values at least 5 days/week and at least 3 days/week of pre- and post-physical activity glucose levels. Participants that met the weekly requirements for physical activity and glucose monitoring were eligible for a $50 gift card to a local Fred Meyer's grocery store. Upon completion of the 12-week intervention, baseline measures were again collected.

Experimental Procedures/Pre-Testing

Before the baseline visit 1 (BV1), all participants completed questionnaires that solicited information about individual health history, sociodemographics, dietary and physical activity behaviors, weight history, family history, home environment and relationships with spouse or cohabiting partner, beliefs about diet and physical activity, depressive symptoms, and concerns about health status. These questionnaires were returned and reviewed during the first baseline visit. The data from these questionnaires were used for general screening only for this portion of the study.

Experimental Procedures/Baseline Visit 1 (BV1)

The following procedures were followed at BV1 and at the post-intervention visit 1 (PV1) (week 12). After an 8 hour fast, subjects reported to the lab for testing. Several tests were administered to ensure eligibility, meeting the eligibility criteria for that test before moving on the next as follows: 1) Height and weight to ensure they were within body mass index (BMI) range for the study ($\geq$ 25 to $\leq$ 35 kg/m^2), 2) fasting blood glucose (FBG) levels checked using a standard glucose monitor, the Ascensia Contour Meter ®, Bayer Corporation (Pittsburg, Pennsylvania)

(≥ 92 mg/dL, and < 126 mg/dL). If participants met requirements listed above, the following two tests were administered: 3) blood pressure measured after 5 minutes of rest by a trained researcher, using a standard digital monitor with automatic cuff (>130/85 mmHg), 4) blood drawn by trained phlebotomist; sample was immediately centrifuged, put on ice and sent to Good Samaritan Hospital Laboratory (Corvallis, Oregon) for blood lipid, glucose and insulin assessments. Participants were given specific instruction on how to use a food scale and record all food and beverages using a 4-day food log and activities on the 4-day physical activity record using the talk test to distinguish intensity of activity. These logs were reviewed with the participants to assure accuracy and to clarify all items. Participants were asked to maintain their current diet and physical activity patterns until the start of the intervention program. At this time participants scheduled their second baseline visit (BV2). BV2 occurred 2 weeks after the BV1 session.

Experimental Procedures/Baseline Visit 2 (BV2)

The following procedures were followed for the BV2 and post-intervention visit 2 (PV2) (week 12). After an 8 hour fast, subjects reported to the lab. After resting 5-10 minutes, blood pressure was measured using a standard digital monitor with an automated arm cuff, Automatic Blood Pressure Monitor HEM-712C, Omron Corporation (Bannockburn, Illinois). The following assessments were then taken in order during the BV2 session.

Assessment Measures

Anthropometric measurements

1) Height (inches) without shoes

2) Weight (kg) with minimal clothing

3) Waist circumference (cm) with a tape measure just above iliac crest

4) Body composition measured by air displacement with the BOD POD® Body Comp. System, Life Measurement, Inc. (LMI) (Concord, California) with a swim cap and minimal and/or tight clothing.

Participants were given information regarding what each measurement was for and how it would be performed to ensure comfort level. Once anthropometric measurements were complete, participants put on comfortable clothing and shoes for the sub-maximal physical activity treadmill test.

Glucose Load and Treadmill Testing

Prior to the treadmill walk, fasting blood glucose was measured using the Ascensia Contour Meter ®, Bayer Corporation (Pittsburg, Pennsylvania) finger prick glucose monitor. Participants were trained on how to test their own blood glucose using the same monitor that they used throughout the intervention. Once fasting blood glucose was measured the participants consumed a 75 g glucose beverage (Koladex; Orangedex, Custom Laboratories, (Baltimore, Maryland)) within four minutes and provided water on request. An explanation for the purpose of the procedure (to demonstrate the effects of exercise on blood glucose after a meal [75 g of glucose]) was provided while a heart rate monitor was attached and subjects relaxed for 30 minutes.

Following the 30 minute rest period, blood glucose was measured again using the Ascensia Contour Meter ®, Bayer Corporation (Pittsburg, Pennsylvania) finger prick glucose monitor. Participants then walked on the treadmill for 30 minutes (5 minutes warm up and 5 minutes cool down), at 50-70% of maximum heart rate (MHR). Rate of perceived exertion (RPE) was also assessed every minute. Treadmill speed was increased, following the warm up, until participant indicated an RPE of over 13 or had a heart rate between 50-70 % MHR. The American College of Sports Medicine (ACSM) guidelines were followed for the exercise testing (American College of Sports Medicine (ACSM), 2000).

Following the treadmill test, blood glucose levels were again tested. At this time the BV2 was complete and the participants were offered food and beverage and given more information about the intervention classes.

Intervention

The intervention consisted of a 12-week program aimed at improving eating and physical activity behaviors. The first week consisted of (1) goals of the intervention program and eligibility requirements (2) demonstration on proper use of the blood glucose monitor, test strips, when to use them during the intervention, and instruction for logging blood glucose tests, (3) logging daily servings of whole fruits, vegetables, and whether or not they were fresh, frozen or canned, and servings of whole grains (4) logging minutes of daily physical activity (walking) and instruction on proper use of the pedometer provided to them. Each week covered various topics concerning diet and physical activity; these topics are outlined in Table 5.

Table 5. 12-Week Intervention Topics

Week	Topic	Week	Topic
Week 1	Introduction to the Lifestyle Balance for Health	Week 7	Be a Fat Detective; 3 Ways to Eat Less Fat; How to Chose Healthy Fat
Week 2	Barriers & Benefits of Physical Activity; Getting Started Being Active	Week 8	Healthy Cooking: Eating Out; Social Occasions
Week 3	Eating Healthy for Life I	Week 9	Taking Charge of Your Environment; Surviving the Holidays
Week 4	Eating Healthy for Life II	Week 10	Jump Start Your Physical Activity Plan & Make it Part of Your Lifestyle
Week 5	Field Trip: Food Shopping & Label Reading	Week 11	Types of Exercise; Fitness Centers
Week 6	Move Those Muscles; Being Active: A Way of Life	Week 12	Problem Solving & the Slippery Slope of Lifestyle Change

Time: Pre and Post 12-week Intervention

Outcome Measures and Methods of Assessment

Diet and Physical Activity Analysis

Of the 15 recruited female participants, five participants failed to complete the study; one participant became injured in the early weeks of the study and was unable to complete the physical activity component of the intervention but completed the diet portion of the study. Food logs were analyzed by a food processing software (Food Processor® SQL, Version 6, ESHA Research [Salem, Oregon]) to generate data for diet composition. All diet logs were carefully entered into Food Processor® by the same researcher to ensure accuracy for all 10 participants both pre- and post-intervention. Participants were instructed to weight foods for accurate portions, provide food labels, recipes and indicate specific brands of foods consumed. Recipes were entered into Food Processor® and each food item was broken down to provide the most closely matched food, including micronutrient content to what was consumed. Servings/day were calculated by Food Processor® and double checked by the researcher.

The 4-day physical activity logs were both pre-and post-intervention. Activities included activities of daily living and purposeful physical activity. Researchers examined the activity logs and averaged minutes of moderate intensity aerobic physical activity /week for purposeful physical activity consisting mainly of walking, but also including swimming, cross-training and cycling.

Outcome Measures	Method of Assessment
Research Question # 1:	
Increased minutes/week of purposeful physical activity (brisk walking)	• 4-day activity records/pre-post (min/day)
Research Question # 2:	
Increase in servings/day of whole fruits, vegetables and whole grains	• 4-day food records/pre-post (# servings/day) • Food Processor SQL 2006 (# servings/day)
Research Question # 3:	
Decrease in saturated fat consumption in grams/day	• 4-day food records/pre-post (grams/day) • Food Processor SQL 2006 (grams/day)

Time: Pre and Post-12week Intervention

Statistical Analysis

Mean and standard deviation were determined for outcome variables for each aim and statistical significance was determined at $p < 0.05$. A paired t-test for the statistical analysis for pre- and post-intervention intake for servings/day of fruit, vegetable, whole grains, total fat (g/day), saturated fat (g/day) and physical activity (min/day). The paired t-test was chosen due to the nature of the study comparing the participants to themselves following the intervention. All analyses were performed by S-PLUS statistical software package (S-PLUS, version 8.0.4, TIBCO Software Inc. (Palo Alto, California)).

Results

Participants

Ten people completed all aspects of the study except for the physical activity portion where 9 people completed all components. Individual characteristics of the 10 participants who completed pre-and post- intervention testing can be seen in Table 6. At baseline, participants were aged 44 - 51 years with a mean (± SD) BMI of 31.1 ± 3.1 kg/m². There were no significant changes in weight or BMI from pre- to post-intervention, as seen in Table 6.

Table 6. Characteristics of Intervention Participants

Characteristics	Mean (SD) Pre-Intervention (n = 10)	Mean (SD) Post-Intervention (n = 10)	*P* value	Normal Range
Age (y)	47.3 (2.5)	47.3 (2.5)		-
Body Weight (kg)	88.6 (14.8)	89.5 (14.2)	0.56	-
BMI* (kg/m²)	31.1 (3.1)	31.4 (3.1)	0.56	18.5 – 24.9 (kg/m²)++
% Body Fat**	41.5 (10.3)	40.5 (9.7)		Obese = ≥ 32% for women ≥ 25% for men
RMR*** (kcal/d)	1564 (169)			-
RMR x 1.3	1994 (292)			-
Blood Pressure, mmHg				
Systolic	125 (13)	122 (10)	0.50	120 mm Hg++
Diastolic	83 (9)	79 (5)	0.14	80 mm Hg++
Serum Insulin (μU/ml)	12.5 (8.4)	14.3 (7.5)		2.6 – 24.9 μU/ml++
Fasting Plasma Glucose (mg/dL)	97 (7)	99 (7)		70-99mg/dL++
Serum Lipids (mg/dL)				
Total Cholesterol	187 (29)	190 (33)		< 200mg/dL+
HDL-C	53 (19)	49 (16)		> 50 mg/dL+
LDL-C	109 (30)	115 (33)		<100 mg/dL+
Triglycerides	124 (39)	127 (42)		< 150 mg/dL+

Abbreviations: BMI = Body Mass Index; RMR,= Resting Metabolic Rate; HDL-C = High Density Lipoprotein Cholesterol; LDL-C = Low Density Lipoprotein Cholesterol
*Calculated as the weight in kg divided by the square of height in meters
** Measured with the Bod Pod
***Predicted using Harris-Benedict, RMR = 655.1 + 9.56(wt) + 1.85 (ht)-6.76 (age), 1.3 = activity factor of moderate physical activity (brisk walking) (National Cholesterol Education Program (NCEP), 2002)
+ (NCEP, 2002), ++ (American Dietetics Association (ADA), 2007)

Diet and Physical Activity

Whole grain intake (servings/day) increased significantly from 1.5 to 3.8 servings/day ($p = 0.005$), with a mean change of 2.6 servings/day (see Table 7 and 8). Fiber intake also significantly increased from a mean of 18.6 g/day to 25.5 g/day, with mean changes of 6.9 g/day ($p < 0.03$). No significant increases were seen for fruit and vegetable intake (servings/day), although fruit intake did improve. Mean fruit intake increased from 1.6 to 2.5 servings/day, a mean change slightly less than 1.0 ($p = 0.12$). A negligible decrease was seen for vegetable intake, 3.5 to 3.2 servings/day. Saturated fat decreased significantly from 27.7 to 20.3 g/day, a mean change of 7.5 g/day ($p = 0.02$). Total fat intake also decreased from 81.4 to 68.4 g/day, although the mean change of 13g/day was not significant ($p = 0.23$).

Total energy intake (kcal/d) did not decrease significantly (1960 to 1859 kcals/day), even though there were decreases in total fat and saturated fat. When energy was expressed as kcal/kg body weight, intake decreased from 23.0 to 21.5 kcal/kg/day. Protein intake increased from 73 to 78 g/day, or approximately 2% of total energy intake (15.2 to 17.5%/day). Carbohydrate intake increased 3% in total energy intake (48.3 to 51.5%/day), an increase from 239 to 242 g/day (see Table 8). Minutes of physical activity significantly increased from 2.9 min/day to 47.4 min/day, an average 39 min/day increase ($p < 0.0001$, $n = 9$) (refer to table 7).

Table 7. Changes in Diet and Physical Activity Following Intervention

Food** (n = 10)	Pre-Intervention	Post-Intervention	Δ	*P* value*
	No. Servings Mean (SD)			
Whole Fruit	1.6 (1.3)	2.5 (1.9)	↑ < 1	0.12
Vegetables	3.5 (1.6)	3.2 (1.1)	↓ < 1	0.32
Whole Grains	1.5 (2.0)	3.8 (2.4)	↑ > 2	0.005
Physical Activity+ (n = 9)				
Minutes/Week	3 (5)	43 (31)	↑ 40	<< 0.0001

*p value based on a 0.05 confidence interval, **Diet assessed using 4-day weighted food records, +Physical Activity assessed using a 4-day physical activity record

Table 8. Nutrient and Energy Intake Pre- and Post-Intervention (n = 10)

Nutrient	Mean (SD) Pre-Intervention	Mean (SD) Post-Intervention	Mean Change	*P* Value	Recommended Values
Total Energy (Kcal/d)	1960 (586)	1859 (512)	-101		Balance energy intake and expenditure to maintain desirable body weight/prevent weight gain
Kcal/kg BW	23.0 (5.2)	21.5 (7.4)	-1.5		
Protein					~ 15 %En* 10-35% En (AMDR)** 46 g/day (RDA/AI)**
g/d	73.0 (19.7)	77.8 (18.6)	4.8		
g/kg	0.8 (0.2)	0.9 (0.2)	0.1		
%En	15.2 (2.3)	17.5 (5.2)	2.3		
Carbohydrate					45-65 % En (AMDR) ~ 130 g/day (RDA/AI)
g/d	239.1 (78.9)	241.8 (81.0)	2.7		
g/kg	2.7 (0.8)	2.8 (1.3)	0.1		
%En	48.3 (6.2)	51.5 (7.0)	3.2		
Total Fat					25-35 %En* 20-35 %En (AMDR)** NA (RDA/AI)**
g/d	81.4 (29.6)	68.4 (24.0)	-13	0.23	
g/kg	0.9 (0.3)	0.8 (0.2)	-0.1		
%En	37.0 (7.2)	32.9 (4.9)	-4.1		
Saturated Fat					< 7 %En NA (AMDR)** NA (RDA/AI)**
g/d	27.7 (12.0)	20.2 (10.8)	-7.5	0.02	
Kcal/d	249(108)	182 (97)	-67		
% kcal total fat	33.5 (5.4)	29.2 (8.5)	-4.3		
% En	12.4 (3.2)	9.7 (3.8)	-2.7	0.11	
MUFA					Up to 20 %En NA (AMDR)** NA (RDA/AI)**
Kcal/d	137 (50)	141 (72)	4		
% kcal total fat	18.7 (2.6)	22.5 (6.4)	3.8		
% En	6.9 (1.6)	7.4 (2.4)	0.5		
PUFA					Up to 10 %En 5-10 %En (AMDR)** 11 g/day (RDA/AI)**
Kcal/d	56 (14)	63 (35)	7		
% kcal total fat	8.1 (1.8)	10.5 (5.4)	2.4		
% En	2.9 (0.6)	3.4 (1.6)	0.5		
trans-Fat (kcal/d)	7(8)	5 (5)	-2		NA (AMDR)** NA (RDA/AI)**
Omega-3 (g/d)	0.4 (0.3)	0.6 (0.4)	0.2	0.32	0.6-1.2 % En (AMDR)** 1.1 g/day (RDA/AI)**
Omega-6 (g/d)	3.9 (1.1)	5.5 (3.1)	1.6	0.20	NA (AMDR)** NA (RDA/AI)**
Alcohol (kcal/d)	50 (78)	23 (38)	-27		-
Fiber (g/d)	18.6 (8.1)	25.5 (6.8)	6.9	0.03	NA (AMDR) 20 – 30 g/day* 21g/day ** (RDA/AI)
g/1000 kcal/day	9.5	14	4.2	0.03	

Abbreviations: MUFA; Monounsaturated Fatty Acid, PUFA; Polyunsaturated Fatty Acid, BW; body weight, %En; % kcal of total energy, * (National Cholesterol Education Program (NCEP), 2002). AMDR = Acceptable Macronutrient Distribution Range, RDA/AI = Recommended Dietary Allowances, Adequate Intakes for women ≥ 50 years of age ** (Institutes of Medicine Food and Nutrition Board, 2006).

Discussion

This study found that a 12-week, education-based diet and physical activity intervention program significantly increased minutes of physical activity/day and intakes of whole grains (servings/day), while significantly decreasing intake of saturated fat in middle-aged women at risk for metabolic syndrome (MetS). Physical activity can shift fuel usage, increasing fat metabolism, exercise-induced muscle glucose uptake and influence metabolic adaptations that can decrease the risk for developing chronic diseases such as MetS and subsequently Type 2 diabetes and cardiovascular disease (CVD) (Sigal et al., 2004). Over the 12-week intervention, participants made the most significant changes in whole grain consumption, increasing servings on average from 1.5 to 3.8 servings/day ($p = 0.005$). This large increase could be explained, in part, by the great interest in the topic of whole grains by the participants. The lack of prior knowledge pertaining to whole grains, the perception of ease in accomplishing the goal, coupled with the growing media push encouraging whole grain consumption all may have influenced the increased consumption of whole grains/day. The significant increase seen in fiber intake (increase of 6.9 g/day) can most likely be explained by the increase in whole grain consumption since whole fruit and vegetable intake did not change.

Fiber and Whole Grain Intake

The significant increase in fiber intake (18.6 g to 25.5 g/day) is in agreement with other lifestyle intervention studies incorporating diet education or intake guidelines (Corpeleijn et al., 2006; Eriksson, 2006; Mayer-Davis et al., 2004; Tuomilehto et al., 2001). The Finnish Diabetes Prevention Program (FDPP) provided participants in the intervention group with goals pertaining to diet, physical activity, and education on how to achieve those goals. Participants were advised to increase total fiber intake to 15 g/1000 kcal/day through whole grains, fruits and vegetables. Following the 3-year intervention, the participants in the intervention group significantly increased their fiber intake, consuming 11.7 to 14.1 g/1000 kcal compared to the control group consuming 11.7 to 12.7 g/1000 kcal ($p < 0.001$) (Tuomilehto et al., 2001). The source of fiber intake was not specified as achieved by increased whole grain or fruit and vegetable consumption. Participants in our study were similar to those in the FDPP, consuming on average 9.5 g/1000 kcals/day pre-intervention and 14 g/1000 kcals/day post-intervention.

The Diabetes Prevention Program (DPP) also found significant differences in dietary intake in the Lifestyle modification group, compared to the Placebo group and a group taking Metformin (glucose lowering medication) just one year post-baseline (Mayer-Davis et al., 2004). These changes were consistent with the goals of the Lifestyle intervention group; low calorie, low fat diet following the Food Pyramid Guidelines and the equivalent to the National Cholesterol Education Program (NCEP) diet. The DPP found a significant increase of about 1.2 g/day in dietary fiber ($p < 0.0001$), as well as an increase in total carbohydrate consumption ($p < 0.003$), compared to an increase of 6.9 g/day in our study. Servings of whole grains/day were not defined, although servings of total grains did not change following the intervention. The increase in dietary fiber and fruit intake ($p < 0.0009$) may explain the significant increase in total carbohydrates. In the current study carbohydrate consumption did not increase significantly with the increase in whole grain and fiber consumption.

Much like the DPP study, the Study on Lifestyle Intervention and Impaired Glucose Tolerance Maastricht (SLIM) (Corpeleijn et al., 2006) measured changes in carbohydrate and fiber intake but did not differentiate servings/day for whole grains or total grains. The SLIM intervention study provided dietary recommendations by a registered dietitian, following the Dutch Guidelines for a healthy diet. The diet recommendations did not emphasize a low calorie diet, but recommended a carbohydrate intake of at least 55% total energy intake, total fat of 30-35%, with saturated fat less than 10%, and cholesterol intake less than 33 mg/MJ (33 mg/240 kcal). Following the lifestyle intervention, which included educational sessions with a registered dietitian, participants significantly increased both carbohydrate and fiber intake ($p < 0.01$) (Corpeleijn et al., 2006). Like whole grains, total fruit and vegetable intake were not specified in servings/day, only grouped as total carbohydrates. The significant increase in fiber could be attributed to an increase in whole grains, whole fruits and/or vegetables. Regardless of the source, increased intake of dietary fiber has been shown to independently decrease markers for the onset of MetS and Type 2 diabetes (Chandalia et al., 2000; Jacobs & Gallaher, 2004; Liese et al., 2003; McKeown et al., 2002; Riccardi & Rivellese, 2000).

Fruit and Vegetable Intake

Intake of whole fruit and vegetable servings/day did not change. The lack of improvement in vegetable intake may be explained by the time of year the intervention took place, middle of October through the end of January. Pacific Northwest vegetables harvested in late fall and winter are not as commonly consumed as spring and summer vegetables, due to the more labor intensive preparation. Though there were no significant increases in whole fruit consumption, there was a positive trend ($p = 0.10$), to increase fruit intake by about 1 serving/day. The positive trend seen in fruit consumption during the winter season could, in part, be explained by the ease of preparation and travel for selected winter fruit such as apples, oranges and pears. Had the intervention taken place over spring and summer we may have seen improvement in whole fruit and vegetable, also a larger sample size may have shown more improvement in servings/day. Since the study took place over a full calendar year, the DPP saw significant increases in whole fruit and a greater intake of vegetables for the intervention group compared to the control group.

Following the 1-year intervention, the DPP saw significant increases in whole fruit intake for the Lifestyle group, participants went from approximately 16.5 to 19 servings/week (about 2.3 to 2.7 servings/day) ($p < 0.009$). While vegetable intake did not significantly increase following the 1-year intervention, there was a significant increase for the Lifestyle group compared to the Placebo and Metformin groups (p value not given) (Mayer-Davis et al., 2004).

Unlike the DPP, the FDPP did not measure whole fruit intake, but did measure vegetable intake. This randomized clinical trial provided participants with detailed advice about how to achieve the goals of the intervention, of which included frequent ingestion of whole-grains, whole fruit and vegetables. Each participant completed a detailed 3-day food record four times per year in addition to seven visits with a registered dietitian during the first year of the study, with one session every three months thereafter for the remaining 3 years. Upon completion of the study, 72% of the intervention group significantly increased their vegetable intake compared to 62% in the control group ($p = 0.01$), (servings/day not reported).

Saturated Fat Intake

In the current study, saturated fat intake decreased by 7.5 g/day and total fat intake decreased 13 g/day, while polyunsaturated and monounsaturated fat increased 7 and 4 g/day, respectively. A decrease of 2 g/day was also seen in *trans*-fat with small increases in omega-3 and omega-6 fatty acids (See Table 8). Although only the changes in saturated fat were significant, the differences seen in all other forms of dietary fat were moving in the direction intended for health benefits (refer to Table 8 for recommendations) (Institutes of Medicine Food and Nutrition Board, 2006). The 13 g/day (117 kcals/day) decrease in total fat intake did not significantly decrease total kcals/day since total carbohydrate and protein increased slightly. Total energy (kcals/day) intake decreased, on average, only

101 kcals/day. This small change may explain why participants' BMI and body weight did not change.

The FDPP found that within the first year of the intervention, 87% of the subjects in the intervention group significantly decreased their consumption of dietary fat compared to 70% in the control group ($p = 0.001$) (Tuomilehto et al., 2001). As well, 70% of the intervention group significantly improved the quality of dietary fat eaten ($p = 0.001$), including a significant decrease in saturated fat intake of < 10% of energy intake ($p = 0.001$) (Tuomilehto et al., 2001). In the PROMIS study, 70% of the participants decreased total fat intake, 30% decreased intake to less than 30% of total energy intake and 70% decreased saturated fat intake to < 10% of total energy intake. Similar decreases in total fat and saturated fat were found in the SLIM study (Corpeleijn et al., 2006). Compared to the control group, participants in the SLIM intervention group had more significant decreases in % total fat (Intervention Group = 35.9 ± 0.9 to 30.7 ± 0.9 vs. Control Group = 35.3 ± 0.9 to 34.0 ± 0.9) and decreases in % saturated fat intake (Intervention Group = 13.6 ± 0.4 to 11.3 ± 0.5 vs Control Group = 13.7 ± 0.4 to 13.0 ± 0.4) ($p < 0.01$ and $p = 0.01$, respectively) following the 1-year intervention. Servings/day data were not provided and intake of dietary fat was only expressed in % of total energy intake. Much like the FDPP and the SLIM study, the DPP found significant decreases in both total fat and saturated fat intake in the intervention group when compared to the Metformin and Placebo groups ($p < 0.0001$ for both). Total dietary fat intake was decreased by 6.5% of total energy intake/day and saturated fat intake was decreased by 2.7% of total energy intake/day, compared to the 4.1% decrease in total fat and 2.7% decrease in saturated fat intake/day (Mayer-Davis et al., 2004).

Physical Activity

Increases in physical activity were the most significant findings in the current study. Participants, on average, increased physical activity by 40 minutes/day ($p << 0.0001$), or > 150 minutes/week. Most women in the study were not participating in regular physical activity before the intervention. The few that had been physically active were not active on a regular basis and were engaging in purposeful physical activity for ≤ 50 minutes/week at a moderate intensity. One way participants may have been motivated to increase physical activity was from the visible changes in blood sugar levels when blood glucose was tested both before and after physical activity. Other possible motivating factors were the use of pedometers to track steps/day, recording daily activity into their physical activity journals and weight loss, although weight loss was not an outcome variable for the study.

Regardless of the motivating factor, the increase in minutes/day of physical activity found in the current study is comparable with findings from other lifestyle intervention studies, such as the Björknäs study (2006). In the Björknäs study, intervention group participants had significant increases in both the rating of total physical activity ($p < 0.001$) and in the rating of time spent in exercise ($p < 0.001$) (Eriksson, 2006). Participants reported physical activity level at baseline and again following the 12 month intervention, those in the intervention group had more positive changes in minutes of physical activity /day than the control group. At baseline, 37% of the intervention group reported no physical activity, while by post-intervention only 15% reported no physical activity, compared to the control group who had no change in physical activity ($p < 0.001$). In the study, participants reporting participating in 30-60 minutes/day increased from 6% to 19% in the intervention group compared to only a 2% increase in the control group, 12% to 14% ($p < 0.001$). Similarly, in the FDPP at baseline, there was no difference between the intervention and control group in level of physical activity (≥ 4 hours/week of physical activity [~34 minutes/day]) ($p = 0.52$). Although, the intervention group had significantly higher amounts of physical activity than the control group at year 1 (64% to 86% vs 67% to 69%), year 3 (up to 82% vs 71%), and at the final visit (81% vs71%), ($p < 0.0001$, $p = 0.0003$, $p = 0.0013$, respectively). In comparison, participants in the PROMIS study increased the number of participants being physically active for about 34 minutes/day by 50%, improving from 0% at baseline. Although there were no post-intervention follow-ups in the PROMIS study, the FDPP intervention group remained significantly higher in proportion of physical activity compared to the control group ($p = 0.0005$) during the first post-intervention follow-up, occurring one year after the final intervention visit, providing further evidence that an educational and supportive lifestyle intervention program continues to have a positive impact on participants after the end of the intervention study.

The significant increase in minutes of physical activity and physical fitness seen in the FDPP were also seen in the SLIM study and the Worksite Diabetes

Prevention Program through a bicycle ergometer VO_{2max} test and a submaximal aerobic walking treadmill test (Aldana et al., 2006; Corpeleijn et al., 2006). During the SLIM study, participants were given a VO_{2max} test on a bicycle ergometer to measure their physical fitness level at baseline and again following the intervention. During the intervention the participants were encouraged to increase physical activity to at least 30 minutes of moderate physical activity a day for at lease 5 days a week, and were given instruction on how to increase daily physical activity with well defined goals to reach recommendation. Participants were also encouraged to participate in a physical activity program with supervised trainers for at least 1 hour per week (data not provided for compliance). Over the course of the intervention participants significantly improved their VO_{2max} ($p < 0.01$). Data were not provided as to the achievement of the physical activity goals of 30 minutes/day for at least 5 days/week, only for VO_{2max} (Corpeleijn et al., 2006).

Participants in the Workplace Diabetes Prevention Program were given similar physical activity goals. They were encouraged to do at least 150 minutes of moderate to vigorous physical activity per week, given a free pass to the employee gym, and encouraged to participate in the daily exercise classes during the 12 month intervention (participation rates not provided) (Aldana et al., 2006). The fitness test administered in this study was a 3 minute treadmill walking test on a motorized, belt-driven treadmill at 2.5 mph and 12% grade. The 1995 American College of Sports Medicine (ACSM) guidelines were followed for heart rate and perceived exertion rate (6- to 20-point Borg scale) measurements during the last 30 seconds of walking and were used to classify the participants' fitness level. Following the intervention, participants' aerobic fitness significantly increased ($p = 0.0001$) (Aldana et al., 2006). Much like the SLIM study (Corpeleijn et al., 2006), data were not provided for minutes of physical activity/week.

Study Limitations

The findings in the present study suggest that a well-designed education based intervention program can encourage lifestyle behaviors proven to improve MetS risk factors, despite some limiting factors. The 12-week intervention took place over 4 major holidays; Halloween, Thanksgiving, Christmas and New Year's, all of which pose a significant challenge for individuals trying to maintain a diet and physical activity regimen. Had the intervention taken place during spring or late summer we may have seen different outcomes regarding diet and possibly an even greater increase in physical activity due to the geographical location (high number of rainy days) of the study and holiday season.

Another limitation to this study is the small sample size and limited geographic region in which the study was conducted. Subject recruitment was difficult due to the time and location of recruitment, summer at a major university, in addition to the overall small size of the community. Subjects served as their own controls and there was no separate control group. Thus, the findings of this study must be interpreted with caution; and further research with a large sample size and a control group is needed. In addition, due to the holiday season, breaks of up to 2 weeks were given in the middle of the intervention, which may have influenced the study outcomes.

Regardless of these limitations, our study showed that a 12-week intervention had positive effects on various outcomes in at risk middle-aged women. Significant increases were found in whole grain and fiber consumption, as well as significant increases in physical activity and significant decreases in saturated fat intake. Additional changes were seen in overall diet, although not significant; a decrease in total energy (-100 kcals/day), an increase in protein (4.8 g/day), an increase in carbohydrates, most likely an increase in whole gains (2.7 g/day), a decrease in total fat (-13 g/day), saturated fat (-7.5 g/day) and *trans*-fat (-2 g/day), and increases in monounsaturated fat (4 g/day), polyunsaturated fat (7 g/day), as well as a small increase in omega-3 fatty acids (0.2 g/day).

In summary, the diet and physical activity intervention program influenced lifestyle behavior changes in all participants to varying degrees. The impact of such lifestyle behaviors should reduce their risk for developing chronic diseases such as MetS, Type 2 diabetes and CVD. The timing of the intervention, falling on three major holidays, may have been the reason for the lack of change in fruit and vegetables, as well as total fat intake.

Conclusion

As middle-aged women progress through menopause, engage in sedentary lifestyles and maintain poor diets low in fresh fruits, vegetables and whole grains, they increase their risk for developing MetS and Type 2 diabetes. The purpose of this study was to determine whether a 12-week educational and psychosocial intervention program, focusing on nutrition, physical activity and psychosocial support would significantly improve lifestyle behaviors for decreasing the onset of MetS and Type 2 diabetes for at risk pre-menopausal, pre-metabolic, middle-aged women. We hypothesized that by increasing programmed, moderate intensity physical activity (brisk walking) ≥ 150 minutes/week, increasing consumption of whole grains, fresh fruits and vegetables and lowering total fat and saturated fat intake, participants at risk for developing MetS will lower their risk factors. Despite the limited number of participants in our study (n = 10), we found participants to significantly increase servings of whole grains/day (1.5 to 3.2 servings/day, p = 0.005), grams of fiber/day (18.6 to 25.5 g/day, p = 0.03), decrease grams of saturated fat intake/day (27.7 to 20.2 g/day, p = 0.02), and significantly increase minutes of physical activity/day (3 to 43 mins/day, p = 0.001) following the lifestyle intervention. Findings from this study indicate that an education-based lifestyle intervention program will have a positive impact on diet and physical activity for at risk middle-aged women, possibly reducing their relative risk for MetS and Type 2 diabetes. Further research is needed to determine long-term success following a lifestyle intervention program.

Bibliography

Aas, A. M., Seljeflot, I., Torjesen, P. A., Diep, L. M., Thorsby, P. M., & Birkeland, K. I. (2006). Blood glucose lowering by means of lifestyle intervention has different effects on adipokines as compared with insulin treatment in subjects with type 2 diabetes. *Diabetologia, 49*(5), 872-880.

Ainy, E., Mirmiran, P., Zahedi Asl, S., & Azizi, F. (2007). Prevalence of metabolic syndrome during menopausal transition Tehranian women: Tehran Lipid and Glucose Study (TLGS). *Maturitas, 58*(2), 150-155.

Aldana, S., Barlow, M., Smith, R., Yanowitz, F., Adams, T., Loveday, L., et al. (2006). A worksite diabetes prevention program: two-year impact on employee health. *Aaohn J, 54*(9), 389-395.

American College of Sports Medicine (ACSM). (2000). *ACSM's guidelines for exercise testing and prescription* (Vol. 137). Philadelphia: Lippincott Williams & Wilkins.

American Dietetics Association (ADA). (2007). Nutrition Recommendations and Interventions for Diabetes: A position statement of the American Diabetes Association. *Diabetes Care, 30 Suppl 1*, S48-65.

Barbagallo, M., Dominguez, L. J., Galioto, A., Ferlisi, A., Cani, C., Malfa, L., et al. (2003). Role of magnesium in insulin action, diabetes and cardio-metabolic syndrome X. *Mol Aspects Med, 24*(1-3), 39-52.

Bazzano, L. A., Serdula, M. K., & Liu, S. (2003). Dietary intake of fruits and vegetables and risk of cardiovascular disease. *Current Atherosclerosis Reports, 5*(6), 492-499.

Borgman, M., & McErlean, E. (2006). What is the metabolic syndrome? Prediabetes and cardiovascular risk. *J Cardiovasc Nurs, 21*(4), 285-290.

Carr, M. (2003). The emergence of the metabolic syndrome with menopause. *J Clin Endocrinol Metab, 88*(6), 2404-2411.

Carr, M., & Brunzell, J. D. (2004). Abdominal obesity and dyslipidemia in the metabolic syndrome: importance of type 2 diabetes and familial combined hyperlipidemia in coronary artery disease risk. *J Clin Endocrinol Metab, 89*(6), 2601-2607.

Carr, M., Utzschneider, K. M., Hull, R. L., Kodama, K., Retzlaff, B. M., Brunzell, J. D., et al. (2004). Intra-abdominal fat is a major determinant of the National Cholesterol Education Program Adult Treatment Panel III criteria for the metabolic syndrome. *Diabetes, 53*(8), 2087-2094.

Cassells, H. B., & Haffner, S. M. (2006). The metabolic syndrome: risk factors and management. *J Cardiovasc Nurs, 21*(4), 306-313.

Centers for Disease Control and Prevention (CDC). (2003). National Diabetes Fact Sheet. In CDC (Ed.), *Data and Trends* (Vol. 2007).

Chandalia, M., Garg, A., Lutjohann, D., von Bergmann, K., Grundy, S. M., & Brinkley, L. J. (2000). Beneficial effects of high dietary fiber intake in patients with type 2 diabetes mellitus. *The New England Journal Of Medicine, 342*(19), 1392-1398.

Cnop, M., Havel, P. J., Utzschneider, K. M., Carr, D. B., Sinha, M. K., Boyko, E. J., et al. (2003). Relationship of adiponectin to body fat distribution, insulin sensitivity and plasma lipoproteins: evidence for independent roles of age and sex. *Diabetologia, 46*(4), 459-469.

Colditz, G. A., Willett, W. C., Rotnitzky, A., & Manson, J. E. (1995). Weight gain as a risk factor for clinical diabetes mellitus in women. *Ann Intern Med, 122*(7), 481-486.

Corpeleijn, E., Feskens, E. J., Jansen, E. H., Mensink, M., Saris, W. H., de Bruin, T. W., et al. (2006). Improvements in glucose tolerance and insulin sensitivity after lifestyle intervention are related to changes in serum fatty acid profile and desaturase activities: the SLIM study. *Diabetologia, 49*(10), 2392-2401.

Despres, J. P. (1993). Abdominal obesity as important component of insulin-resistance syndrome. *Nutrition, 9*(5), 452-459.

Eddy, D. M., Schlessinger, L., & Kahn, R. (2005). Clinical outcomes and cost-effectiveness of strategies for managing people at high risk for diabetes. *Ann Intern Med, 143*(4), 251-264.

Eriksson, K., Westborg, C. J., Eliasson, M. C. (2006). A randomized trial of lifestyle intervention in primary healthcare for the modification of cardiovascular risk factors. *Scand J Public Health, 34*(5), 453-461.

Esmaillzadeh, A., Kimiagar, M., Mehrabi, Y., Azadbakht, L., Hu, F. B., & Willett, W. C. (2006). Fruit and vegetable intakes, C-reactive protein, and the metabolic syndrome. *Am J Clin Nutr, 84*(6), 1489-1497.

Ford, E. S., Giles, W. H., & Dietz, W. H. (2002). Prevalence of the metabolic syndrome among US adults: findings from the third National Health and Nutrition Examination Survey. *Jama, 287*(3), 356-359.

Fujimoto, W. Y. (2000). Background and recruitment data for the U.S. Diabetes Prevention Program. *Diabetes Care, 23 Suppl 2*, B11-13.

Ginsberg, H. N., Zhang, Y. L., & Hernandez-Ono, A. (2006). Metabolic syndrome: focus on dyslipidemia. *Obesity (Silver Spring), 14 Suppl 1*, 41S-49S.

Golay, A., & Bobbioni, E. (1997). The role of dietary fat in obesity. *Int J Obes Relat Metab Disord, 21 Suppl 3*, S2-11.

Grundy, S. M., Cleeman, J. I., Daniels, S. R., Donato, K. A., Eckel, R. H., Franklin, B. A., et al. (2005). Diagnosis and management of the metabolic syndrome. An American Heart Association/National Heart, Lung, and Blood Institute Scientific Statement. Executive summary. *Cardiol Rev, 13*(6), 322-327.

Hayes, S. N. (2006). Preventing cardiovascular disease in women. *Am Fam Physician, 74*(8), 1331-1340.

He, K., Hu, F. B., Colditz, G. A., Manson, J. E., Willett, W. C., & Liu, S. (2004). Changes in intake of fruits and vegetables in relation to risk of obesity and weight gain among middle-aged women. *International Journal Of Obesity And Related Metabolic Disorders: Journal Of The International Association For The Study Of Obesity, 28*(12), 1569-1574.

He, K., Liu, K., Daviglus, M. L., Morris, S. J., Loria, C. M., Van Horn, L., et al. (2006). Magnesium intake and incidence of metabolic syndrome among young adults. *Circulation, 113*(13), 1675-1682.

Holland, W. L., Knotts, T. A., Chavez, J. A., Wang, L. P., Hoehn, K. L., & Summers, S. A. (2007). Lipid mediators of insulin resistance. *Nutr Rev, 65*(6 Pt 2), S39-46.

Hollman, P. C., & Katan, M. B. (1999). Dietary flavonoids: intake, health effects and bioavailability. *Food Chem Toxicol, 37*(9-10), 937-942.

Homko, C. J., & Trout, K. (2006). Women and diabetes. *Nurs Clin North Am, 41*(4), 549-565, vi.

Hu, F. B., Li, T. Y., Colditz, G. A., Willett, W. C., & Manson, J. E. (2003). Television watching and other sedentary behaviors in relation to risk of obesity and type 2 diabetes mellitus in women. *Jama, 289*(14), 1785-1791.

Hu, F. B., Manson, J. E., Stampfer, M. J., Colditz, G., Liu, S., Solomon, C. G., et al. (2001). Diet, lifestyle, and the risk of type 2 diabetes mellitus in women. *N Engl J Med, 345*(11), 790-797.

Institutes of Medicine Food and Nutrition Board. (2006). *Dietary Reference Intakes: The Essential Guide to Nutrient Requirements*. Washington, D.C.: The National Academies Press.

Iribarren, C., Go, A. S., Husson, G., Sidney, S., Fair, J. M., Quertermous, T., et al. (2006). Metabolic syndrome and early-onset coronary artery disease: is the whole greater than its parts? *J Am Coll Cardiol, 48*(9), 1800-1807.

Jacobs, D. R., Jr., & Gallaher, D. D. (2004). Whole grain intake and cardiovascular disease: a review. *Curr Atheroscler Rep, 6*(6), 415-423.

Jenum, A. K., Anderssen, S. A., Birkeland, K. I., Holme, I., Graff-Iversen, S., Lorentzen, C., et al. (2006). Promoting physical activity in a low-income multiethnic district: effects of a community intervention study to reduce risk factors for type 2 diabetes and cardiovascular disease: a community intervention reducing inactivity. *Diabetes Care, 29*(7), 1605-1612.

Joshipura, K. J., Hu, F. B., Manson, J. E., Stampfer, M. J., Rimm, E. B., Speizer, F. E., et al. (2001). The effect of fruit and vegetable intake on risk for coronary heart disease. *Ann Intern Med, 134*(12), 1106-1114.

Joubert, L. M., & Manore, M. M. (2006). Exercise, nutrition, and homocysteine. *Int J Sport Nutr Exerc Metab, 16*(4), 341-361.

Kao, W. H., Folsom, A. R., Nieto, F. J., Mo, J. P., Watson, R. L., & Brancati, F. L. (1999). Serum and dietary magnesium and the risk for type 2 diabetes mellitus: the Atherosclerosis Risk in Communities Study. *Arch Intern Med, 159*(18), 2151-2159.

Kirwan, J. P., del Aguila, L. F., Hernandez, J. M., Williamson, D. L., O'Gorman, D. J., Lewis, R., et al. (2000). Regular exercise enhances insulin activation of

IRS-1-associated PI3-kinase in human skeletal muscle. *J Appl Physiol, 88*(2), 797-803.

Knowler, W. C., Barrett-Connor, E., Fowler, S. E., Hamman, R. F., Lachin, J. M., Walker, E. A., et al. (2002). Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med, 346*(6), 393-403.

Lee, C. D., Blair, S. N., & Jackson, A. S. (1999). Cardiorespiratory fitness, body composition, and all-cause and cardiovascular disease mortality in men. *Am J Clin Nutr, 69*(3), 373-380.

Liberopoulos, E. N., Mikhailidis, D. P., & Elisaf, M. S. (2005). Diagnosis and management of the metabolic syndrome in obesity. *Obes Rev, 6*(4), 283-296.

Liese, A. D., Roach, A. K., Sparks, K. C., Marquart, L., D'Agostino, R. B., Jr., & Mayer-Davis, E. J. (2003). Whole-grain intake and insulin sensitivity: the Insulin Resistance Atherosclerosis Study. *Am J Clin Nutr, 78*(5), 965-971.

Liese, A. D., Schulz, M., Fang, F., Wolever, T. M., D'Agostino, R. B., Jr., Sparks, K. C., et al. (2005). Dietary glycemic index and glycemic load, carbohydrate and fiber intake, and measures of insulin sensitivity, secretion, and adiposity in the Insulin Resistance Atherosclerosis Study. *Diabetes Care, 28*(12), 2832-2838.

Lin, W. Y., Yang, W. S., Lee, L. T., Chen, C. Y., Liu, C. S., Lin, C. C., et al. (2006). Insulin resistance, obesity, and metabolic syndrome among non-diabetic pre- and post-menopausal women in North Taiwan. *Int J Obes (Lond), 30*(6), 912-917.

Lindstrom, J., Ilanne-Parikka, P., Peltonen, M., Aunola, S., Eriksson, J. G., Hemio, K., et al. (2006). Sustained reduction in the incidence of type 2 diabetes by lifestyle intervention: follow-up of the Finnish Diabetes Prevention Study. *Lancet, 368*(9548), 1673-1679.

Lindstrom, J., Peltonen, M., Eriksson, J. G., Louheranta, A., Fogelholm, M., Uusitupa, M., et al. (2006). High-fibre, low-fat diet predicts long-term weight loss and decreased type 2 diabetes risk: the Finnish Diabetes Prevention Study. *Diabetologia, 49*(5), 912-920.

Liu, S., Manson, J. E., Lee, I. M., Cole, S. R., Hennekens, C. H., Willett, W. C., et al. (2000). Fruit and vegetable intake and risk of cardiovascular disease: the Women's Health Study. *The American Journal Of Clinical Nutrition, 72*(4), 922-928.

Liu, S., Manson, J. E., Stampfer, M. J., Hu, F. B., Giovannucci, E., Colditz, G. A., et al. (2000). A prospective study of whole-grain intake and risk of type 2 diabetes mellitus in US women. *American Journal Of Public Health, 90*(9), 1409-1415.

Liu, S., Serdula, M., Janket, S. J., Cook, N. R., Sesso, H. D., Willett, W. C., et al. (2004). A prospective study of fruit and vegetable intake and the risk of type 2 diabetes in women. *Diabetes Care, 27*(12), 2993-2996.

Lopez-Ridaura, R., Willett, W. C., Rimm, E. B., Liu, S., Stampfer, M. J., Manson, J. E., et al. (2004). Magnesium intake and risk of type 2 diabetes in men and women. *Diabetes Care, 27*(1), 134-140.

Mayer-Davis, E. J., Sparks, K. C., Hirst, K., Costacou, T., Lovejoy, J. C., Regensteiner, J. G., et al. (2004). Dietary intake in the diabetes prevention program cohort: baseline and 1-year post randomization. *Ann Epidemiol, 14*(10), 763-772.

McKeown, N. M. (2004). Whole grain intake and insulin sensitivity: evidence from observational studies. *Nutrition Reviews, 62*(7 Pt 1), 286-291.

McKeown, N. M., Meigs, J. B., Liu, S., Wilson, P. W., & Jacques, P. F. (2002). Whole-grain intake is favorably associated with metabolic risk factors for type 2 diabetes and cardiovascular disease in the Framingham Offspring Study. *The American Journal Of Clinical Nutrition, 76*(2), 390-398.

Mesch, V. R., Boero, L. E., Siseles, N. O., Royer, M., Prada, M., Sayegh, F., et al. (2006). Metabolic syndrome throughout the menopausal transition: influence of age and menopausal status. *Climacteric, 9*(1), 40-48.

Meyer, K. A., Kushi, L. H., Jacobs, D. R., Jr., & Folsom, A. R. (2001). Dietary fat and incidence of type 2 diabetes in older Iowa women. *Diabetes Care, 24*(9), 1528-1535.

Meyer, K. A., Kushi, L. H., Jacobs, D. R., Jr., Slavin, J., Sellers, T. A., & Folsom, A. R. (2000). Carbohydrates, dietary fiber, and incident type 2 diabetes in older women. *Am J Clin Nutr, 71*(4), 921-930.

Moller, D. E., & Kaufman, K. D. (2005). Metabolic syndrome: a clinical and molecular perspective. *Annu Rev Med, 56*, 45-62.

Montonen, J., Knekt, P., Jarvinen, R., Aromaa, A., & Reunanen, A. (2003). Whole-grain and fiber intake and the incidence of type 2 diabetes. *Am J Clin Nutr, 77*(3), 622-629.

Mosca, C. L., Marshall, J. A., Grunwald, G. K., Cornier, M. A., & Baxter, J. (2004). Insulin resistance as a modifier of the relationship between dietary fat intake and weight gain. *Int J Obes Relat Metab Disord, 28*(6), 803-812.

Murdoch, S. J., Carr, M. C., Hokanson, J. E., Brunzell, J. D., & Albers, J. J. (2000). PLTP activity in premenopausal women. Relationship with lipoprotein lipase, HDL, LDL, body fat, and insulin resistance. *J Lipid Res, 41*(2), 237-244.

Murtaugh, M. A., & Jacobs, D. R. (2003). Epidemiological support for the protection of whole grains against diabetes. *Procedings of the Nutrition Society, 62*, 143-149.

National Cholesterol Education Program (NCEP). (2002). Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) final report. *Circulation, 106*(25), 3143-3421.

Norris, S. L., Zhang, X., Avenell, A., Gregg, E., Bowman, B., Schmid, C. H., et al. (2005). Long-term effectiveness of weight-loss interventions in adults with pre-diabetes: a review. *Am J Prev Med, 28*(1), 126-139.

Oh, K., Hu, F. B., Manson, J. E., Stampfer, M. J., & Willett, W. C. (2005). Dietary fat intake and risk of coronary heart disease in women: 20 years of follow-up of the nurses' health study. *Am J Epidemiol, 161*(7), 672-679.

Opie, L. H. (2007). Metabolic syndrome. *Circulation, 115*(3), e32-35.

Pannier, B., Thomas, F., Eschwege, E., Bean, K., Benetos, A., Leocmach, Y., et al. (2006). Cardiovascular risk markers associated with the metabolic syndrome in a large French population: the "SYMFONIE" study. *Diabetes Metab, 32*(5 Pt 1), 467-474.

Park, Y. W., Zhu, S., Palaniappan, L., Heshka, S., Carnethon, M. R., & Heymsfield, S. B. (2003). The metabolic syndrome: prevalence and associated risk factor findings in the US population from the Third National Health and Nutrition Examination Survey, 1988-1994. *Arch Intern Med, 163*(4), 427-436.

Pepys, M. B., Hirschfield, G. M., Tennent, G. A., Gallimore, J. R., Kahan, M. C., Bellotti, V., et al. (2006). Targeting C-reactive protein for the treatment of cardiovascular disease. *Nature, 440*(7088), 1217-1221.

Phillips, G. B., Jing, T., & Heymsfield, S. B. (2008). Does insulin resistance, visceral adiposity, or a sex hormone alteration underlie the metabolic syndrome? Studies in women. *Metabolism, 57*(6), 838-844.

Rader, D. J. (2007). Effect of insulin resistance, dyslipidemia, and intra-abdominal adiposity on the development of cardiovascular disease and diabetes mellitus. *Am J Med, 120*(3 Suppl 1), S12-18.

Reaven, G. M. (1988). Banting lecture 1988. Role of insulin resistance in human disease. *Diabetes, 37*(12), 1595-1607.

Riccardi, G., & Rivellese, A. A. (2000). Dietary treatment of the metabolic syndrome--the optimal diet. *Br J Nutr, 83 Suppl 1*, S143-148.

Rimm, E. B., Willett, W. C., Hu, F. B., Sampson, L., Colditz, G. A., Manson, J. E., et al. (1998). Folate and vitamin B6 from diet and supplements in relation to risk of coronary heart disease among women. *Jama, 279*(5), 359-364.

Rosano, G. M., Vitale, C., & Tulli, A. (2006). Managing cardiovascular risk in menopausal women. *Climacteric, 9 Suppl 1*, 19-27.

Russell, J. C. (2001). Reduction and prevention of the cardiovascular sequelae of the insulin resistance syndrome. *Curr Drug Targets Cardiovasc Haematol Disord, 1*(2), 107-120.

Salmeron, J., Hu, F. B., Manson, J. E., Stampfer, M. J., Colditz, G. A., Rimm, E. B., et al. (2001). Dietary fat intake and risk of type 2 diabetes in women. *Am J Clin Nutr, 73*(6), 1019-1026.

Schulze, M. B., & Hu, F. B. (2005). Primary prevention of diabetes: what can be done and how much can be prevented? *Annual Review Of Public Health, 26*, 445-467.

Sheard, N. F., Clark, N. G., Brand-Miller, J. C., Franz, M. J., Pi-Sunyer, F. X., Mayer-Davis, E., et al. (2004). Dietary carbohydrate (amount and type) in the prevention and management of diabetes: a statement by the american diabetes association. *Diabetes Care, 27*(9), 2266-2271.

Sigal, R. J., Kenny, G. P., Wasserman, D. H., & Castaneda-Sceppa, C. (2004). Physical activity/exercise and type 2 diabetes. *Diabetes Care, 27*(10), 2518-2539.

Slack, M. K. (2006). Interpreting current physical activity guidelines and incorporating them into practice for health promotion and disease prevention. *Am J Health Syst Pharm, 63*(17), 1647-1653.

Slavin, J. L., Martini, M. C., & Jacobs, D. R. (1999). Plausible mechanisms for the protectiveness of whole grains. *Am J Clin Nutr, 70*(Suppl), 495S-463S.

Song, Y., Manson, J. E., Buring, J. E., & Liu, S. (2004). Dietary magnesium intake in relation to plasma insulin levels and risk of type 2 diabetes in women. *Diabetes Care, 27*(1), 59-65.

Song, Y., Manson, J. E., Buring, J. E., Sesso, H. D., & Liu, S. (2005). Associations of dietary flavonoids with risk of type 2 diabetes, and markers of insulin resistance and systemic inflammation in women: a prospective study and cross-sectional analysis. *J Am Coll Nutr, 24*(5), 376-384.

Summers, L. K., Fielding, B. A., Bradshaw, H. A., Ilic, V., Beysen, C., Clark, M. L., et al. (2002). Substituting dietary saturated fat with polyunsaturated fat changes abdominal fat distribution and improves insulin sensitivity. *Diabetologia, 45*(3), 369-377.

Thanopoulou, A., Karamanos, B., Angelico, F., Assaad-Khalil, S., Djordjevic, P., Katsilambros, N., et al. (2006). Epidemiological evidence for the non-random clustering of the components of the metabolic syndrome: multicentre study of the Mediterranean Group for the Study of Diabetes. *Eur J Clin Nutr, 60*(12), 1376-1383.

The Diabetes Prevention Program (DPP). (1999). The Diabetes Prevention Program. Design and methods for a clinical trial in the prevention of type 2 diabetes. *Diabetes Care, 22*(4), 623-634.

The Diabetes Prevention Program (DPP). (2002). The prevention or delay of type 2 diabetes. *Diabetes Care, 25*(4), 742-749.

Tuomilehto, J., Lindstrom, J., Eriksson, J. G., Valle, T. T., Hamalainen, H., Ilanne-Parikka, P., et al. (2001). Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. *N Engl J Med, 344*(18), 1343-1350.

United States Department of Health and Human Services (DHHS). (2001). *The Surgeon General's call to action to prevent and decrease overweight and ovesity, 2001*. Washington DC: Office of the Surgeon General.

United States Department of Health and Human Services and the Department of Agriculture (USDA). (2005). Dietary Guidelines for Americans. Nutrition and Your Health.

Vatten, L. J., Nilsen, T. I., Romundstad, P. R., Droyvold, W. B., & Holmen, J. (2006). Adiposity and physical activity as predictors of cardiovascular mortality. *Eur J Cardiovasc Prev Rehabil, 13*(6), 909-915.

Verhoef, P., Kok, F. J., Kruyssen, D. A., Schouten, E. G., Witteman, J. C., Grobbee, D. E., et al. (1997). Plasma total homocysteine, B vitamins, and risk of coronary atherosclerosis. *Arterioscler Thromb Vasc Biol, 17*(5), 989-995.

Wajchenberg, B. L. (2000). Subcutaneous and visceral adipose tissue: their relation to the metabolic syndrome. *Endocr Rev, 21*(6), 697-738.

Walker, K. Z., Piers, L. S., Putt, R. S., Jones, J. A., & O'Dea, K. (1999). Effects of regular walking on cardiovascular risk factors and body composition in normoglycemic women and women with type 2 diabetes. *Diabetes Care, 22*(4), 555-561.

Willett, W. C. (2002). Balancing life-style and genomics research for disease prevention. *Science, 296*(5568), 695-698.

Wing, R. R., Hamman, R. F., Bray, G. A., Delahanty, L., Edelstein, S. L., Hill, J. O., et al. (2004). Achieving weight and activity goals among diabetes prevention program lifestyle participants. *Obes Res, 12*(9), 1426-1434.

Attention Women 35-55 years!

Overweight? Diagnosed with higher than normal blood glucose?

Researchers at Oregon State University seek volunteer women to help them learn more about methods to reduce the risk of chronic disease. You may be eligible to participate in a nutrition and exercise education program led by trained professionals. You will receive a free blood lipid, glucose and body composition analysis <u>FREE!</u>

Interested? Call NOW!
737-4925

Does this sound like you?

- Age 35-60 years
- PRE-Diabetic
- Low activity or Sedentary

If so, call now for more information:

- Healthy Lifestyles
- Nutrition and Diet
- Exercise

Brought to you by:
Department of Public Health
Department of Human Development and Family Sciences
Department of Nutrition and Exercise Science
Samaritan Health Services

Public Health
Oregon State University, BUILDING ADDRESS, Corvallis, Oregon 97331
Tel 541-737-2686 | **Fax** 541-737-4001| publichealth@oregonstate.edu/ http://www.hhs.oregonstate.edu/ph/index.html

INFORMED CONSENT DOCUMENT

Project Title: **Prevention of Metabolic Syndrome: Intervention Strategies (PROMIS)**
Principal Investigator: **Rebecca Donatelle, PhD, Public Health**
Co-Investigator(s): **Alexis Walker, PhD, Human Development and Family Services**
Melinda Manore, PhD, Nutrition

WHAT IS THE PURPOSE OF THIS STUDY?

You are being invited to take part in a research study designed to explore two ideas: 1) how social relationships impact the development of chronic disease and 2) potential methods for reducing the onset of chronic disease. It is hypothesized that monitoring blood sugar and using techniques known as motivational interviewing will reduce the risks for chronic disease. This study aims to reduce the health risks of women aged 35-60 years who are at risk for, and/or who have the potential to develop, Metabolic Syndrome. The outcomes from this study will be used to develop a large scale project to help a larger group of women reduce their risk for chronic disease and increase their quality of life. You can help us see which methods work best from your point of view.

WHAT IS THE PURPOSE OF THIS FORM?

This consent form gives you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask any questions about the research, the possible risks and benefits, your rights as a volunteer, and anything else that is not clear. When all of your questions have been answered, you can decide if you want to be in this study or not.

WHY AM I BEING INVITED TO TAKE PART IN THIS STUDY?

You are being invited to take part in this study because you meet the following study criterion to participate in our Metabolic Syndrome Women's Study:

- Female
- Pre-menopausal or not menopausal (i.e., still having periods)
- Age range of 35-60
- Fasting blood glucose ≥ 100 mg/dL
- Body mass index range of: 25-34.9 kg/m^2

WHAT WILL HAPPEN DURING THIS STUDY AND HOW LONG WILL IT TAKE?

If you agree to take part in this study within two weeks, we will schedule you for the first of two screening visits. If you agree to participate in the intervention group, you will be asked to participate in a series of classes and experiences designed to reduce your health risks. A project staff member will contact you to schedule the first education session.

These classes will take approximately 60 minutes per week. Participation in these classes will enter you into a weekly lottery to win $100.

WHEN YOU JOIN THE STUDY:

- You will be asked to answer some written questions about me and about my health.
- You will be asked to give a blood sample (about 2 tablespoons) taken by a trained phlebotomist.
- You will have your height, weight and body fat composition measured.
- You will be asked to walk on a treadmill for 20-30 minutes at a relaxed, comfortable speed (not more than 3 mph).
- You will be asked to complete a follow-up interview about your experiences in the project.

Weekly: If you are assigned to the intervention group, when you come in for weekly classes you will be learning about glucose testing, shopping, cooking, nutrition, and physical activity. Your finger will also be pricked for a small blood sample (one to two drops of blood) to test your blood sugar.

AT THE END OF THE PROGRAM

- You will be asked to give a final blood sample (approximately 2 tablespoons) taken by a trained phlebotomist.
- You will be asked to complete a written survey to answer questions about how effective the program was, your current physical activity, and your nutrition.
- You will be asked to complete a follow- up interview with program staff about your experiences in the program. This interview will be audio taped with your permission.

If you agree to take part in this study, your involvement will last for approximately 12-14 weeks. This includes the first introductory visit, the 12-week education course and the final, follow-up interview.

WHAT ARE THE RISKS OF THIS STUDY?

Possible risks or discomforts:

- One potential discomfort might be taking the time to complete the written surveys at the beginning and the end of the study.
- You may experience temporary discomfort when the finger is pricked by the needle, and tenderness around the site where the finger prick was administered.
- There are some discomforts associated with walking for exercise, such as increased blood pressure, increased heart rate, shortness of breath, and physical

discomfort (e.g. soreness, muscle fatigue, exhaustion). However, trained technicians will carefully explain treadmill activities and will allow participants to slowly acclimate to walking on the treadmill while wearing appropriate footwear and clothing.

- There are a few potential risks associated with blood draws. Among them are: temporary discomfort from where the needle is inserted into your arm, bruising around the site where the blood was taken from, and rarely infection. To minimize these risks you will be instructed to keep pressure on the site where the blood was drawn for 1 minute and keep a bandage over the area for at least 1 hour.
- Questionnaires that ask about personal substance use and depression may cause mild discomfort.

WHAT ARE THE BENEFITS OF THIS STUDY?

Benefits to be expected from the research: You will get advice, materials, and support to reduce your risk factors related to metabolic syndrome and other illnesses. All tests will be conducted FREE of charge.

WILL I BE PAID FOR PARTICIPATING?

If you are assigned to the intervention group, you can choose to participate in the 12-14 week physical activity and nutrition education class. These classes will take approximately 60 minutes per week. If you choose to participate in these classes you will be entered into a weekly lottery to win $100 at the end of the study.

If you are assigned to the control or no-intervention group, you will receive a packet of educational materials about Metabolic Syndrome, physical activity, and nutrition. You will also be given $5.00 for the completion of each of your questionnaires and blood draws.

WHO WILL SEE THE INFORMATION I GIVE?

Any information that you give will be kept confidential to the extent permitted by law. A code number will be used to identify any test results or other information that you provide. Neither your name nor any information from which you might be identified will be used in any data summaries or publications. All answers will be assessed on a group basis only.

AUDIO RECORDING

One aspect of this study involves making an audio recording of your final thoughts and impressions about your experience in the study. Only study investigators will have access to these recordings and your confidentiality will be maintained. These recordings will be coded to determine patterns in experiences with the program in an effort to better understand the impact of the program and to make changes that might enhance future materials.

If the results of this project are published your identity will not be made public.

DO I HAVE A CHOICE TO BE IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any benefits or rights you would normally have if you choose not to volunteer. You can stop at any time during the study and still keep the benefits and rights you had before volunteering.

You will not be treated differently if you decide to stop taking part in the study. If may skip any questions that you are not comfortable answering without adverse effects. If you choose to withdraw from this project before it ends, the researchers may keep information collected about you and this information may be included in study reports.

WHAT IF I HAVE QUESTIONS?

If you have any questions about this research project, please contact:
Rebecca J. Donatelle, PhD: 541-737-3839

If you have questions about your rights as a participant, please contact the Oregon State University Institutional Review Board (IRB) Human Protections Administrator, at (541) 737-4933 or by email at IRB@oregonstate.edu.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Participant's Name (printed):

____

____ ______________________________
(Signature of Participant) (Date)

Prevention of Metabolic Syndrome: Intervention Strategies
(PROMIS)

____

Please print your name here.

For office Use—Tear Here

Participant ID: ___ ___ ___ ___
Date: ___ ___ /___ ___ /___ ___ ___ ___
Baseline
Cohort: ___ ___

A. Please answer these questions about your life by checking the responses that best fit your current situation.

1. What is the date and year of your birth? ________

2. What is the highest degree you have earned?
__ a. Less than high school
__ b. High school diploma or equivalency (GED)
__ c. Associates degree (junior college)
__ d. Bachelor's degree
__ e. Master's degree
__ f. Doctorate
__ g. Professional (MD, JD, DDS, etc)
__ g. Other, specify____

3. What is your current employment status?
__a. Working full time (35 or more hours per week)
__b. Working part time (34 or fewer hours per week)
__c. Unemployed or laid off
__d. Looking for work
__e. Retired
__f. Disabled
__g. Other: ____________________________________

4. What is your primary occupation *(if unemployed please list your past occupation)*? *Please be specific:-*
____

5. What is was total household income, before taxes and other deductions, during the past 12 months?
_____a. Less than $5,000
_____b. $5,000 through $11,999
_____c. $12,000 through $15,999
_____d. $16,000 through $24,999
_____e. $25,000 through $34,999
_____f. $35,000 through $49,999
_____g. $50,000 through $74,999
_____h. $75,000 through $99,999
_____i. $100,000 and greater

6. How many people are currently living in your household, including yourself?

_____a. Number of people
_____b. Of these people, how many are children?
_____c. Of these people, how many are adults?

7. What is your current marital or partner status?

_______a. married or living with a partner

_______b. widowed

_______c. divorced or separated

_______d. never married

8. Please **list** the names and ages of you children. Please **circle** those living in your household currently.

SONS		DAUGHTERS	
1. ______________________	age:___ ___	1. ______________________	age:___ ___
2. ______________________	age:___ ___	2. ______________________	age:___ ___
3. ______________________	age:___ ___	3. ______________________	age:___ ___
4. ______________________	age:___ ___	4. ______________________	age:___ ___
5. ______________________	age:___ ___	5. ______________________	age:___ ___

9. Do you. . .
__ a. Own your home?
__ b. Rent your home?
__ c. Live with a friend?
__ d. Live with a relative?
__ e. Other (describe): ____

10. If you lost all your current source(s) of household income (your paycheck, public assistance, or other forms of income), how long could you continue to live at your current address and standard of living?

______ a. Less than 1 month
______ b. 1 to 2 months
______ c. 3 to 6 months
______ d. 7 to 12 months
______ e. More than 1 year

11. Do you have health insurance? _____ YES _______ NO
If So,
___ a. Through your job? Name of insurer:____
___ b. Through your spouse or partner's job? Name of Insurer: ______________________
___ c. Oregon Health Plan?
___ d. Medicare?
___ e. I don't have health insurance.
___ f. Other: _________________________________

B. Please put a check mark beside all that apply to you.

1. My ethnicity is (*please mark those that apply)*:
__ a. Asian, or Asian American
__ b. Black or African American
__ c. Hispanic or Latino
__ d. White, Caucasian, European, not Hispanic
__ e. American Indian
__ f. My parents are from two different groups
__ g. Other (describe): ____

C. On the following questions, please rate how confident you feel that you that you would exercise in the described conditions.

1. When you are under a lot of stress, how confident are you that you will exercise?

1	2	3	4	5
Not at all confident	somewhat confident	moderately confident	very confident	completely confident

2. When you don't have the time, how confident are you that you will exercise?

1	2	3	4	5
Not at all confident	somewhat confident	moderately confident	very confident	completely confident

3. When you have to exercise alone, how confident are you that you will exercise?

1	2	3	4	5
Not at all confident	somewhat confident	moderately confident	very confident	completely confident

4. When you don't have access to exercise equipment, how confident are you that you will exercise?

1	2	3	4	5
Not at all confident	somewhat confident	moderately confident	very confident	completely confident

5. When you are spending time with your friends and/or family who do not exercise, how confident are you that you will exercise?

1	2	3	4	5
Not at all confident	somewhat confident	moderately confident	very confident	completely confident

6. When the weather is bad outside, how confident are you that you will exercise?

1	2	3	4	5
Not at all confident	somewhat confident	moderately confident	very confident	completely confident

Participant ID: __ __ __ __ __
108
Cohort: __ __
Baseline

D. Please put a check beside the answer that best describes your planned physical activity.
Note: *Planned physical activity* is any planned activity performed to increase your physical fitness. Such activity should be performed 3-5 times per week for 20-60 minutes per session.
1. Do you exercise regularly according to the above definition?

__ a. Yes, I have been exercising according to this definition for MORE than 6 months.
__ b. Yes, I have been exercising according to this definition for FEWER than 6 months.
__ c. No, but I intend to exercise according to this definition in the next 30 days.
__ d. No, but I intend to exercise according to this definition in the next 6 months.
__ e. No, and I do NOT intend to exercise according to this definition in the next 6 months.

E. Please circle yes or no for each of the following questions about your weight.

1. In the past month, have you been purposefully trying to lose weight?
YES NO
2. In the past month, have you been actively trying to keep from gaining weight?
YES NO
3. Are you seriously considering trying to lose weight to reach your goal in the next six months?
YES NO
4. Have you maintained your desired weight for more than six months?
YES NO

F. Please answer the following questions about your social support. Circle the response that best describes your experience. Then, list the people, or person, that you are thinking of as you answer each question, and list her/his relationship to you.

1. Is there someone available to whom you can count on to listen to you when you need to talk?

1	2	3	4	5
None of the time	A little of the time	Some of the time	Most of the time	All of the time

Please list the first name of the person you are thinking of here, and their relationship to you:
(Example: Lynn, sister)____

____

____

2. Is there someone available to you to give you good advice about a problem?

1	2	3	4	5
None of the time	A little of the time	Some of the time	Most of the time	All of the time

Please list the first name of the person you are thinking of here, and their relationship to you:
(Example: Lynn, sister)____

____

____

3. Is there someone available to you who shows you love and affection?

1	2	3	4	5
None of the time	A little of the time	Some of the time	Most of the time	All of the time

Please list the first name of the person you are thinking of here, and their relationship to you:
(Example: Lynn, sister)____
____
____

4. Is there someone available to help with daily chores?

1	2	3	4	5
None of the time	A little of the time	Some of the time	Most of the time	All of the time

Please list the first name of the person you are thinking of here, and their relationship to you:
(Example: Lynn, sister)____
____
____

5. Can you count on anyone to provide you with emotional support?

1	2	3	4	5
None of the time	A little of the time	Some of the time	Most of the time	All of the time

Please list the first name of the person you are thinking of here, and their relationship to you:
(Example: Lynn, sister)____
____
____

6. Do you have as much contact as you would like with someone you feel close to, someone in whom you can trust and confide?

1	2	3	4	5
None of the time	A little of the time	Some of the time	Most of the time	All of the time

Please list the first name of the person you are thinking of here, and their relationship to you:
(Example: Lynn, sister)____
____
____

7. Is there someone available to you who helps you make decisions about your health?
YES NO

7b. If yes, please indicate how available that person is to help you to make decisions about your health.

1	2	3	4	5
None of the time	A little of the time	Some of the time	Most of the time	All of the time

Please list the first name of the person you are thinking of here, and their relationship to you:
(Example: Lynn, sister)____
____
____

If no one who helps you to make decisions about your health, please skip to question 9.

8. If there is someone available to you who helps you to make decisions about your health, how much do you trust this person's opinion?

1 ______ 2 ______ 3 ______ 4 ______ 5

Do not trust at all — Trust a little — Trust somewhat — Mostly Trust — Trust very much

Please list the first name of the person you are thinking of here, and their relationship to you:
(Example: Lynn, sister) ____________________

____

____

9. Is there someone in your life that can support you in an exercise and diet program?

1 ______ 2 ______ 3 ______ 4 ______ 5

Not at all — A moderate amount — A great deal

Please list the first name of the person you are thinking of here, and their relationship to you:
(Example: Joe, spouse) ____________________

____

____

10. Over the past three months, have family members or friends exercised with you?

1 ______ 2 ______ 3 ______ 4 ______ 5

Not at all — A moderate amount — A great deal

11. Over the past three months, have you shared healthy low-fat recipes with friends or family members?

1 ______ 2 ______ 3 ______ 4 ______ 5

Not at all — A moderate amount — A great deal

12. Over the past three months have family members or friends bought food or prepared food for you that was especially healthy or recommended?

1 ______ 2 ______ 3 ______ 4 ______ 5

Not at all — A moderate amount — A great deal

13. How important is family and friend support in managing your health issues?

1 ______ 2 ______ 3 ______ 4 ______ 5

Not at all Important — Somewhat Important — Very Important

G. Please think back to a family member's experience with illness and disease.

1. Based on your family member's experiences with illness and disease, what, if any, diseases do you worry about developing yourself?

a. ____________________
b. ____________________
c. ____________________
d. ____________________
e. ____________________
f. ____________________
g. ____________________

2. Have any of your <u>family members</u> experienced any serious or life threatening complications for diabetes?

YES NO

7b. If so, please describe:

____
____
____
____
____

Now, please think about a <u>friend's</u> experience with illness and disease.

3. Based on your friend's experiences with illness and disease, what, if any, diseases do you worry about developing yourself?

a. ______________________________________
b. ______________________________________
c. ______________________________________
d. ______________________________________
e. ______________________________________
f. ______________________________________
g. ______________________________________

4. Have any of your <u>friend's</u> experienced any serious or life threatening complications for diabetes?

YES NO

7b. If so, please describe:

____
____
____
____
____

Now, please think about your own experience with illness and disease.

3a. Has your health care provider talked to you about your weight?

YES NO

3b. If yes, please rate your comfort level with the discussion about your weight.

1	2	3	4	5
Not at all comfortable	A little uncomfortable	Somewhat comfortable	Comfortable	Very Comfortable

4. Has your health care provider encouraged you to lose weight?

1	2	3	4
Not at all	A little	Somewhat	Very much

5. Did your health care provider seem comfortable talking you to you about your weight?

1 Not at all	2 A little	3 Somewhat	4 Very much

6. Was your health care provider…

___ Male ___ Female

7. Has your health care provider encouraged you to change your lifestyle in some way?

1 Not at all	2 A little	3 Somewhat	4 Very much

8. During discussions with your health care provider about your pre-diabetes, did s/he say anything that motivated you to want to make any changes?

YES NO

9. If YES, please describe: ______________________________
____
____
____
____

10. Did your health care provider make any specific suggestions about how to reduce your risk for developing diabetes?

YES NO

11. If YES, what suggestions were made?

____
____
____
____
____

12. Has your health care provider involved you as an equal partner in making decision about illness management strategies and goals?

1 Not at all	2	3 A moderate amount	4	5 A great deal

13. Has your health care provider listened carefully to what you had to say about your illness?

1 Not at all	2	3 A moderate amount	4	5 A great deal

Participant ID: __ __ __ __ __
113
Cohort: __ __
Baseline

14. Has your health care provider thoroughly explained the results of test you had done (e.g., cholesterol, blood pressure, or other laboratory tests)?

1	2	3	4	5
Not at all		A moderate amount		A great deal

15. How important are health care team resources to you in managing your illness?

1	2	3	4	5
Not at all		A moderate amount		A great deal

16. Was the discussion with your health care provider about your pre-diabetes respectful?

1	2	3	4	5
Not at all respectful	A little respectful	Somewhat respectful	Respectful	Very respectful

17. Has your health care provider been encouraging?

1	2	3	4	5
Not at all encouraging	A little encouraging	Somewhat encouraging	Encouraging	Very encouraging

18. Did your health care provider refer you to a Diabetes Specialist, Registered Dietitian or some other health care advisor?

YES NO

If no, please skip to *section H.*

19. If yes, have you met with that person?

YES NO

20. Was this person….

___ Male ___ Female

H. Please answer these questions based on your knowledge and experience with testing your blood sugar.

1. Have you had your blood sugar tested by a doctor or other health care provider?

___ Yes ___ No

1b. If yes, what was your blood sugar level? _________________

2. Have you ever tested your blood sugar yourself?

___ Yes ___ No

2b. If yes, what was your blood sugar level? _________________

3. How important is testing your blood sugar to you?

1	2	3	4	5
Not at All Important	A little Important	Somewhat Important	Important	Very Important

4. How important is testing your blood sugar to your health?

1	2	3	4	5
Not at All Important	A little Important	Somewhat Important	Important	Very Important

5. How important is testing your blood sugar in preventing diabetes?

1	2	3	4	5
Not at All Important	A little Important	Somewhat Important	Important	Very Important

6. How frequently do you test your blood sugar?

1	2	3	4	5
Never	Once or twice monthly	Weekly	Almost Daily	Daily

7. How comfortable are you with testing your blood sugar?

1	2	3	4	5
Not at All Comfortable	A little Comfortable	Somewhat Comfortable	Comfortable	Very Comfortable

8. How much does the result of testing your blood sugar motivate you to exercise?

1	2	3	4	5
Not at All Motivating	A little Motivating	Somewhat Motivating	Motivating	Very Motivating

9. How much does testing your blood sugar motivate you to change your diet?

1	2	3	4	5
Not at All Motivating	A little Motivating	Somewhat Motivating	Motivating	Very Motivating

I. The next questions ask you about your feelings and thoughts during the past month. In each case, please circle how often you felt or thought a certain way.

1. In the last month, how often have you felt that you were unable to control the important things in your life?

0	1	2	3	4
Never	almost never	sometimes	fairly often	very often

2. In the last month, how often have your felt confident about your ability to handle your personal problems?

0	1	2	3	4
Never	almost never	sometimes	fairly often	very often

Participant ID: __ __ __ __ __
115
Cohort: __ __
Baseline

3. In the last month, how often have you felt that things were going your way?

0	1	2	3	4
Never	almost never	sometimes	fairly often	very often

4. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?

0	1	2	3	4
Never	almost never	sometimes	fairly often	very often

J. Over the last 2 weeks, how often have you been bothered by any of the following problems?

1. Have you often felt down, depressed, or hopeless?
☐ **Yes** ☐ **No**

2. Have you had little interest or pleasure in doing things?
☐ **Yes** ☐ **No**

K. The next questions are about your use of alcohol and tobacco. Please answer each question by placing a check mark beside the response that best describes your situation. For questions that require a number, please write in the number the best describes your experience.

1a. Do you currently smoke?
___ YES ____ NO
If no, please skip to question 3.

1b. How many cigarettes a day do you smoke on the average (*0 if none*)? ___ ___

2. Please indicate how old you were when you first began smoking: _____ years old

3. Did you use tobacco during any of these time periods (*please mark all that apply)*?

___ Before High School
___ During High School
___ After HS
___ Currently
___ Never

4. Did you use alcohol during any of these time periods (*please mark all that apply)*?

___ Before High School
___ During High School
___ After
___ Currently
___ Never

Participant ID: __ __ __ __ __
116
Cohort: __ __
Baseline

5. Did you use illegal drugs during any of these time periods (*please mark all that apply*)?

___ Before High School
___ During High School
___ After HS
___ Currently
___ Never

--Please continue on to the next page--

L. Please circle the response that best describes your feelings about exercise.

	Strongly Agree	Agree	Disagree	Strongly Disagree
1. I enjoy exercise.	SA	A	D	SD
2. Exercise decreases feelings of stress and tension for me.	SA	A	D	SD
3. Exercise improves my mental health.	SA	A	D	SD
4. Exercising takes too much of my time.	SA	A	D	SD
5. I will prevent heart attacks by exercising.	SA	A	D	SD
6. Exercise tires me.	SA	A	D	SD
7. Exercise increases my muscle strength.	SA	A	D	SD
8. Exercise gives me a sense of personal accomplishment.	SA	A	D	SD
9. Places for me to exercise are too far away.	SA	A	D	SD
10. Exercising makes me feel relaxes.	SA	A	D	SD
11. Exercising lets me have contact with friends and persons I enjoy	SA	A	D	SD
12. I am too embarrassed to exercise.	SA	A	D	SD
13. Exercising will keep me from having high blood pressure.	SA	A	D	SD
14. It costs too much money to exercise.	SA	A	D	SD
15. Exercising increases my level of physical fitness.	SA	A	D	SD
16. Exercise facilities do not have convenient schedules for me.	SA	A	D	SD
17. My muscle tone is improved with exercise.	SA	A	D	SD
18. Exercising improves functioning of my cardiovascular system.	SA	A	D	SD
19. I am fatigued by exercise.	SA	A	D	SD
20. I have improved feelings of well being from exercise.	SA	A	D	SD
21. My spouse (or significant other) does not encourage exercising.	SA	A	D	SD
22. Exercise increases my stamina.	SA	A	D	SD
23. Exercise improves my flexibility.	SA	A	D	SD
24. Exercise takes too much time from family relationships.	SA	A	D	SD
25. My disposition is improved by exercise.	SA	A	D	SD
26. Exercising helps me sleep better at night.	SA	A	D	SD
27. I will live longer if I exercise.	SA	A	D	SD
28. I think people in exercise clothes look funny.	SA	A	D	SD
29. Exercise helps me decrease fatigue.	SA	A	D	SD
30. Exercising is a good way for me to meet new people.	SA	A	D	SD
31. My physical endurance is improved by exercising.	SA	A	D	SD
32. Exercising improves my self-concept.	SA	A	D	SD
33. My family members do not encourage me to exercise.	SA	A	D	SD
34. Exercising increases my mental alertness.	SA	A	D	SD
35. Exercise allows me to carry out normal activities without becoming tired.	SA	A	D	SD
36. Exercise improves the quality of my work.	SA	A	D	SD

Participant ID: __ __ __ __ __

Cohort: __ __
Baseline

	Strongly Agree	Agree	Disagree	Strongly Disagree
37. Exercise takes too much time from my family responsibilities.	SA	A	D	SD
38. Exercise is good entertainment for me.	SA	A	D	SD
39. Exercising increases my acceptance by others.	SA	A	D	SD
40. Exercise is hard work for me.	SA	A	D	SD
41. Exercise improves overall body functioning for me.	SA	A	D	SD
42. There are too few places for me to exercise.	SA	A	D	SD
43. Exercise improves the way my body looks.	SA	A	D	SD
44. Exercise improves my balance and coordination	SA	A	D	SD

THE END

Thank You!

Prevention of Metabolic Syndrome: Intervention Strategies (PROMIS)

Welcome to the Promis Study!

Thank you for agreeing to participate in this exciting study to prevent Metabolic Syndrome. You will find the following materials enclosed in this packet:
Consent Form (to be signed in person with us)
Questionnaires
Information about your first visit with us

Please read over the consent form. We will answer any of your questions before you sign it at your first visit with us on campus. Also, please read and complete the questionnaires prior to your first visit. We will happily answer any of your questions during the visit. Please feel free to skip any questions that you are uncomfortable answering.

Your first visit is scheduled for: ________________

Please fast for 8 hours prior to this scheduled visit (no food or drink except water). We will provide a snack for you after the testing is complete.

Kari and Jennifer will meet you in Milam Hall room 105 for your visit. We are looking forward to meeting you in person. If you have any concerns or questions before your first visit, please feel free to call us at **737-4925**.

All the very best,

OSU Oregon State University

Oregon State University
Department of Public Health
Department of Human Development and Family Sciences
Department of Nutrition and Exercise Science
Project Phone: 541-737-4925

INSTRUCTIONS FOR RECORDING 4-DAY DIETARY RECORDS

1. Please record your food & beverage intake over three (3) week days & one (1) weekend day. Each day recorded should correspond with your 4-day physical activity records.

2. Please record each food & beverage item you consume on a separate line. Be sure to include all snacks & all beverages (including water).

3. Please record the time the food/beverage was consumed.

4. Record each item after weighing in exact amounts:
   - liquids in cups or **fluid** ounces
   - vegetables and fruits in cups, grams, or ounces
   - beans, grains, and pasta in cups **dry** or cups **cooked** (please be specific)
   - bread in slices, indicate what kind of bread (brand name and type)
   - meats, fish, poultry and cheeses in ounces
   - nuts in cups, ounces, or grams
   - chips or other snack type foods in cups, ounces, or grams
   - Spread (butter, cream cheese, margarine, etc.) in tsp or Tbs

5. Please specify if food is consumed raw. Also indicate if it was prepared from fresh, frozen, or canned products.

6. Indicate how the foods were prepared, such as fried, baked, boiled, etc.

7. If a food has a mixture of ingredients (sandwich or casserole), list the major ingredients separately in their proportions or amounts.

8. Use brand names whenever possible, or mention comparable brand.

9. For fruits and vegetables, please indicate if the skin was removed.

10. Indicate if dairy products are whole, 2%, 1%, or skim.

11. Be sure to include sauces, gravies, marinades, milk/sugar in coffee, etc.

12. Check food labels for weights, etc. Candy bars, cheeses, cookies, juices are all labeled with their weights -----Write this information down!

13. Provide any other information you feel might be helpful, such as food labels and/or recipes.

14. Record EVERYTHING edible that goes in your mouth.
15. MOST IMPORTANTLY, eat as you normally would -- please don't change your usual eating habits or modify your portion size.

4-DAY FOOD/BEVERAGE INTAKE RECORD

For Staff Use Only:
Height _______
Weight _______
Age _______
Gender _______
Activity Level

Please measure and weigh all food and beverages you eat throughout the day and write them down as you eat them. Remember to give as many details as possible and keep any food labels if you think it will help describe the food better than you are able to. Providing us with recipes for homemade foods is helpful for us, too. Please list any vitamin or mineral supplements or any other supplements taken on the backside of this form and attach these labels if possible. It's best to be as descriptive as possible

Meal or Snack	Time	Food or Beverage item	Brand/source (manufacturer)	Type of preparation (bake, boil, fry, etc.)	Amount/Wt (ounces, grams, fluid ounces, cups, tsp, TBS)
Meal	8:15 am	Total Cereal	General Mills	NA	1 oz/1 cup
M	8:15 am	Light Soy milk, vanilla	Silk	NA	4 fl oz / .5 cup

Participant ID: __ __ __ __ __
122
Cohort: __ __
Baseline

Meal or Snack	Time	Food or Beverage item	Brand/source (manufacturer)	Type of preparation (bake, boil, fry, etc.)	Amount/Wt (ounces, grams, fluid ounces, cups, tsp, TBS)

List any vitamin/mineral pills or other supplements here:

Participant ID: __ __ __ __ __
123
Cohort: __ __
Baseline

INSTRUCTIONS FOR RECORDING 4 DAYS OF PHYSICAL ACTIVITY

1. Please maintain your normal activity level -- do NOT increase your activity level or change your normal intensity (how difficult) or duration (how long) of activities.

2. Record all your daily activities for three (3) week days and one (1) weekend day.

3. Please record all activity for the same 24-hour periods as your food intake records, starting at 5am each day and continuing until 5am the next day. Estimate as closely as possible the length of time sleeping as well as length of time for each activity.

   Example:

   Wednesday 5am - Thursday 5am = day 1
   Thursday 5am - Friday 5am = day 2
   Friday 5am - Saturday 5am = day 3
   Saturday 5am - Sunday 5am = day 4

4. Be as prompt as possible when recording your activities. Try to record all daily physical activities on your activity log as soon as you have completed them in **minutes**. Also, be as specific and accurate as possible when recording intensity and length of time the activity was performed.

5. How to estimate intensity:
   Resting = sleeping, watching tv, reading
   Very light = desk work or activities that still allows you to sing a song
   Light = Activity allows you to converse freely and breathing fine (full sentences)
   Moderate = Activity allows you to converse, but you find yourself needing to take a breath every few words (partial sentences)
   Heavy = unable to converse due to exertion level (minimal words)

Example of how to record in log:

Clock Time	Total Minutes	Activity Description	Intensity of Activity (record minutes)				
			Resting	Very Light	Light	Moderate	Heavy
5:00am - 7:15am	135	sleeping	135				
7:16am - 8:30am	74	Eat, shower, dress		64	10		
8:31am - 8:54am	23	House chores		4	6	10	3
8:55am – 10:59pm	848	walk to work & sit		793	50	5	
11:00pm - 5:00am	360	sleeping	360				
TOTAL = 1440 minutes ***Total the minutes for each level of intensity:***			495	861	66	15	3

For Staff Use only:
Height _____
Weight _____
Age _____
Gender _____

4-DAY PHYSICAL ACTIVITY LOG

			Intensity of Activity (allocate minutes)				
Clock Time	**Total Minutes**	**Activity Description**	Resting	Very Light	Light	Moderate	Heavy
5:00 AM -							

			Intensity of Activity (allocate minutes)				
Clock Time	**Total Minutes**	**Activity Description**	Resting	Very Light	Light	Moderate	Heavy
- 5:00 AM							
TOTAL =	**1440 minutes**	**Total the minutes for each level of intensity:**					

Prevention of Metabolic Syndrome: Intervention Strategies (PROMIS)

Congratulations!

You have completed the first visit with the PROMIS Study!

Your next visit is scheduled for:_______________

Please fast for at least 4 hours prior to this visit (no food or drink except water). We will provide a meal for you after the testing is complete.

For this visit, please dress comfortably for 30-minutes of walking. We recommend that you wear shorts or sweatpants, a tee-shirt, and comfortable walking shoes (such as tennis shoes).

You will also need to bring or wear the following items for your next appointment:

Water bottle

Fitted or tight fitting clothing

(ie, bathing suit, sports bra and spandex shorts)

Robe (optional)

Walking Shoes

See you then!!!

Please call if you have any questions or concerns!

737-4925

OSU
Oregon State
UNIVERSITY

Oregon State University
Department of Public Health
Department of Human Development and Family Sciences
Department of Nutrition and Exercise Science

Project Phone: 541-737-4925

OREGON STATE UNIVERSITY

Promis Study: Health Profile Goals!

Name:______________________ **Date:**________________________

MY GOALS:

1. ____

2. ____

My Menu of Options:

Brief Consultation
Telephone Support/Check-In
__weekly
__ bi-weekly
__ monthly
Individual Nutrition Consultation
Individual Exercise Consultation
Walking Maps
Information about Walking Groups or Clubs
Brochures about Glucose Testing
Email Check-Ins/Support

Other:____

Using Your Glucose Monitor

PROMIS Study

1. Remove one test strip from the strip canister.

2. Remove one lancet and put it in the ‘penlet’ (the device that the lancet goes into to prick your finger).

3. Twist the round top on the lancet 10 or so times, then pull straight back from the needle.

4. Put the cap on the penlet (droplet image facing you).

5. Put the test strip into the monitor. The gray ‘circuit’ looking end is placed face-up into the monitor.

6. The monitor will beep and display an image on the screen that indicates it is ready for your blood.

7. Swab your finger with an alcohol wipe and wipe excess alcohol off with a cotton ball.

8. Hold the penlet to your finger and press the blue button.

9. Squeeze a droplet of blood from your finger.

10. Hold the test strip (that is secured in the monitor) up to the droplet of blood.

11. The test strip will soak up your blood droplet quickly and beep to indicate that it is testing your blood. The screen will count down from 15. If there is an error an ‘E’ will be displayed on the screen. If this occurs, start over with a NEW test strip.

12. Remove the lancet from the penlet and place lancet into biohazard cardboard container. When disposing of cardboard container, close the top and throw away entire container. DO NOT empty lancets into trash without biohazard container.

The PROMIS Study

COMPLETING YOUR **LIFESTYLE LOG**

1. List your goal for the week in the space provided. This goal should be small, attainable, and in line with the overall goals of the study.
2. List any potential obstacles that may get in the way of achieving your weekly goal, or successfully completing your exercise and nutrition plans for the week.
3. List possible solutions to alleviate the disturbances that may be caused by any potential obstacles.
4. Plan out your week of exercise (see example below).
5. Record your FASTING blood glucose 5 days a week. The best time to achieve a fasting level is first thing in the morning, before you drink that first cup of coffee☺
6. Record a PRE-EXERCISE and POST-EXERCISE blood glucose reading 3 days a week. This obviously implies that you should be exercising *at least* 3 days a week☺
7. Record the number of steps showing on your pedometer at the end of the day. Once you have recording your number of daily steps, clear the pedometer with the yellow button.
8. On the days you exercise, please record the number of minutes you exercised, and the type of exercise you completed. Exercise in this study is defined as whole body physical activity that is continuous and completed at a moderate intensity (13-14 RPE intensity).
9. Record the total number of WHOLE GRAIN servings consumed each day. Your goal is to consume at least 3 servings each day.
10. Record the total number of fresh (F), frozen (Z) and canned (C) FRUIT and VEGETABLE servings consumed each day. Place an F (fresh), Z (frozen), or C (canned) next your tallied fruit servings. Your goal is to eat 2-4 fruit and 3-5 vegetable servings each day.
11. Record the number of meals and snacks consumed each day.

EXERCISE PLAN (TIME & TYPE)

Friday 10/27	Saturday 10/28	Sunday 10/29	Monday 10/30	Tuesday 10/31	Wednesday 11/1	Thursday 11/2
30 min, walk during lunch	45 min, aqua jogging	OFF	30 min, walk during lunch	OFF	30 min, walk during lunch	OFF

WEEKLY EXERCISE & NUTRITION

	Glucose Testing			Exercise			Nutrition			Patterns	
	Fasting 5 d/wk	Pre-Exercise 3 d/wk	Post-Exercise 3 d/wk	Daily Steps	Minutes of Exercise	Type of Exercise	Whole Grains (≥ 3)	Fruit Servings (2-4; F, Z, C)	Vegetable Servings (3-5; F, Z, C)	# of Meals	# of Snacks
Friday 10/20	112 mg/dl	196 mg/dl	160 mg/dl	5622	35	walking	4	1F, 1C	2Z, 1C	3	2

THE PROMIS STUDY

LIFESTYLE LOG

Goal for this week: ______________________________

Potential Obstacles: ______________________ Possible Solutions: ______________________

______________________ ______________________

EXERCISE PLAN

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday

WEEKLY EXERCISE & NUTRITION

	Glucose Testing			Exercise			Diet			Patterns	
	Fasting Glucose 5d/wk	PreExercise Glucose	Post Exercise Glucose	Daily Steps	Minutes of Exercise	Type of Exercise	Whole Grains (≥ 3)	Fruit Servings (3-4)	Vegetable Servings (3-4)	# of Meals	# of Snacks
Friday	mg/dl	mg/dl	mg/dl								
Saturday	mg/dl	mg/dl	mg/dl								
Sunday	mg/dl	mg/dl	mg/dl								
Monday	mg/dl	mg/dl	mg/dl								
Tuesday	mg/dl	mg/dl	mg/dl								
Wednesday	mg/dl	mg/dl	mg/dl								
Thursday	mg/dl	mg/dl	mg/dl								

Slippery Slope of Lifestyle Change

What causes you to slip from healthy eating habits?

____

____

____

What causes you to slip from exercise habits?

____

____

____

How do you react to each of these slips?

____

____

____

____

Write down new 'healthy' reactions that you could have.

____

____

____

Write down roadblocks to these that you need to be prepared for.

____

____

____

Prevention of Metabolic Syndrome: Intervention Strategies

(PROMIS)

____

Please print your name here.

For office Use—Tear Here

Participant ID: ___ ___ ___ ___
Date: ___ ___ /___ ___ /___ ___ ___ ___
Follow-Up
Cohort: ___ ___

A. On the following questions, please rate how confident you feel that you that you would exercise in the described conditions.

1. When you are <u>under a lot of stress</u>, how confident are you that you will exercise?

1	2	3	4	5
Not at all confident	somewhat confident	moderately confident	very confident	completely confident

2. When you <u>don't have the time</u>, how confident are you that you will exercise?

1	2	3	4	5
Not at all confident	somewhat confident	moderately confident	very confident	completely confident

3. When you have to <u>exercise alone</u>, how confident are you that you will exercise?

1	2	3	4	5
Not at all confident	somewhat confident	moderately confident	very confident	completely confident

4. When you <u>don't have access to exercise equipment</u>, how confident are you that you will exercise?

1	2	3	4	5
Not at all confident	somewhat confident	moderately confident	very confident	completely confident

5. When you are <u>spending time with your friends and/or family who do not exercise</u>, how confident are you that you will exercise?

1	2	3	4	5
Not at all confident	somewhat confident	moderately confident	very confident	completely confident

6. When the <u>weather is bad outside</u>, how confident are you that you will exercise?

1	2	3	4	5
Not at all confident	somewhat confident	moderately confident	very confident	completely confident

B. Please put a check beside the answer that best describes your planned physical activity.
Note: *<u>Planned physical activity</u>* is any planned activity performed to increase your physical fitness. Such activity should be performed 3-5 times per week for 20-60 minutes per session.

1. Do you exercise regularly according to the above definition?

__ a. Yes, I have been exercising according to this definition for <u>MORE than 6 months.</u>
__ b. Yes, I have been exercising according to this definition for <u>FEWER than 6 months.</u>
__ c. No, but I intend to exercise according to this definition in the <u>next 30 days.</u>
__ d. No, but I intend to exercise according to this definition in the <u>next 6 months.</u>
__ e. No, and I do <u>NOT</u> intend to exercise according to this definition in the <u>next 6 months.</u>

C. Please circle yes or no for each of the following questions about your weight.

1. In the past month, have you been purposefully trying to lose weight?
YES NO

2. In the past month, have you been actively trying to keep from gaining weight?
YES NO
3. Are you seriously considering trying to lose weight to reach your goal in the next six months?
YES NO
4. Have you maintained your desired weight for more than six months?
YES NO

D. Please answer the following questions about your social support. Circle the response that best describes your experience. Then, list the people, or person, that you are thinking of as you answer each question, and list her/his relationship to you.

1. Is there someone available to whom you can count on to listen to you when you need to talk?

1	2	3	4	5
None of the time	A little of the time	Some of the time	Most of the time	All of the time

Please list the first name of the person you are thinking of here, and their relationship to you:
(Example: Lynn, sister)______________________________

____

____

2. Is there someone available to you to give you good advice about a problem?

1	2	3	4	5
None of the time	A little of the time	Some of the time	Most of the time	All of the time

Please list the first name of the person you are thinking of here, and their relationship to you:
(Example: Lynn, sister)______________________________

____

____

3. Is there someone available to you who shows you love and affection?

1	2	3	4	5
None of the time	A little of the time	Some of the time	Most of the time	All of the time

Please list the first name of the person you are thinking of here, and their relationship to you:
(Example: Lynn, sister)______________________________

____

____

4. Is there someone available to help with daily chores?

1	2	3	4	5
None of the time	A little of the time	Some of the time	Most of the time	All of the time

Please list the first name of the person you are thinking of here, and their relationship to you:
(Example: Lynn, sister)______________________________

____

____

5. Can you count on anyone to provide you with emotional support?

1	2	3	4	5
None of the time	A little of the time	Some of the time	Most of the time	All of the time

Please list the first name of the person you are thinking of here, and their relationship to you:
(Example: Lynn, sister)____
____
____

6. Do you have as much contact as you would like with someone you feel close to, someone in whom you can trust and confide?

1	2	3	4	5
None of the time	A little of the time	Some of the time	Most of the time	All of the time

Please list the first name of the person you are thinking of here, and their relationship to you:
(Example: Lynn, sister)____
____
____

7. Is there someone available to you who helps you make decisions about your health?
YES NO

7b. If yes, please indicate how available that person is to help you to make decisions about your health.

1	2	3	4	5
None of the time	A little of the time	Some of the time	Most of the time	All of the time

Please list the first name of the person you are thinking of here, and their relationship to you:
(Example: Lynn, sister)____
____
____

If no one who helps you to make decisions about your health, please <u>skip to question 9</u>.

8. If there is someone available to you who helps you to make decisions about your health, how much do you trust this person's opinion?

1	2	3	4	5
Do not trust at all	Trust a little	Trust somewhat	Mostly Trust	Trust very much

Please list the first name of the person you are thinking of here, and their relationship to you:
(Example: Lynn, sister)____
____
____

9. Is there someone in your life that can support you in an exercise and diet program?

1	2	3	4	5
Not at all		A moderate amount		A great deal

Please list the first name of the person you are thinking of here, and their relationship to you:
(Example: Lynn, sister)____
____
____

10. Over the past three months, have family members or friends exercised with you?

1 2 3 4 5
Not at all A moderate amount A great deal

11. Over the past three months, have you shared healthy low-fat recipes with friends or family members?

1 2 3 4 5
Not at all A moderate amount A great deal

12. Over the past three months have family members or friends bought food or prepared food for you that was especially healthy or recommended?

1 2 3 4 5
Not at all A moderate amount A great deal

13. How important is family and friend support in managing your health issues?

1 2 3 4 5
Not at all A moderate amount A great deal

E. Please think back to a family member's experience with illness and disease.

1. Based on your family member's experiences with illness and disease, what, if any, diseases do you worry about developing yourself?

a. ____
b. ____
c. ____
d. ____
e. ____
f. ____
g. ____

2. Have any of your family members experienced any serious or life threatening complications for diabetes?

YES NO

2b. If so, please describe:

____
____
____
____
____

Now, please think about a <u>friend's</u> experience with illness and disease.

3. Based on your friend's experiences with illness and disease, what, if any, diseases do you worry about developing yourself?

a. ____
b. ____
c. ____
d. ____
e. ____
f. ____
g. ____

4. Have any of your <u>friend's</u> experienced any serious or life threatening complications for diabetes?

YES NO

4b. If so, please describe:

____
____
____
____
____

Now, please think about your own experience with illness and disease.

3a. Has your health care provider talked to you about your weight?

YES NO

3b. If yes, please rate your comfort level with the discussion about your weight.

1	2	3	4	5
Not at all comfortable	A little uncomfortable	Somewhat comfortable	Comfortable	Very Comfortable

4. Has your health care provider encouraged you to lose weight?

1	2	3	4
Not at all	A little	Somewhat	Very much

5. Did your health care provider seem comfortable talking you to you about your weight?

1	2	3	4
Not at all	A little	Somewhat	Very much

6. Was your health care provider…

___ Male ___ Female

7. Has your health care provider encouraged you to change your lifestyle in some way?

1	2	3	4
Not at all	A little	Somewhat	Very much

8. During discussions with your health care provider about your pre-diabetes, did s/he say anything that motivated you to want to make any changes?

YES NO

9. If YES, please describe:

____
____
____
____
____

10. Did your health care provider make any specific suggestions about how to reduce your risk for diabetes?

YES NO

11. If YES, what suggestions were made?

____
____
____
____
____

12. Has your health care provider involved you as an equal partner in making decision about illness management strategies and goals?

1	2	3	4	5
Not at all		A moderate amount		A great deal

13. Has your health care provider listened carefully to what you had to say about your illness?

1	2	3	4	5
Not at all		A moderate amount		A great deal

14. Has your health care provider thoroughly explained the results of test you had done (e.g., cholesterol, blood pressure, or other laboratory tests)?

1	2	3	4	5
Not at all		A moderate amount		A great deal

15. How important are health care team resources to you in managing your illness?

1	2	3	4	5
Not at all		A moderate amount		A great deal

16. Was the discussion with your health care provider about your pre-diabetes respectful?

1	2	3	4	5
Not at all respectful	A little respectful	Somewhat respectful	Respectful	Very respectful

17. Has your health care provider been encouraging?

1	2	3	4	5
Not at all encouraging	A little encouraging	Somewhat encouraging	Encouraging	Very encouraging

18. Did your health care provider refer you to a Diabetes Specialist, Registered Dietitian or some other health care advisor?
    YES NO

If no, please skip to *section F*.

19. If yes, have you met with that person?
    YES NO

20. Was this person….
___ Male ___ Female

F. Please answer these questions based on your knowledge and experience with testing your blood sugar.

1. Have you had your blood sugar tested by a doctor or other health care provider?
    ___ Yes ___ No

1b. If yes, what was your blood sugar level? ________________

2. Have you ever tested your blood sugar yourself?
    ___ Yes ___ No

2b. If yes, what was your blood sugar level? ________________

3. How important is testing your blood sugar to you?

1	2	3	4	5
Not at All Important	A little Important	Somewhat Important	Important	Very Important

4. How important is testing your blood sugar to your health?

1	2	3	4	5
Not at All Important	A little Important	Somewhat Important	Important	Very Important

5. How important is testing your blood sugar in preventing diabetes?

1	2	3	4	5
Not at All Important	A little Important	Somewhat Important	Important	Very Important

6. How frequently do you test your blood sugar?

1	2	3	4	5
Never	Once or twice monthly	Weekly	Almost Daily	Daily

7. How comfortable are you with testing your blood sugar?

1	2	3	4	5
Not at All Comfortable	A little Comfortable	Somewhat Comfortable	Comfortable	Very Comfortable

8. How much does the result of testing your blood sugar motivate you to exercise?

1	2	3	4	5
Not at All Motivating	A little Motivating	Somewhat Motivating	Motivating	Very Motivating

9. How much does testing your blood sugar motivate you to change your diet?

1	2	3	4	5
Not at All Motivating	A little Motivating	Somewhat Motivating	Motivating	Very Motivating

G. Please answer these questions about your experience with the Metabolic Syndrome Women's Study.

1. How motivating were the one-on-one coaching sessions in changing your diet?

1	2	3	4	5
Not at All Motivating	A little Motivating	Somewhat Motivating	Motivating	Very Motivating

2. How motivating were the one-on-one coaching sessions in changing your exercise habits?

1	2	3	4	5
Not at All Motivating	A little Motivating	Somewhat Motivating	Motivating	Very Motivating

3. How important is goal setting for your successful program completion?

1	2	3	4	5
Not at All	A little	Somewhat	More than Somewhat	Very Important

4. How easy was it for you to set realistic goals during the program?

1	2	3	4	5
Not at All	A little	Somewhat	More than Somewhat	Very Easy

5. How motivating were your goals?

1	2	3	4	5
Not at All	A little	Somewhat	More than Somewhat	Very Much

6. How satisfied are you with your goals?

1	2	3	4	5
Not at All	A little	Somewhat	More than Somewhat	Very Much

7. How much did the one-on-one coaching sessions help you meet your goals?

1	2	3	4	5
Not at All	A little	Somewhat	More than Somewhat	Very Much

8. What was most motivating about the one-on-one sessions?

____
____
____
____

9. What was least motivating about the one-on-one sessions?

____
____
____
____

10. If you could change anything about the one-on-one coaching sessions, what would you change and how?

____
____
____
____

11. Did you reach your goals by the end of the program?

1	2	3	4	5
Not at All	A little	Somewhat	More than Somewhat	Very Much

12. On a scale from 1-10 (1 = not at all important, 10= extremely important), how important were the following components of the program to attaining your goals?

___ One-on-One Coaching Sessions
___ Exercise and Nutrition Classes
___ Results from Blood Samples
___ Tracking Daily Physical Activity
___ Counting Steps (pedometers)
___ Incentives
___ One-on-One Telephone Contact
___ Daily Blood Sugar Testing
___ Tracking Daily Food Intake
___ Goal Setting
___ Social Support

13. From the above list, which was your greatest motivator?

____
____
____

14. What part of the program was the most enjoyable to you?

____
____
____
____
____

15. Please describe how you feel having completed the program.

16. What behaviors have you changed as a result of this program?

17. How have your behaviors changed as a result of this program?

18. What would you change about the program to make it more interesting?

19. What was the least important component of the program for you?

H. The next questions ask you about your feelings and thoughts during the past month. In each case, please circle how often you felt or thought a certain way.

1. In the last month, how often have you felt that you were unable to control the important things in your life?

0	1	2	3	4
Never	almost never	sometimes	fairly often	very often

2. In the last month, how often have your felt confident about your ability to handle your personal problems?

0	1	2	3	4
Never	almost never	sometimes	fairly often	very often

3. In the last month, how often have you felt that things were going your way?

0	1	2	3	4
Never	almost never	sometimes	fairly often	very often

4. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?

0	1	2	3	4
Never	almost never	sometimes	fairly often	very often

I. Over the last 2 weeks, how often have you been bothered by any of the following problems?

1. Have you often felt down, depressed, or hopeless?

☐ **Yes** ☐ **No**

2. Have you had little interest or pleasure in doing things?

☐ **Yes** ☐ **No**

--Please continue on to the next page--

J. Please circle the response that best describes your feelings about exercise.

	Strongly Agree	Agree	Disagree	Strongly Disagree
1. I enjoy exercise.	SA	A	D	SD
2. Exercise decreases feelings of stress and tension for me.	SA	A	D	SD
3. Exercise improves my mental health.	SA	A	D	SD
4. Exercising takes too much of my time.	SA	A	D	SD
5. I will prevent heart attacks by exercising.	SA	A	D	SD
6. Exercise tires me.	SA	A	D	SD
7. Exercise increases my muscle strength.	SA	A	D	SD
8. Exercise gives me a sense of personal accomplishment.	SA	A	D	SD
9. Places for me to exercise are too far away.	SA	A	D	SD
10. Exercising makes me feel relaxes.	SA	A	D	SD
11. Exercising lets me have contact with friends and persons I enjoy	SA	A	D	SD
12. I am too embarrassed to exercise.	SA	A	D	SD
13. Exercising will keep me from having high blood pressure.	SA	A	D	SD
14. It costs too much money to exercise.	SA	A	D	SD
15. Exercising increases my level of physical fitness.	SA	A	D	SD
16. Exercise facilities do not have convenient schedules for me.	SA	A	D	SD
17. My muscle tone is improved with exercise.	SA	A	D	SD
18. Exercising improves functioning of my cardiovascular system.	SA	A	D	SD
19. I am fatigued by exercise.	SA	A	D	SD
20. I have improved feelings of well being from exercise.	SA	A	D	SD
21. My spouse (or significant other) does not encourage exercising.	SA	A	D	SD
22. Exercise increases my stamina.	SA	A	D	SD
23. Exercise improves my flexibility.	SA	A	D	SD
24. Exercise takes too much time from family relationships.	SA	A	D	SD
25. My disposition is improved by exercise.	SA	A	D	SD
26. Exercising helps me sleep better at night.	SA	A	D	SD
27. I will live longer if I exercise.	SA	A	D	SD
28. I think people in exercise clothes look funny.	SA	A	D	SD
29. Exercise helps me decrease fatigue.	SA	A	D	SD
30. Exercising is a good way for me to meet new people.	SA	A	D	SD
31. My physical endurance is improved by exercising.	SA	A	D	SD
32. Exercising improves my self-concept.	SA	A	D	SD
33. My family members do not encourage me to exercise.	SA	A	D	SD
34. Exercising increases my mental alertness.	SA	A	D	SD
35. Exercise allows me to carry out normal activities without becoming tired.	SA	A	D	SD
36. Exercise improves the quality of my work.	SA	A	D	SD

	Strongly Agree	Agree	Disagree	Strongly Disagree
37. Exercise takes too much time from my family responsibilities.	SA	A	D	SD
38. Exercise is good entertainment for me.	SA	A	D	SD
39. Exercising increases my acceptance by others.	SA	A	D	SD
40. Exercise is hard work for me.	SA	A	D	SD
41. Exercise improves overall body functioning for me.	SA	A	D	SD
42. There are too few places for me to exercise.	SA	A	D	SD
43. Exercise improves the way my body looks.	SA	A	D	SD
44. Exercise improves my balance and coordination	SA	A	D	SD

The End

Thank You!